Application for Inclusion to the 23rd Expert Committee on the Selection and Use of Essential Medicines for Children: Methylphenidate Hydrochloride

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Author Disclosures of Potential Conflicts of Interest

In the past year, Dr. Faraone received income, potential income, travel expenses continuing education support and/or research support from Takeda, OnDosis, Tris, Otsuka, Arbor, Ironshore, Rhodes, Akili Interactive Labs, Sunovion, Supernus and Genomind. With his institution, he has US patent US20130217707 A1 for the use of sodium-hydrogen exchange inhibitors in the treatment of ADHD. He also receives royalties from books published by Guilford Press: Straight Talk about Your Child's Mental Health, Oxford University Press: Schizophrenia: The Facts and Elsevier: ADHD: Non-Pharmacologic Interventions. He is Program Director of www.adhdinadults.com.

Dr. Banaschewski served in an advisory or consultancy role for Lundbeck, Medice, Neurim Pharmaceuticals, Oberberg GmbH, Takeda, and Infectopharm. He received conference support or speaker's fee by Lilly, Medice, and Takeda. He received royalities from Hogrefe, Kohlhammer, CIP Medien, Oxford University Press.

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Dr. Newcorn is/has been an advisor and/or consultant for Adlon Therapeutics, Arbor, Eisai, Medice, Myriad Neuroscience, NLS, OnDosis, Rhodes, Shire/Takeda, and Supernus, and was a DSMB member for Sunovion. He has received research support from the National. Institute on Drug Abuse (NIDA), the Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), Otsuka, Shire and Supernus. He also has received speaker fees from Shire/Takeda for diseasestate presentations, and served as a consultant for the US National Football League.

Dr Cortese declares honoraria and reimbursement for travel and accommodation expenses for lectures from the following non-profit associations: Association for Child and Adolescent Central Health (ACAMH), Canadian ADHD Alliance Resource (CADDRA), British Association of Pharmacology (BAP), and from Healthcare Convention for educational activity on ADHD

Drs. Katz and Moscibrodzki have no potential conflicts of interest to declare.

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1. Summary Statement of the Proposal for Inclusion of Methylphenidate

Methylphenidate (MPH), a central nervous system (CNS) stimulant, of the phenethylamine class, is proposed for inclusion in the WHO Model List of Essential Medications (EML) & the Model List of Essential Medications for Children (EMLc) for treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) under ICD-11, 6C9Z mental, behavioral or neurodevelopmental disorder, disruptive behavior or dissocial disorders. To date, the list of essential medications does not include stimulants, which play a critical role in the treatment of ADHD. Methylphenidate is proposed for inclusion on the complimentary list for children. This application provides a systematic review of the use, efficacy, safety, availability, and cost-effectiveness of methylphenidate compared with other stimulant (first-line) and non-stimulant (second-line) medications.

Untreated ADHD is not a benign condition and pharmacological interventions such as methylphenidate have wide ranging beneficial effects for children world-wide, not just those in industrialized or western countries. For most patients, the impairing symptoms of ADHD persist into adulthood (Faraone et al., 2006). Annual incremental costs of ADHD have been estimated at \$143-\$266 billion in the US (Doshi et al., 2012), \$12.8 billion in Australia (Australian ADHD Professionals Association, 2019) and (Sciberras et al., 2020) are substantial in other countries as well (Le et al., 2014). Because ADHD is a common neurodevelopmental disorder in childhood affecting 5% of children (Polanczyk et al., 2014) and 2.8% of adults (Fayyad et al., 2017) worldwide, limiting access to methylphenidate has profound repercussions.

In 2018 the European ADHD Guidelines Group (EAGG) published the most comprehensive meta-analysis of short-term RCTs of ADHD medications across the lifespan (Cortese et al., 2018). When assessing efficacy, the standardized mean differences (SMDs) comparing methylphenidate to placebo were 0.78 for children (95% CI: 0.62-0.93) and 0.49 for adults (0.35-0.64). Both SMDs were based on clinician ratings of outcome in double-blinded RCTs. These SMDs are not only statistically significant, they are among the highest in psychiatry and other areas of medicine (Leucht et al., 2012). Because long-term RCTs are not ethical, we rely on large, naturalistic population registry studies to assess longer term functional outcomes. These show that methylphenidate treatment for ADHD reduces accidental injuries, traumatic brain injury, substance abuse, cigarette smoking, educational underachievement, bone fractures, sexually transmitted infections, depression, suicide, criminal activity and teenage pregnancy Given this strong evidence for efficacy from RCTs and effectiveness, in the longer term, from naturalistic studies along with a profile of minor, adverse effects, methylphenidate warrants inclusion in WHO's list of Essential Medicines for Children.

In 2020, WHO rejected a request to place methylphenidate on the list of Essential Medicines for Children. The Expert Committee's decision to exclude methylphenidate from their list stands in stark contrast to the decisions of many regulatory agencies and professional groups around the world. As regards regulatory agencies, the safety and efficacy of methylphenidate have been approved by the US Food and Drug Administration, the European Medicine Agency, The Chinese National Medical Products Administration, Health Canada, the Australian Therapeutic Goods Administration, the Japanese Pharmaceuticals and Medical Devices Agency and the Israeli Ministry of Health, Pharmaceutical Division, Medical Preparations Registration Department.

The Expert Committee cited the meta-analysis of randomized controlled trials (RCTs) of methylphenidate for children with ADHD by Storebø et al. (2015) as a source supporting the notion that the evidence for the use of methylphenidate for ADHD is of poor quality, likely overestimates the positive effects of methylphenidate and underestimates its harms. However, relying on the Storebø et al. (2015) meta-analysis is problematic for several reasons. That meta-analysis is flawed due to its use of idiosyncratic methods to assess the quality of the evidence and factual errors, such as inappropriate study

inclusion, incorrect downgrading of the evidence based on the GRADE system, and incorrect data imputation. For further details, see Banaschewski et al. (2016) and Hoekstra et a. (2016),.

The 2018 European ADHD Guidelines Group (EAGG) meta-analysis of RCTs of ADHD across the lifespan (Cortese et al., 2018) was based on a more advanced and precise meta-analytic method (network meta-analysis) compared with the standard approach (pairwise) used by Storebø and colleagues. Cortese et al. concluded that, considering all the included outcomes related to efficacy/safety, methylphenidate should be considered the first line pharmacological option for ADHD in children and adolescents.

In Cortese et al.'s meta-analysis, the quality of the evidence of the RCTs on methylphenidate on the primary outcome (clinicians rating) was judged as moderate, as opposed to the very low quality of evidence reported by Storebø and colleagues. This difference stems from two sources. First, Storebø et al.'s use of the GRADE system for rating risk of bias in meta-analysis did not follow usual practice. For example, they rated overall study bias as 'high risk' if only one item was uncertain. Most guidelines for rating quality define 'high risk' if one item clearly indicates a high risk of bias, and this procedure was followed in Cortese et al. Second, the rating of the quality of the evidence is based on the information available to the researchers who perform the rating. Cortese et al. gathered unpublished data after systematically contacting study authors and drug manufacturers. After including this information, which was not available to Storebø et al., the overall number of uncertain quality items across all items of the Risk of Bias decreased from 63.5% to 35.2%. This suggests that what previous meta-analyses assessed as "very low" may refer more to the quality of the study reporting, rather than the evidence per se.

We acknowledge that there are gaps in the evidence for almost all medicines used to treat both physical and mental health problems. It is however important that the decision-making process about which treatments should be made available is applied consistently across different disorders and in such a way that ensures parity between physical and mental disorders. As pointed out by Leucht et al. (2012) medications for mental and behavioural disorders have a similar range of efficacies to those for physical health problems. For example, when investigating the effects of digoxin on atrial fibrillation and flutter Sethi and colleagues (Sethi et al., 2018) were unable to identify any trials with follow-up longer than 24 weeks. We also note that state-of-the-art tools to rate the quality of the evidence, such as GRADE used by Storebo et al. and Cortese et al., set the highest standards of reporting. Indeed, using GRADE, the UK National Institute for Clinical Care and Excellence failed to rate as high level most of the evidence from studies on the efficacy and tolerability of some commonly used treatments in general medicine, such as antihypertensive (https://www.nice.org.uk/guidance/ng136) and anti-asthmatic drugs (https://www.nice.org.uk/guidance/ng80), yet these drugs are still recommended for use.

The decision by the Expert Committee to not recommend the addition of methylphenidate to the complementary list of the EML and EMLc for the treatment of ADHD will continue to make access to methylphenidate challenging for millions of people around the world. Your decision will disproportionately affect the poorest and highest risk of children due to economic and educational disadvantages. This will increase morbidity, create chaos in families and drive up health care costs.

Considering the evidence given above, we urge the Expert Committee to reconsider their decision regarding the inclusion of methylphenidate in the complementary list of the EML and EMLc.

2. Relevant WHO technical department and focal point

Dr. Lorenzo Moja, Technical Officer Policies, Access and Use (PAU) Team Essential Medicines and Health Products (EMP) World Health Organization

3. Names of the Organization(s) Consulted and Supporting the Application

This application has been submitted by Stephen V. Faraone, President of the World Federation of ADHD, <u>https://www.adhd-federation.org/</u>, on behalf of the following organizations. See Appendix A for letters of support.

 ADH ASSO Children and A Asso Children, Spain Asso Children, Spain Austr Beliz Central Ameri Beliz Central Ameri Beliz Central Ameri Cana Cana Catal Affected by A Central Affected by A Central Affected by A Central Affected by A Central Child Chind Psychiatry Balvia Europ Psychiatry 	ID, ASC & LD, Belgium ID Association Axarquia, Spain ID Association Iceland ID Association Palencia, Spain ID Europe ID Germany ID Ireland ID Malta, European Union ID Solutions CIC, UK ID Terres de L'Ebre, Spain alusian Federation of Associations for Aid ic Disorder and Attention Deficit, Spain n Federation of ADHD ciation for Attention Deficit , Spain ciation for ADHD, Spain ciation for Understanding ADHD, Croatia ciation of Mothers and Fathers of Adolescents with ADHD, Spain ciation of Parents of Hyperactive in ciation of People with ADH of Bizkaia, ralian ADHD Professionals Association a de Cádiz ADHD Association, Spain te Ministry of Health, Mental Health Unit, ica ilian Association for Attention Deficit dian ADHD Resource Alliance lan Federation of Relatives and People DHD, Catalonia, Spain re for ADHD Awareness, Canada dren and Adults with ADHD, USA ese Society of Child and Adolescent sh ADHD Organization thydis Network, European Union pean Society for Child and Adolescent	 31. Associat 32. (Proyect ADHD i 33. Attention 34. 35. Psychiat (DGKJP 36. 37. 38. 39. Individu 40. 41. 42. 43. ADHD 44. of Child Profession 44. of Child Profession 45. 46. 47. Information 48. Neuropside 49. Lifespan 50. Associat 51. treatmen 52. 53. 54. Attention 55. 56. and Relation 57. 	Federation of ADHD Castilla y Leon ions, Spain Fundación Cultural Federico Hoth, A.C. odah, seeks knowledge and solutions around n all Spanish-speaking countries) Galician Federation of Associations for a Deficit and Hyperactivity, Spain Geha Mental Health Center, Israel German Society for Child and Adolescent ry, Psychosomatics, and Psychotherapy) GMERS Medical College and Hospital, India Grenada Ministry of Health HyperSupers - ADHD France Impuls en Woortblind, Organisation for als with ADHD and Dyslexia, Netherlands Israeli Society of ADHD Italian Association of ADHD Families Japanese Society of ADHD Latin American League for the Study of Latin American Federation and Association and Adolescent Psychiatric and Related ons Madrid Association of ADHD, Spain Meeting Point ADHD, Luxemburg National Attention Deficit Disorder tion and Support Service, UK Network of Child Adolescent ychopharmacology, European Union Neurodevelopmental Disorders Across a, European Psychiatric Association Paediatric Neurology and Development ion of South Africa Possibilities Clinic for assessment and et of ADHD, Canada PsyQ, Netherlands Saudi ADHD Society, Saudi Arabia Spanish Federation of Associations of n Deficit and Hyperactivity Swiss Society for ADHD The American Professional Society of ADHD
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4. International Nonproprietary Name (INN, generic name) of the medicine

Methylphenidate Hydrochloride, ATC Code: N06BA04

5. Dose forms(s) and strength(s) proposed for inclusion; including adult and age-appropriate paediatric dose forms/strengths (if appropriate).

The Figure below gives an overview of current methylphenidate formulations:



Doses Available for each Formulation (from <u>www.pdr.net</u>):

- Adhansia XR/Aptensio XR/Jornay/Metadate CD/Methylphenidate Hydrochloride/Ritalin LA Oral Cap ER: 10mg, 15mg, 20mg, 25mg, 30mg, 35mg, 40mg, 45mg, 50mg, 55mg, 60mg, 70mg, 80mg, 85mg, 100mg
- Concerta/Metadate ER/Methylin/Methylphenidate Hydrochloride/RELEXXII/Ritalin SR Oral Tab ER: 10mg, 18mg, 20mg, 27mg, 36mg, 54mg, 72mg
- Daytrana Topical Film ER: 1h, 1.1mg, 1.6mg, 2.2mg, 3.3mg
- Methylin/Methylphenidate Hydrochloride Oral Sol: 5mL, 5mg, 10mg
- Methylin/Methylphenidate Hydrochloride Oral Tab Chew: 2.5mg, 5mg, 10mg
- Methylin/Methylphenidate Hydrochloride/Ritalin Oral Tab: 5mg, 10mg, 20mg
- Methylphenidate Oral Tab Orally Dis DR: 8.6mg, 17.3mg, 25.9mg
- QuilliChew ER Oral Tab Chew ER: 20mg, 30mg, 40mg
- Quillivant XR Oral Susp ER: 5mL, 25mg

Note: the above are names in the USA. Other countries may use different names for the same formulation.

6. Whether listing is requested as an individual medicine or as representative of a pharmacological class.

We request that methylphenidate be listed as a representative of a pharmacologic class. It represents all products containing methylphenidate approved for use by any government regulatory agency for the treatment of ADHD.

7. Treatment details (requirements for diagnosis, treatment and monitoring).

Diagnosis

ADHD can only be diagnosed by a licensed clinician who interviews the parent or caregiver and/or patient to document criteria for the disorder (American Psychiatric Association, 2013; Chinese Society of Psychiatry, 2001; Faraone et al., 2015; Feldman and Reiff, 2014; Pearl et al., 2001; Stein, 2008; World Health Organization, 2018a). It cannot be diagnosed by rating scales alone, neuropsychological tests or methods for imaging the brain. Professional associations have endorsed and published guidelines for diagnosing ADHD (Alliance, 2011; Banaschewski T, 2018; Bolea-Alamanac et al., 2014; Crunelle et al., 2018; Flisher, 2013; Graham et al., 2011; Kooij et al., 2019; National Collaborating Centre for Mental Health, 2018; National Institute for Health Care and Excellence, 2018; Pliszka, 2007; Schoeman and Liebenberg, 2017; Seixas et al., 2012; Taylor et al., 2004; Wolraich et al., 2011). The diagnosis requires: 1) the presence of developmentally inappropriate levels of hyperactiveimpulsive and/or inattentive symptoms for at least 6 months; 2) symptoms occurring in different settings (e.g., home and school); 3) symptoms that cause impairments in living; 4) some of the symptoms and impairments first occurred in early to mid-childhood; and 4) no other disorder better explains the symptoms (American Psychiatric Association, 2013; World Health Organization, 2018a; Yi and Jing, 2015).

Treatment

As determined by governmental regulatory agencies around the world, methylphenidate is safe and effective for treating ADHD symptoms as determined by randomized controlled clinical trials that typically study patients for several weeks.

Dosage Guidelines for Pediatric Patients with ADHD from www.pdr.net

Children and Adolescents 6 years and older not currently taking methylphenidate

Initially, 18 mg PO once daily in the morning. Dose may be increased by 18 mg increments at weekly intervals. A 27-mg tablet is available for prescribers who wish to utilize a dosage between 18 to 36 mg. FDA-approved Max: 54 mg/day in children and 72 mg/day (not to exceed 2 mg/kg/day) in adolescents; however, some experts recommend doses up to 108 mg, which may be appropriate in patients weighing more than 50 kg. Individualize dosage based on psychosocial and comorbid factors; use lowest effective dose. If no improvement within 1 month, discontinue methylphenidate and consider an alternative treatment/therapy. If paradoxical aggravation of symptoms or other adverse effects occur, reduce dosage or discontinue the drug.

Children and Adolescents 6 years and older currently taking 10 to 15 mg/day methylphenidate

Initially, 18 mg PO once daily in the morning. Titrate dose by 18 mg increments at weekly intervals as needed. A 27-mg tablet is available for patients who may benefit from a dosage between 18 to 36 mg. FDA-approved Max: 54 mg/day in children and 72 mg/day (not to exceed 2 mg/kg/day) in adolescents; however, some experts recommend doses up to 108 mg, which may be appropriate in patients weighing more than 50 kg. Individualize dosage based on psychosocial and comorbid factors; use lowest effective dose. If no improvement within 1 month, discontinue methylphenidate and consider an alternative treatment/therapy. If paradoxical aggravation of symptoms or other adverse effects occur, reduce dosage or discontinue the drug.

Children and Adolescents 6 years and older currently taking 20 to 30 mg/day methylphenidate

Initially, 36 mg PO once daily in the morning. Titrate dose by 18 mg increments at weekly intervals as needed. FDA-approved Max: 54 mg/day in children and 72 mg/day (not to exceed 2 mg/kg/day) in adolescents; however, some experts recommend doses up to 108 mg, which may be appropriate in patients weighing more than 50 kg. Individualize dosage based on psychosocial and comorbid factors; use lowest effective dose. If no improvement within 1 month, discontinue methylphenidate and consider an alternative treatment/therapy. If paradoxical aggravation of symptoms or other adverse effects occur, reduce dosage or discontinue the drug.

Children and Adolescents 6 years and older currently taking 30 to 45 mg/day methylphenidate

Initially, 54 mg PO once daily in the morning. Titrate dose by 18 mg increments at weekly intervals as needed and as clinically appropriate. FDA-approved Max: 54 mg/day in children and 72 mg/day (not to exceed 2 mg/kg/day) in adolescents; however, some experts recommend doses up to 108 mg, which may be appropriate in patients weighing more than 50 kg. Individualize dosage based on psychosocial and comorbid factors; use lowest effective dose. If no improvement within 1 month, discontinue methylphenidate and consider an alternative treatment/therapy. If paradoxical aggravation of symptoms or other adverse effects occur, reduce dosage or discontinue the drug.

Adolescents currently taking 40 to 60 mg/day methylphenidate

Initially, 72 mg PO once daily in the morning. While the FDA-approved maximum dosage is 72 mg/day (not to exceed 2 mg/kg/day), some experts recommend doses up to 108 mg, which may be appropriate in patients weighing more than 50 kg. Titrate dosage by 18 mg increments no more frequently than weekly intervals as clinically appropriate. Individualize dosage based on psychosocial and comorbid factors; use lowest effective dose. If no improvement within 1 month, discontinue methylphenidate and consider an alternative treatment/therapy. If paradoxical aggravation of symptoms or other adverse effects occur, reduce dosage or discontinue the drug.

Oral dosage (extended-release once-daily capsules; Metadate CD)

Children and Adolescents 6 years and older not currently taking methylphenidate

Initially, 20 mg PO once daily in the morning. Dose may be increased by 10 to 20 mg increments at weekly intervals. FDA-approved Max: 60 mg/day; however, some experts recommend doses up to 100 mg/day for patients weighing more than 50 kg. Individualize dosage based on psychosocial and comorbid factors; use lowest effective dose. If no improvement within 1 month, discontinue methylphenidate and consider an alternative treatment/therapy. If paradoxical aggravation of symptoms or other adverse effects occur, reduce dosage or discontinue the drug.

Children and Adolescents 6 years and older currently taking other dosage forms of methylphenidate

Initially, 20 mg PO once daily in the morning. Alternatively, give no more than the equivalent total daily dose of the previous methylphenidate product, rounded to the nearest available capsule size, PO once daily. For example, patients already taking 10 mg of immediate-release methylphenidate twice daily (20 mg/day) should start with 20 mg Metadate CD once daily; those taking 20 mg twice daily (40 mg/day) could start with 40 mg Metadate CD once daily. Dose may be increased by 10 to 20 mg increments at weekly intervals. FDA-approved Max: 60 mg/day; however, some experts recommend doses up to 100 mg/day for patients weighing more than 50 kg. Individualize dosage based on psychosocial and comorbid factors; use lowest effective dose. If no improvement within 1 month, discontinue methylphenidate and consider an alternative treatment/therapy. If paradoxical aggravation of symptoms or other adverse effects occur, reduce dosage or discontinue the drug.

Oral dosage (extended-release once-daily capsules; Ritalin LA)

Children and Adolescents 6 years and older not currently taking methylphenidate

Initially, 20 mg PO once daily in the morning. If a lower initial dose is desired, 10 mg PO once daily may be used. Dose may be increased by 10 mg increments at weekly intervals. FDA-approved Max: 60 mg/day; however, some experts recommend doses up to 100 mg/day in patients weighing more than 50 kg. Individualize dosage based on psychosocial and comorbid factors; use lowest effective dose. If no improvement within 1 month, discontinue methylphenidate and consider an alternative treatment/therapy. If paradoxical aggravation of symptoms or other adverse effects occur, reduce dosage or discontinue the drug.

Children and Adolescents 6 years and older currently taking other dosage forms of methylphenidate

Initially, give no more than the total daily dosage of the previous methylphenidate product PO once daily in the morning. For example, patients already taking 10 mg of immediate-release methylphenidate twice daily (20 mg/day) should start with 20 mg Ritalin LA once daily; those taking 20 mg of extended-release methylphenidate once daily (20 mg/day) should also start with 20 mg of Ritalin LA once daily. Dose may be increased by 10 mg increments at weekly intervals. FDA-approved Max: 60 mg/day; however, some experts recommend doses up to 100 mg/day in patients weighing more than 50 kg. Individualize dosage based on psychosocial and comorbid factors; use lowest effective dose. If no improvement within 1 month, discontinue methylphenidate and consider an alternative treatment/therapy. If paradoxical aggravation of symptoms or other adverse effects occur, reduce dosage or discontinue the drug.

Oral dosage (extended-release once-daily capsules; Aptensio XR)

Children and Adolescents 6 years and older

Initially, 10 mg PO once daily in the morning. Dose may be increased by 10 mg increments at weekly intervals. FDA-approved Max: 60 mg/day; however, some experts have recommended doses up to 100 mg/day of other methylphenidate formulations in patients weighing more than 50 kg. Individualize dosage based on psychosocial and comorbid factors; use lowest effective dose. If no improvement within 1 month, discontinue methylphenidate and consider an alternative treatment/therapy. If paradoxical aggravation of symptoms or other adverse effects occur, reduce dosage or discontinue the drug.

Oral dosage (extended-release once-daily chewable tablets; QuilliChew ER)

Children and Adolescents 6 years and older

Initially, 20 mg PO once daily in the morning. Dose may be titrated up or down in increments of 10 mg, 15 mg, or 20 mg at weekly intervals. The 10 mg and 15 mg doses can each be achieved by breaking in half the functionally scored 20 mg and 30 mg tablets, respectively. FDA-approved Maximum: 60 mg/day PO; however, some experts have recommended doses up to 100 mg/day of other methylphenidate formulations in patients weighing more than 50 kg. If switching from another methylphenidate product, discontinue that treatment and titrate with QuilliChew ER as previously described; do not substitute QuilliChew ER for other methylphenidate products on a mg-for-mg basis. Individualize dosage based on psychosocial and comorbid factors; use lowest effective dose. If no improvement within 1 month, discontinue methylphenidate and consider an alternative treatment/therapy. If paradoxical aggravation of symptoms or other adverse effects occur, reduce dosage or discontinue the drug.

Oral dosage (extended-release once-daily suspension; Quillivant XR)

Children and Adolescents 6 years and older

Initially, 20 mg PO once daily in the morning. Dose may be increased by 10 to 20 mg increments at weekly intervals. FDA-approved Max: 60 mg/day; however, some experts have recommended doses up to 100 mg/day of other methylphenidate formulations in patients weighing more than 50 kg. Individualize dosage based on psychosocial and comorbid factors; use lowest effective dose. If no improvement within 1 month, discontinue methylphenidate and consider an alternative treatment/therapy. If paradoxical aggravation of symptoms or other adverse effects occur, reduce dosage or discontinue the drug.

Oral dosage (extended-release orally disintegrating tablets; Cotempla XR-ODT)

Children and Adolescents 6 years and older

Initially, 17.3 mg PO once daily in the morning; take consistently with or without food. Dose may be increased by 8.6 to 17.3 mg increments at weekly intervals. FDA-approved Max: 51.8 mg/day. Individualize dosage based on psychosocial and comorbid factors; use lowest effective dose. If no improvement within 1 month, discontinue methylphenidate and consider an alternative treatment/therapy. If paradoxical aggravation of symptoms or other adverse effects occur, reduce dosage or discontinue the drug.

Transdermal dosage (transdermal system; Daytrana)

Children and Adolescents 6 years and older

Initially, apply a 10 mg/9-hour patch topically once daily in the morning, 2 hours before an effect is needed, regardless of previous methylphenidate therapy. If response is not maximized after 1 week, titrate to the next available patch strength in weekly intervals. The suggested upward titration schedule is Week 1: apply 10 mg/9-hour patch once daily; Week 2: apply 15 mg/9-hour patch once daily; Week 3: apply 20 mg/9-hour patch once daily; Week 4: apply 30 mg/9-hour patch once daily. Dose titration, final dosage, and wear time should be individualized according to the needs and response of the patient. Maximum: 30 mg/9-hour patch once daily. In clinical trials, there was no additional benefit of increasing the patch dose from 20 mg/9-hours to 30 mg/9-hours. Remove the patch 9 hours after application or may remove earlier if late day side effects appear and shorter duration of effect is desired.

Oral dosage (extended-release once-daily capsules; Jornay PM)

Children and Adolescents 6 years and older

Initially, 20 mg PO once daily in the evening. Dose may be titrated in increments of 20 mg at weekly intervals. Max: 100 mg/day. If switching from another methylphenidate product, discontinue that treatment and titrate with Jornay PM as previously described; do not substitute Jornay PM for other methylphenidate products on a mg-for-mg basis. Individualize dosage based on psychosocial and comorbid factors; use lowest effective dose. If no improvement within 1 month, discontinue methylphenidate and consider an alternative treatment/therapy. If paradoxical aggravation of symptoms or other adverse reactions occur, reduce dosage or discontinue the drug.

Oral dosage (extended-release once-daily capsules; Adhansia XR)

Children and Adolescents 6 years and older

Initially, 25 mg PO once daily in the morning. Dose may be titrated in increments of 10 to 15 mg at intervals of no less than 5 days. Max: 85 mg/day. Although 85 mg was efficacious in short-term controlled trials, dosages above 70 mg daily were associated with a disproportionate increase in the

incidence of certain adverse reactions. If switching from another methylphenidate product, discontinue that treatment and titrate with Adhansia XR as previously described; do not substitute Adhansia XR for other methylphenidate products on a mg-for-mg basis. Individualize dosage based on psychosocial and comorbid factors; use lowest effective dose. If no improvement within 1 month, discontinue methylphenidate and consider an alternative treatment/therapy. If paradoxical aggravation of symptoms or other adverse reactions occur, reduce dosage or discontinue the drug.

Oral dosage (immediate-release preparations; Ritalin, Methylin, Methylin oral solution, Methylin chewable tablets).

Children and Adolescents 6 years and older

Initially, 5 mg PO twice daily before breakfast and lunch. Dose may be increased by 5 to 10 mg/day at weekly intervals; some patients may require dosing up to 3 times daily (administer last dose of day before 6 pm to limit sleep interference). Max: 60 mg/day per FDA-approved labeling; however, some experts state that doses up to 100 mg/day may be needed in patients weighing more than 50 kg. Individualize dosage based on psychosocial and comorbid factors; use lowest effective dose. If no improvement within 1 month, discontinue methylphenidate and consider an alternative treatment/therapy. If paradoxical aggravation of symptoms or other adverse effects occur, reduce dosage or discontinue the drug.

Children 3 to 5 years†

The National Institute of Mental Health's Preschool ADHD Treatment Study (PATS) provides clinical guidance for children with ADHD 3 to 5 years of age. In the PATS, the initial dose of immediate-release methylphenidate was 1.25 mg PO 3 times daily. Doses were increased gradually up to a maximum of 10 mg PO 3 times daily to reach optimum therapeutic response. The mean optimal total daily dose was 14.2 +/- 8.1 mg (0.7 +/- 0.4 mg/kg/day). Max: 30 mg/day. In all cases, treatment should start with a low dose and be titrated upward slowly. Use lowest effective dose. Higher doses have lead to social withdrawal in some children. Behavior therapy, parental training, and a structured preschool environment are considered first line treatment for preschool-aged children with ADHD; lack of significant improvement with such modalities may warrant the addition of methylphenidate.

Oral dosage (extended-release tablets; Ritalin SR, Metadate ER, Methylin ER)

The extended-release (ER) tablets have a duration of action of approximately 8 hours. Use in place of immediate-release (IR) tablets when the 8-hour dosage of the ER tablets corresponds to the previously titrated 8-hour dosage of the IR tablets. Alternatively, some experts recommend an initial dose of 10 mg PO once daily. Ritalin SR may be administered once or twice daily. Max: 60 mg/day per FDA-approved labeling; however, some experts state that doses up to 100 mg/day may be needed in patients weighing more than 50 kg. Individualize dosage based on psychosocial and comorbid factors; use lowest effective dose. If paradoxical aggravation of symptoms or other adverse effects occur, reduce dosage or discontinue the drug.

Maximum Doses

(from www.pdr.net):

Adolescents

85 mg/day PO for Adhansia XR; 72 mg/day (Max: 2 mg/kg/day) PO for Concerta (FDAapproved labeling); 60 mg/day PO for all other oral formulations excluding Cotempla XR-ODT and Jornay PM (FDA-approved labeling); 51.8 mg/day PO for Cotempla XR-ODT and 100 mg/day PO for Jornay PM; however, doses up to 100 to 108 mg/day PO have been used in patients weighing more than 50 kg for some formulations. For the transdermal patch, 30 mg/9-hour patch per day is the maximum.

Children

6 to 12 years: 85 mg/day PO for Adhansia XR; 54 mg/day PO for Concerta (FDA-approved labeling); 60 mg/day PO for all other oral formulations excluding Cotempla XR-ODT and Jornay PM (FDA-approved labeling); 51.8 mg/day PO for Cotempla XR-ODT and 100 mg/day PO for Jornay PM; however, doses up to 100 to 108 mg/day PO have been used in patients weighing more than 50 kg for some formulations. For the transdermal patch, 30 mg/9-hour patch per day is the maximum.

3 to 5 years: Safety and efficacy have not been established. Maximum doses have not been adequately studied; however, The Preschool ADHD Treatment Study (PATS) has suggested immediate-release doses up to 30 mg/day PO.

1 to 2 years: Safety and efficacy have not been established.

<u>Infants</u>

Safety and efficacy have not been established.

<u>Neonates</u>

Safety and efficacy have not been established.

Elderly

Some patients may tolerate lower doses better

Special Populations (Stahl, 2018)

Renal Impairment

• No dose adjustment necessary

Hepatic Impairment

• No dose adjustment necessary

Cardiac Impairment

- Use with caution, particularly in patients with recent myocardial infarction or other conditions that could be negatively affected by increased heart rate and/or blood pressure
- Do not use in patients with structural cardiac abnormalities or outflow obstructions

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Pregnancy

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- Effective June 30, 2015, the US FDA requires changes to the content and format of pregnancy and lactation information in prescription drug labels, including the elimination of the pregnancy letter categories; the Pregnancy and Lactation Labeling Rule (PLLR or final rule) applies only to prescription drugs and will be phased in gradually for drugs approved on or after June 30, 2001
- Controlled studies have not been conducted in pregnant women
- Infants whose mothers took methylphenidate during pregnancy may experience withdrawal symptoms
- Racemic methylphenidate has been shown to have teratogenic effects in rabbits when given in doses of 200mg/kg/day throughout organogenesis
- Use in women of childbearing potential requires weighing potential benefits to the mother against potential risks to the fetus.
- For ADHD patients, methylphenidate should generally be discontinued before anticipated pregnancies

Breast Feeding

- Unknown if methylphenidate is secreted in human breast milk, but all psychotropics assumed to be secreted in breast milk
- Recommended either to discontinue drug or bottle feed
- If infants show signs of irritability, drug may need to be discontinued

Other Issues (Stahl, 2018)

Pharmacokinetics (Stahl, 2018)

- Average half-life in adults is 3.5hours (1.3-7.7hours)
- Average half-life in children is 2.5hours (1.5-5hours)
- There is considerable inter-individual variability in metabolism and dosing by weight (mg/kg) is not generally recommended
- First-pass metabolism is not extensive with transdermal dosing, thus resulting in notably higher exposure to l-methylphenidate and lower exposure to metabolites as compared with oral dosing

Onset of Action (Stahl, 2018)

- Some immediate effects can be seen with first dosing
- Can take several weeks to attain maximum therapeutic benefit

Long-Term Use (Stahl, 2018)

- Often used long-term for ADHD when ongoing monitoring documents continued efficacy
- Dependence and/or abuse may develop. However, the best current information, controlling for confounding factors, suggests that the therapeutic use of stimulant medications such as methylphenidate decreases the risk for substance use disorders (Chang et al., 2014c).
- Tolerance to therapeutic effects may develop in some patients
- Long-term stimulant use may be associated with growth suppression in children (controversial)
- Periodic monitoring of weight, blood pressure, CBC, platelet counts, and liver function may be prudent

Overdose (Stahl, 2018)

• Vomiting, tremor, coma, convulsion, hyperreflexia, euphoria, confusion, hallucination, tachycardia, flushing, palpitations, sweating, hyperpyrexia, hypertension, arrhythmia, mydriasis

Dependence or Abuse (Stahl, 2018)

- Schedule II drug
- Patient may develop tolerance, psychological dependence
- Treatment with methylphenidate and other stimulants reduces the risk for substance use, abuse and dependence (Chang et al., 2014c; Schoenfelder et al., 2014).

Discontinuation (Stahl, 2018)

- Taper to avoid withdrawal effects
- Withdrawal following chronic therapeutic use may unmask symptoms of the underlying disorder and may require follow-up and reinstitution of treatment
- Careful supervision is required during withdrawal from abusive use since severe depression may occur

Storage and Handling of Methylphenidate (from: www.pdr.net)

Generic:

- Protect from moisture
- Store between 68 to 77 degrees F, excursions permitted 59 to 86 degrees F

Adhansia XR:

- Protect from light
- Protect from moisture
- Store between 68 to 77 degrees F, excursions permitted 59 to 86 degrees F

Aptensio XR:

• Store at controlled room temperature (between 68 and 77 degrees F)

Concerta:

- Avoid excessive humidity
- Store at controlled room temperature (between 68 and 77 degrees F)

Cotempla XR:

- Product should always be stored in the blister and only removed immediately before use
- Store between 68 to 77 degrees F, excursions permitted 59 to 86 degrees F

Daytrana:

- Do not freeze
- Do not refrigerate
- Product should be used within 2 months after opening
- Store at 77 degrees F; excursions permitted to 59-86 degrees F
- Store unused product in foil pouch

Jornay:

• Store at controlled room temperature (between 68 and 77 degrees F)

Metadate CD:

• Store at controlled room temperature (between 68 and 77 degrees F)

Metadate ER:

- Protect from moisture
- Store between 68 to 77 degrees F, excursions permitted 59 to 86 degrees F

Methylin:

- Protect from moisture
- Store between 68 to 77 degrees F, excursions permitted 59 to 86 degrees F

QuilliChew ER:

• Store between 68 to 77 degrees F, excursions permitted 59 to 86 degrees F

Quillivant XR:

- Store and dispense in original container
- Store reconstituted product in accordance with package insert instructions
- Store unreconstituted product at 77 degrees F; excursions permitted to 59-86 degrees F

RELEXXII:

- Avoid excessive humidity
- Store at 77 degrees F; excursions permitted to 59-86 degrees F

Ritalin:

• Protect from light

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• Store between 68 to 77 degrees F, excursions permitted 59 to 86 degrees F

Ritalin LA:

• Store at controlled room temperature (between 68 and 77 degrees F)

Ritalin SR:

- Protect from moisture
- Store between 68 to 77 degrees F, excursions permitted 59 to 86 degrees F

Need for Special Diagnostics, Treatment or Monitoring Facilities and Skills When Prescribing Methylphenidate

Assessing Cardiovascular Status (Torres-Acosta et al., 2020)

Children, adolescents or adults who are being considered for treatment with stimulant medications should have a careful history (including assessment for family history of sudden death or ventricular arrhythmia) and physical exam to assess for presence of cardiac disease and should receive further cardiac evaluation including baseline heart rate and blood pressure, and an electrocardiogram if personal or family history, or findings on physical exam suggest risk for cardiac disease. Patients who develop symptoms such as exertional chest pain, unexplained syncope, or other symptoms suggestive of cardiac disease during stimulant treatment should undergo a prompt cardiac evaluation. Heart rate and blood pressure should be monitored regularly.

Growth (Faraone et al., 2008)

Careful follow-up of weight and height should be monitored during treatment with stimulants, and patients who are not growing or gaining weight as expected may need to have their treatment adjusted or interrupted.

Other Considerations

Before prescribing methylphenidate, appropriate attention needs to be given to the psychosocial environment. In children, attention should be paid as to whether the family is intact or separated, whether both parents are supportive of the child's treatment, and whether any concerns exist about abuse or maltreatment. Additionally, legal concerns, psychopathology and substance use in the parents, psychosocial stressors (such as financial and medical distress), access to firearms, and the intellectual abilities of the parents are assessed because treatments may not be effective in chaotic or dangerous environments. Access to medications may be an issue due to lack of health insurance or restrictive policies by some governments or managed care formularies. Pharmacotherapy for ADHD will not address these issues, but they can be targeted by appropriate social services or non-pharmacologic treatments. It is important to educate parents and patients about ADHD and its treatments to help them understand the value of treatment options.

Methylphenidate is indicated as an integral part of a comprehensive treatment program for ADHD which typically includes other remedial measures (psychological, educational, social) for a stabilizing effect in children with a behavioral syndrome characterized by the following group of developmentally inappropriate symptoms of inattention, hyperactivity and impulsivity. The diagnosis of this syndrome should not be made without evidence of impairment in two or more settings and onset prior to age 12 (Faraone et al., 2015; National Institute for Health Care and Excellence, 2018).

Methylphenidate treatment is not indicated for all children with this syndrome. Methylphenidate is not intended for use in the child who exhibits symptoms secondary to environmental factors and/or other primary psychiatric disorders, especially psychotic illness. Psychoeducation should form the foundation of all treatment for ADHD (National Institute for Health Care and Excellence, 2018). Educational accommodations and psychosocial interventions are often attempted before or in conjunction with medication trials. When remedial measures alone are insufficient, the decision to prescribe stimulant medication will depend upon the physician's assessment of the chronicity and severity of the child's symptoms. Methylphenidate should be used cautiously or not at all in patients at risk for diversion or misuse (Faraone et al., 2020).

8. Information Supporting the Public Health Relevance of Methylphenidate

Epidemiological information on disease burden

ADHD is a disorder associated with serious distress and/or impairments in living. Although significant impairment across at least two settings is a prerequisite for a diagnosis of ADHD and, as documented below, many severe adverse outcomes have been associated with ADHD, the typical patient does not experience all, or even most, of these problems and many patients live enjoyable and productive lives, especially if they receive treatment. Much of the following comes from the International Consensus Statement on ADHD (Faraone et al., 2020 Submitted).

Quality of Life

1. A meta-analysis of seven studies with over 5,000 youths and their parents reported large impairments in the quality of life of youths with ADHD relative to typically developing peers, regardless of whether evaluated by the youths themselves or by their parents. Physical functioning was only moderately impaired, but emotional, social and school functioning were strongly impaired. As youths with ADHD grew older, their quality of life, when compared with typically developing peers, grew worse in physical, emotional, and school domains. (Lee et al., 2016b).

2. A meta-analysis of six studies encompassing 647 families evaluated the quality of life of parents whose children had ADHD relative to parents with typically developing children. Parents of the former reported a moderate deficit in quality of life relative to parents of the latter (Dey et al., 2019).

Emotional and Social Impairment

3. A study of over 8,600 youths from the US National Health Interview Survey found that those with ADHD were six times as likely to have a high level of emotional, conduct, and peer problems, and nine times as likely to manifest a high level of impairment including interference with home life, friendships, classroom learning, and leisure activities (Strine et al., 2006).

4. A meta-analysis of 22 studies with almost 22,000 participants found that youth with ADHD were strongly impaired in the ability to modulate their reactivity to novel or stressful events. ADHD was also associated with medium-to-large impairments identifying emotions and expressing empathy (Graziano and Garcia, 2016). Another meta-analysis, combining four studies with over 600 adults, reported a very strong correlation between ADHD symptom severity and emotional dysregulation (Beheshti et al., 2020).

5. A meta-analysis of 109 studies of over a hundred thousand participants found that children with ADHD had medium-to-large impairments in socializing with peers as measured by rejection/likability, popularity, and friendships. They also had medium impairments in social skills (e.g., sharing, cooperating, turn-taking, reciprocity) and social-information processing (e.g., recognizing social cues, identifying problems, generating solutions, and avoiding biases) (Ros and Graziano, 2018).

6. A study of over 53,000 U.S. children from the National Survey of Children's Health found that those with ADHD were 2.4 times as likely to engage in bullying (Montes and Halterman, 2007). A more recent study of some 64,000 children using the same database confirmed this finding, reporting that those with ADHD were 2.8 times more likely to engage in bullying (Benedict et al., 2015).

Accidental Injuries

7. A nationwide cohort study of over 50,000 youths with ADHD and an equal number of age-, sex-, and comorbidity-matched controls drawn from Taiwan's National Health Insurance Research Database reported that having ADHD was associated with a more than three-quarters greater likelihood of burn injury. For those under six years old, the risk was doubled. For youths between six and seventeen years old, the increase in risk was about 70 percent. There were no significant differences between boys and girls (Yeh et al., 2020).

8. A meta-analysis of 32 studies covering more than four million people found that those with ADHD had a 40 to 50% greater risk of accidental physical injuries (Ruiz-Goikoetxea et al., 2018a).

9. A Swedish national registers study followed 17,408 individuals with ADHD from 2006 to 2009 and found that patients with ADHD had an almost 50% greater risk of serious transport accidents (Chang et al., 2014b).

10. A U.S. study of over 8,000 high school and collegiate athletes (predominantly male football players) found that those with ADHD were three times as likely to have had three or more reported concussions (Nelson et al., 2016).

11. A meta-analysis of 32 studies encompassing over 175,000 people estimated that controlling for mileage driven, those with ADHD were 23% more likely to be involved in vehicular crashes (Vaa, 2014).

12. A retrospective cohort study of over 18,000 New Jersey drivers found that the crash risk for those with ADHD was a third greater than for those without (Curry et al., 2017).

13. A meta-analysis of five studies, comprising over three thousand patients with minor traumatic brain injury (mTBI) and over nine thousand controls found that those with mTBI were twice as likely to have ADHD than those without mTBI (Adeyemo et al., 2014).

Premature Death and Suicide

14. A Danish study of almost two million people found ADHD is associated with a small risk for premature death, mostly due to accidents. When ADHD was accompanied by other psychiatric and substance use disorder, the chances of premature death increased (Dalsgaard et al., 2015b).

15. A cohort study of more than 2.2 million Taiwanese found no increased risk of death from natural-causes associated with ADHD. But people with ADHD had twice the rate of suicide, twice the rate of death by homicide, and a 30% greater rate of death from unintentional injury (Chen et al., 2019).

16. Using nationwide registers in Denmark, a cohort study of 2.9 million people reported a fourfold higher rate of suicide attempts and deaths in patients with ADHD. The risk was over tenfold in those with ADHD plus another psychiatric diagnosis (Fitzgerald et al., 2019).

17. A meta-analysis of 57 studies with over 330,000 people found that those with ADHD attempted suicide at twice the rate of typically developing people, had over three times the rate of suicidal ideation, and over six times the rate of completed suicide (Septier et al., 2019).

18. A Taiwanese study of over 20,000 adolescents and young adults with ADHD and over 61,000 age- and sex-matched non-ADHD individuals found that those with ADHD were almost four times as likely to attempt suicide, and over six times as likely to repeat suicide attempts. Methylphenidate or atomoxetine treatment did not increase the risk of suicide attempts or repeated suicide attempts. Long-term methylphenidate treatment was associated with a lower risk for repeated suicide attempts among men (Huang et al., 2018).

19. In a prospective cohort study of more than 2.6 million Swedes, adults with ADHD had a small increase in premature death, mostly due to accidents and suicide. There was no significant association for children with ADHD (Sun et al., 2019b).

Crime and Delinquency

20. A study of the Danish population using nationwide registers found that, compared with other youth, those diagnosed with ADHD were more than twice as likely to be convicted of criminal offenses and were three times as likely to be incarcerated. After adjusting for other risk factors, those with ADHD were 60% more likely to have been convicted of a crime, and 70% more likely to have been incarcerated (Mohr-Jensen et al., 2019).

21. A meta-analysis reported the prevalence of ADHD among adolescents in juvenile detention to be just over 17%, both for males (24 studies, over 24,000 individuals) and females (12 studies, over 3,900 individuals), which is much higher than the prevalence in the population (Beaudry et al., 2020). Another meta-analysis comprising 21 studies and 19,575 prison inmates found that the prevalence of ADHD in prisons was 20.5% with no differences observed between males and females or adolescents and adults (Young et al., 2015).

22. A study using a nationally representative American sample of over 5,000 adults found that those with ADHD were over twice as likely to be perpetrators of physical dating violence, and 65% more likely to be victims of such violence (McCauley et al., 2015).

23. In a nationwide study of over 21,000 Icelandic adolescents and young adults, 14% reported having been interrogated at a police station. Of these, 15% reported making a false confession. Those with ADHD were twice as likely to make a false confession (Gudjonsson et al., 2016).

24. A study using the Danish national registries looked at violent crimes against youth aged 7-18 years, among a total of 678,000 individuals. Children with ADHD were 2.7 times more likely to be victims of violent crimes than their typically developing peers, after adjusting for confounding risk factors (Christoffersen, 2019).

Educational Underachievement

25. A study of a U.S. sample of almost 30,000 adults found that those with ADHD were twice as likely not to have graduated from high school on time, after adjusting other psychiatric disorders (Breslau et al., 2011).

26. A nationwide cohort study of over 750,000 Scottish school children using linked national registers identified those who had been prescribed medicine for ADHD. Even while receiving medication, these children were more than three times as likely as typically developing peers to have low educational achievement, more than twice as likely to drop out of school before age 16, more than eight times as likely to have a record of special educational needs, 50% more likely to get injured, 40% more likely to

be unemployed. These results were adjusted for socioeconomic confounders and other psychiatric conditions (Fleming et al., 2017).

27. A meta-analysis of ten studies and 830 youths found that ADHD was strongly associated with poorer performance on measures of overall, expressive, receptive, and pragmatic language (Korrel et al., 2017).

Substance Use Disorders

28. A meta-analysis of twelve studies covering over 5,400 people found that those with ADHD were almost three times more likely to be nicotine-dependent. Combining eleven studies with almost 2,400 participants, those with ADHD were 50% more likely to develop a drug or alcohol use disorder than those without ADHD (Lee et al., 2011).

29. A meta-analysis of 23 studies with over 22,000 participants found that ADHD was associated with a more than twofold greater risk of addiction, alcohol-related disorders, drug-related disorder, and nicotine-related disorder (Groenman et al., 2017).

30. A Swedish study of over half a million people found a more than threefold association between ADHD and subsequent drug use disorders after adjusting for sex and parental education (Sundquist et al., 2015).

Other

31. Studies of 2.7 million girls from Denmark (Ostergaard et al., 2017), 380,000 from Sweden (Skoglund et al., 2019) and 7,500 from Taiwan (Hua et al., 2020) found that those with ADHD were more likely to have teen pregnancies than those without ADHD. Consistent with these results, large studies from Sweden (Chang et al., 2014a), Finland (Chudal et al., 2015) and a consortium of eight European countries (Pohlabeln et al., 2017) each found ADHD to be more likely among children of teenage mothers than among children of older mothers.

32. A study of over 36,000 people from the US reported that ADHD increased the risks for problem gambling, spending too much money, reckless driving, and quitting a job without a plan for what to do next (Bernardi et al., 2012).

33. A nationwide study using Taiwan's National Health Insurance Research Database compared 675 adults with ADHD and 2,025 without ADHD, matched by age and sex. After adjusting for other psychiatric disorders, urbanization level of residence, and monthly income, those with ADHD had 3.4 times the risk of developing dementia (Tzeng et al., 2019).

34. A meta-analysis of nine studies encompassing almost a million and a half people found that ADHD is associated with a threefold greater risk of poisoning in children (Ruiz-Goikoetxea et al., 2018b). In a study from Taiwan comparing 3,685 children with ADHD with 36,000 controls, those with ADHD had a more than fourfold greater risk of deliberate self-poisoning (Chou et al., 2014).

35. A longitudinal study of some 15,000 U.S. adolescents reported that those with ADHD had a 12% reduction in employment and a 34% reduction in earnings relative to non-ADHD siblings (Fletcher, 2014).

36. Using Danish registers, a nationwide population study of over 675,000 youths between the ages of 7 and 18 found that youths with ADHD were 3.7 times as likely to be reported as victims of sexual crimes than normally developing controls. After adjusting for covariates, such as parental violence, parental inpatient mental illness, parental suicidal behavior or alcohol abuse, parental long-term unemployment, family separation, and child in public care outside the family, youths with ADHD remained almost twice as likely to be reported as victims of sexual crimes (Christoffersen, 2020).

The Economic Burden of ADHD

1. A nationwide population study of over 83,000 persons with ADHD and 334,446 non-ADHD controls matched by age and sex used Danish national registries to calculate the net socioeconomic cost of ADHD. Relative to controls, and summing net direct health costs and net losses from lower income and employment, the yearly average cost per individual with ADHD came to just over \in 16,000. Including additional social transfers, the total rose to just over \notin 23,000. For partners of persons with ADHD, the additional yearly average cost per individual was almost \notin 5,500. With additional social transfers, the total rose to \notin 8,000 (Jennum et al., 2020).

2. A systematic review of seven European studies of hundreds of thousands of participants estimated total ADHD-related costs in the Netherlands as \notin 9,860 to \notin 14,483 per patient per year, with annual national costs more than \notin 1 billion (Le et al., 2014).

3. A review of the costs of child, youth and adult ADHD in Australia estimated the total annual costs to be over \$20 billion Australian dollars, or \$25,000 per person with ADHD. This includes financial costs of \$12.8 billion, well-being losses of \$7.6 billion, and productivity losses of \$10.2 billion (Australian ADHD Professionals Association, 2019).

4. A systematic review of 19 U.S. studies of hundreds of thousands of people found that ADHD was associated with overall national annual costs from \$143 to \$266 billion, mostly associated with adults (\$105 to \$194 billion). Costs borne by family members of people with ADHD ranged from \$33 - \$43 billion (Doshi et al., 2012).

5. A study with over 7,000 workers in ten nations found that those with ADHD had an average of 22 annual days of lost role performance compared with those without ADHD (de Graaf et al., 2008).

6. A study of a U.S. national Fortune 100 company's database of over 100,000 beneficiaries compared healthcare costs for youths with ADHD with matched controls without ADHD. The annual average cost per family member was \$2,728 for non-ADHD family members of ADHD patients, almost double the \$1,440 for family members of matched controls (Swensen et al., 2003).

7. German health insurance records, including over 25,000 patients with ADHD, indicate that patients with ADHD cost roughly \notin 1,500 more annually than those without ADHD. Main cost drivers were inpatient care, psychiatrists, and psychotherapists. Mood, anxiety, substance use disorders, and obesity were significantly more frequent in patients with ADHD. The additional costs resulting from these conditions added as much as \notin 2,800 per patient (Libutzki et al., 2019).

8. Using the National Health Insurance Service claims data for the population aged 19 years or younger in South Korea (69,353 diagnosed with ADHD), the total annual economic burden due to ADHD was estimated to be \$47.55 million (Hong et al., 2020).

9. Using the Danish national registers, over 5,000 adults with a diagnosis of ADHD in adulthood who had not received a diagnosis in childhood were identified. Excluding cases with missing data, other psychiatric diagnoses, and cases without a same-sex sibling free of any diagnosed psychiatric diagnoses, a final cohort was formed consisting of 460 sibling pairs. On average, adults with ADHD had an annual economic burden of just over \notin 20,000 compared with their normally developing siblings (Daley et al., 2019).

10. A nationwide cohort study of over 445,000 people in the Swedish national registers compared healthcare costs for three groups: those with childhood ADHD that persisted into adulthood, those whose ADHD remitted in adulthood, and those who never had ADHD. Those who never had ADHD had average annual healthcare costs of \in 304. Those in remission had double the cost, and those with persistent ADHD over triple the cost (Du Rietz et al., 2020).

Assessment of current use

Methylphenidate is recommended as a first line treatment for ADHD in many treatment guidelines for ADHD from around the world. (Alliance, 2011; Banaschewski T, 2018; Bolea-Alamanac et al., 2014; Crunelle et al., 2018; Flisher, 2013; Graham et al., 2011; Kooij et al., 2019; National Collaborating Centre for Mental Health, 2018; National Institute for Health Care and Excellence, 2018; Pliszka, 2007; Schoeman and Liebenberg, 2017; Seixas et al., 2012; Taylor et al., 2004; Wolraich et al.,

	(S-DDD per	1,000 inhabita	ants per day)
Country or territory	2016	2017	2018
Iceland	25.10	31.94	29.05
Israel	16.14	13.95	11.75
Canada	8.21	8.09	9.49
Sweden	8.35	7.83	8.00
Netherlands	7.97	7.40	7.98
United States	7.91	6.82	7.60
Denmark	6.60	7.04	7.31
Switzerland	3.85	3.90	4.11
New Zealand	4.56	2.62	3.92
Finland	2.38	2.73	3.23
Belgium	2.71	2.36	2.86
Germany	1.84	1.26	1.68
Chile	2.14	1.61	1.60
Falkland Islands (Malvinas)	_	1.70	1.46
South Africa	1.04	1.22	1.45
Sint Maarten	1.59	0.94	1.04
Portugal	\rightarrow	0.98	1.02
Turkey	0.83	0.00	0.96
Gibraltar	0.88	0.99	0.89
Turks and Caicos Islands		0.92	0.83

Table 10. Methylphenidate: rates of consumption in the

2011). As a result, it is widely used in many countries.

The following Table was extracted from a Technical Publication of the International Narcotics Control Board. It lists methylphenidate rates of consumption in the 20 countries and territories reporting the highest rates of consumption in 2018 and compares those rates with rates in 2016 and 2017. Rates are expressed in 'defined daily dose for statistical purposes' (S-DDD) per 1,000 inhabitants per day. DDD is the assumed average maintenance dose per day for a drug used for its main indication.

By comparison and although its dosing range is different than methylphenidate, another controlled substance already among the psychotropic medications on the EML is diazepam. Historically the most produced benzodiazepine in the world, the consumption of diazepam was reported by 92 countries in 2018. Rates of reported consumption were higher than 10 S-DDD by Uruguay, Montenegro, Brazil, Serbia, Portugal and Ghana. A further 27 countries, most of them in Europe, reported rates

of consumption higher than 2 S-DDD.

Target population(s)

The target population for methylphenidate comprises all patients diagnosed with ADHD. In guidelines, it is typically recommended as a first line treatment (Alliance, 2011; Banaschewski T, 2018; Bolea-Alamanac et al., 2014; Crunelle et al., 2018; Flisher, 2013; Graham et al., 2011; Kooij et al., 2019; National Collaborating Centre for Mental Health, 2018; National Institute for Health Care and Excellence, 2018; Pliszka, 2007; Schoeman and Liebenberg, 2017; Seixas et al., 2012; Taylor et al., 2004; Wolraich et al., 2011; Zheng and Liu, 2015) except for children younger than six for whom a trial of behavior therapy is recommended first.

Likely impact of treatment on the disease

As determined by governmental regulatory agencies around the world, methylphenidate is safe and effective for treating ADHD symptoms as determined by randomized controlled clinical trials that typically study patients for several weeks. Methylphenidate is as efficacious, or more efficacious, than many medications used in physical medicine (Leucht et al., 2012).

<u>ADHD</u> <u>Randomized Controlled Clinical Trials Comparing Methylphenidate and Placebo in Patients with</u>

A network meta-analysis of 133 RCTs including more than 24,000 participants found stimulants to be highly effective in reducing the symptoms of ADHD. Compared with placebo, methylphenidate treatment led to large improvements in youths with a mean standardized mean difference of -0.78 (-0.93 to -0.62) (Cortese et al., 2018).

A meta-analysis of 19 parallel group trials with over 1,600 participants, found methylphenidate produced moderate to large improvements in teacher-rated ADHD symptoms, teacher-rated behavior and parent-rated quality of life. There was no evidence of serious adverse events, and just a slightly elevated risk of non-serious side effects (Storebo et al., 2015).

A meta-analysis of 21 studies with over 2,300 adult participants found that methylphenidate led to small-to-moderate reductions in symptoms of emotional dysregulation (Lenzi et al., 2018).

A meta-analysis of eight studies with 423 participants reported moderate-to-strong improvements in ADHD symptoms with methylphenidate in ADHD patients with borderline intellectual functioning or intellectual disability. It was equally effective for hyperactivity and inattention. It also led to small-to-moderate improvements on a continuous performance test (Sun et al., 2019a).

Clinical Trials Comparing Methylphenidate and Placebo in ADHD & Tic Disorder

A Cochrane review included eight randomized controlled trials to assess the effects of pharmacological treatments for ADHD in children with comorbid tic disorder on symptoms of ADHD and tics (Osland et al., 2018). Standard methodological procedures of Cochrane were utilized, in that two review authors independently selected studies, extracted data using standardized forms, assessed risk of bias, and graded the overall quality of the evidence by using the GRADE approach. Risk of bias of included studies was low for blinding; low or unclear for random sequence generation, allocation concealment, and attrition bias; and low or high for selective outcome reporting. Meta-analysis was unable to be performed due to important clinical heterogeneity and unit-of-analysis issues. Participants in these studies were children with both ADHD and a chronic tic disorder (n=500; 443 boys and 67 girls). Medications assessed included methylphenidate, clonidine, desipramine, dextroamphetamine, guanfacine, atomoxetine, and deprenyl. Safety was evaluated by adverse effects including: cardiovascular effects such as changes in heart rate, blood pressure or electrocardiogram; and weight changes. There was appetite suppression or weight loss in associated with methylphenidate, dextroamphetamine, atomoxetine, and desipramine. There was insomnia associated with methylphenidate and dextroamphetamine, and sedation associated with clonidine.

Clinical Trials Comparing Methylphenidate and Placebo in ADHD & Mental Retardation

In a 4-week, single-blind, parallel-group trial, 45 subjects with moderate mental retardation and ADHD were randomized to risperidone or methylphenidate and assessed using objective rating scales for efficacy (SNAP [Swanson, Nolan, and Pelham]-IV and Nisonger Child Behavior Rating Form) (Correia Filho et al., 2005). Subjects enrolled in the study were between the ages of 6 and 16. The study was a 28 day randomized single-blind, parallel-group clinical trial. Subjects were randomly assigned to either risperidone or methylphenidate for 4 weeks. An individualized flexible titration procedure was used to adjust the dose for optimal efficacy and tolerability. Risperidone was titrated to a maximum tolerable dose with a minimum target dose of 0.5 mg/day at the beginning of the trial. The overall upper dose limit was 4 mg/day. methylphenidate was titrated to a maximum daily dose of 0.7 mg/kg/day at the end of the trial

administered twice daily (8 A.M. and noon). At the end of any of the 4 weeks, the principal investigator could increase the dose of either medicine, depending on efficacy and tolerability. Compliance was checked by returning the blister packs used each week, when pills were counted. Both groups had reduced ADHD symptoms during trial, but findings suggested that risperidone is associated with greater reductions in ADHD total score (F = 3.26; p = .05) than methylphenidate in children with moderate mental retardation and ADHD. Comorbidity and side effects profile might be of importance in choosing between medications, although it is usually prudent to try stimulants before antipsychotics in such children.

Clinical Trials Comparing Methylphenidate and Placebo in ADHD & Autism Spectrum Disorders

A Cochrane systematic review investigated the effects of methylphenidate for symptoms of ADHD and autistic spectrum disorder (ASD) in children and adolescents aged 6 to 18 years (Sturman et al., 2017). Four cross-over randomized clinical trials were included with a total of 113 children. The primary outcome was clinical efficacy, defined as an improvement in ADHD-like symptoms (inattention, impulsivity and hyperactivity) and in the core symptoms of ASD (impaired social interaction, impaired communication, and stereotypical behaviors) and overall ASD. The meta-analysis suggested that highdose methylphenidate had a significant and clinically relevant benefit on hyperactivity as rated by teachers (SMD -0.78, 95% confidence interval (CI) -1.13 to -0.43; 4 studies, 73 participants; P < 0.001; low-quality evidence) and parents (mean difference (MD) -6.61 points, 95% CI -12.19 to -1.03, rated on the hyperactivity subscale of the Aberrant Behavior Checklist, range 0 to 48; 2 studies, 71 participants; P = 0.02; low-quality evidence) and a significant but not clinically relevant benefit on teacher-rated inattention (MD -2.72 points, 95% CI -5.37 to -0.06, rated on the inattention subscale of the Swanson, Nolan and Pelham, Fourth Version questionnaire, range 0 to 27; 2 studies, 51 participants; P = 0.04; lowquality evidence). There was no evidence that methylphenidate worsens the core symptoms of ASD or benefits social interaction (SMD -0.51, 95% CI -1.07 to 0.05; 3 studies, 63 participants; P = 0.07; very low-quality evidence), stereotypical behaviors (SMD -0.34, 95% CI -0.84 to 0.17; 3 studies, 69 participants; P = 0.19; low-quality evidence), or overall ASD (SMD -0.53, 95% CI -1.26 to 0.19; 2 studies, 36 participants; P = 0.15; low-quality evidence), as rated by teachers.

<u>Clinical Trials Comparing Methylphenidate and Placebo in ADHD & Oppositional Defiant</u> <u>Disorder and Aggression</u>

In an open-label comparative study, children with DSM-IV-TR ADHD, aged 8-18years with (n=30) and without (n=30) oppositional defiant disorder (ODD) received methylphenidate treatment for 12 weeks (Golubchik and Weizman, 2018).. The severity of ODD symptoms was assessed by the Kiddie-Schedule for Affective Disorders and Schizophrenia. The severity of ADHD symptoms was assessed by the ADHD-Rating Scale-IV and suspiciousness was assessed at baseline and at endpoint by a scale designed especially for assessment of suspiciousness and named Suspiciousness Rating Scale (SRS). Significant reductions in SRS scores were detected in both groups following methylphenidate treatment (before and after: p = .0012 and p = .0273, respectively). Only in the ADHD/ODD group a significant correlation was found between the rate of improvement in ADHD, as assessed by the ADHD-RS, and the reduction in suspiciousness, as assessed by the SRS (Spearman r = 0.48, p = .0066). In addition to the beneficial effect of methylphenidate treatment on ADHD and ODD symptoms it also diminishes suspiciousness.

Another study aimed to assess the effectiveness of monotherapy with stimulant methylphenidate and risperidone in a consecutive sample of 40 drug-naïve male youths diagnosed as having ADHD-combined presentation, comorbid with ODD and aggression, without psychiatric comorbidities (Masi et al., 2017). Twenty males treated with methylphenidate (mean age, 8.95 ± 1.67 years) and 20 males treated with risperidone (mean age, 9.35 ± 2.72 years) followed up to 6 months, were assessed according to efficacy measures, Child Behavior Checklist (CBCL), Clinical Global Impression-Severity (CGI-S)

and Improvement (CGI-I) and Children Global Assessment Scale. At the end of follow-up, both medications were similarly effective based on subscales of aggression and rule-breaking behaviors, but only methylphenidate was effective on attention problems (8.44 ± 2.55 (P < 0.001)) and attention-deficit/hyperactivity problems (7.83 ± 2.36 (P < 0.001)).

Longer Term Outcomes Associated with Methylphenidate Treatment in Youth with ADHD

Because methylphenidate has been used for many decades, it has been feasible for researchers to study its longer-term effects using naturalistic study designs. Much of the following comes from the International Consensus Statement on ADHD (Faraone et al., 2020 Submitted)

A Swedish registry study of over 650,000 students found that treatment with ADHD medication for three months resulted in a more than nine-point gain in grade point sum (on a scale of 0 to 320); treatment was associated with an increase in the probability of completing upper secondary school by two-thirds (Jangmo et al., 2019).

A Swedish national register study of over 61,000 youths with ADHD found that their test scores were higher during periods they were taking medication vs non-medicated periods (Lu et al., 2017). A Danish study of over half a million children (over 6,400 with ADHD) found that discontinuation of ADHD medication was associated with a small but significant decline in grade point averages (Keilow et al., 2018). A meta-analysis of nine RCTs comprising 1,463 patients found that discontinuing medications led to a worsening in quality of life for children and adolescents but not adults (Tsujii et al., 2020).

A Swedish cohort study of over 25,000 ADHD patients found a one-third reduction in criminality among men receiving ADHD medication, and a 40% reduction for women (Lichtenstein et al., 2012). A Danish national registry study of over 4,200 individuals with childhood ADHD found that crime rates in adulthood were 30-40% lower during periods of taking ADHD medication (Mohr-Jensen et al., 2019).

A Danish cohort study of over 700,000 people, including 4,557 with ADHD, found that among teenagers with ADHD, stimulant treatment was associated with a decrease in rates of injuries (30% for ten-year olds and 40% for twelve-year olds) (Dalsgaard et al., 2015a).

Using the Swedish national registries, a study followed 9,421 youths with ADHD and 2,986 youths with both ADHD and other psychiatric diagnoses from 2006 to 2013. It compared periods when they were taking ADHD medication with periods when they were not. During medicated periods both groups had a greater than 10% reduction in unintended injuries, and a greater than 70% reduction in traumatic brain injuries (Ghirardi et al., 2020).

A Taiwanese study of over 124,000 youths with ADHD found that methylphenidate treatment decreased the risk for traumatic brain injuries, after adjusting for confounders (Liao et al., 2018).

A nationwide study compared 7,200 Taiwanese youths with ADHD with 36,000 children without ADHD. After adjusting by age, sex, urbanization level, and geographic region, boys with ADHD were almost 40% more likely and girls with ADHD 60% more likely to suffer bone fractures (Guo et al., 2016). Another study from Taiwan identified over 6,200 youths newly diagnosed with ADHD and assessed the effect of methylphenidate treatment. The risk of bone fractures was 20% lower in those who had over half a year of methylphenidate treatment (Chen et al., 2017).

A population-based, electronic medical records database in Hong Kong identified over 17,000 individuals aged 6-19 years who had been prescribed methylphenidate. Of these, almost 5,000 had at least one trauma-related emergency room admission. Researchers found a 9% reduction in such admissions during periods covered by a methylphenidate prescription compared with periods with no active prescription (Man et al., 2015).

A meta-analysis of five studies with over 13,000 participants found that ADHD medications (primarily stimulants) were associated with a greater than 10% reduction in unintentional injuries (Ruiz-Goikoetxea et al., 2018a).

Using Swedish national registers, a study of over 17,000 people with ADHD found that medication for ADHD was associated with a greater than 50% reduction in the risk of serious transport accidents among males but not females. Over 40% of crashes by male patients would have been avoided if they had been receiving treatment during the entire period (Chang et al., 2014b). A U.S. national cohort study of 2.3 million people with ADHD examined emergency room visits for motor vehicle crashes over ten years. Males with ADHD had a 38% lower risk of crashes in months when receiving ADHD medication. About a fifth of crashes would have been avoided if they had been avoided with months when not receiving medication, and females a 42% lower risk in months when receiving ADHD medication. About a fifth of crashes would have been avoided if they had been on medication throughout the period of the study (Chang et al., 2017).

A longitudinal study using the Taiwan Health Insurance Research Database compared almost 18,000 adolescent and young adults with ADHD with over 70,000 age- and sex-matched controls. Short-term use of ADHD medications was associated with a 30% reduction in sexually transmitted infections, and long-term use with a 40% reduction, though these reductions were only among males (Chen et al., 2018).

A nationwide longitudinal cohort study using the Swedish national registers found that among more than 38,000 individuals with ADHD, ADHD medication was associated with a greater than 40% reduction in the risk for depression three years later. The risk decreased with the duration of ADHD medication use. Depression was 20% less common when patients received ADHD medication compared with periods when they did not (Chang et al., 2016).

A Swedish population-based study of 38,000 people with ADHD found a 20% decline in suicide related events among those prescribed stimulants during periods when they were under treatment as opposed to during periods when they were not under treatment. No such benefit was found for non-stimulant medications (Chen et al., 2014).

A Taiwanese study identified 85,000 youths with ADHD using National Health Insurance data to examine whether methylphenidate use affected suicide attempts. After adjusting for relevant variables, it found a 60% lower risk of suicide in those using methylphenidate for 3 months to half a year, and a 70% reduction among those using methylphenidate for more than half a year (Liang et al., 2018b).

A study using the Swedish national registers investigated the association between prescription stimulant medication for ADHD in 2006 and substance abuse during 2009 among all 38,753 people born between 1960 and 1998 and diagnosed with ADHD. After controlling for relevant variables, it found a greater than 30% reduction in indicators of substance abuse among those prescribed stimulants. The longer the duration of medication, the lower the rate of substance abuse (Chang et al., 2014c). A meta-analysis of 14 studies with over 2,300 participants found that people with ADHD were half as likely to smoke cigarettes when regularly treated with stimulant medications (Schoenfelder et al., 2014). A meta-analysis of 15 studies with over 2,500 participants found that stimulants did not increase the risk for alcohol, nicotine, cocaine, or cannabis abuse or dependence (Humphreys et al., 2013).

A nationwide study of over 7,500 Taiwanese adolescents with ADHD and over 30,000 matched controls found that long-term use of ADHD medication use was associated with a 30% decrease in teenage pregnancy (Hua et al., 2020).

A nationwide population-based cohort using Taiwan's National Health Insurance Research Database identified over 68,000 children and adolescents with a diagnosis of ADHD and who were prescribed methylphenidate and compared them with an identical number of controls matched on age, gender and year of first ADHD diagnosis. After controlling for potential confounders, ADHD individuals prescribed methylphenidate had a one-fifth lower rate of all-cause mortality than ADHD individuals not prescribed methylphenidate. Delayed use of methylphenidate, on the other hand, was associated with slightly higher (5%) mortality. Long-term methylphenidate use was associated with a one-sixth lower rate of all-cause mortality. The authors caution, however, that "information lacking in the database precluded the measurement of other possible confounders, such as family history, psychosocial stressors, effect of behavioural therapy or severity of comorbidities," and thus unmeasured confounding cannot be excluded (Chen et al., 2020a).

A nationwide population-based cohort using Taiwan's National Health Insurance Research Database identified over 90,000 individuals younger than 18 years with a diagnosis of ADHD, and compared risk of burn injury between those not on methylphenidate, those on methylphenidate for less than 90 days, and this on methylphenidate for more than 90 days. The data suggested that fully half the incidence of burn injuries could have been prevented by taking methylphenidate. Compared with patients not taking methylphenidate, those taking it for less than 90 days had a 30% lesser risk of burn injuries, and those taking it for 90 days or more a 57% reduction in risk, after adjusting for confounders (Chen et al., 2020b).

9. Review of benefits: summary of evidence of comparative effectiveness

Identification of Clinical Evidence for Short Term Efficacy from Randomized Controlled Trials (RCTs)

A recent meta-review (Cortese et al., 2019) sought to identify available network meta-analyses (NMAs) aimed at assessing the comparative effectiveness of medications used in child and adolescent psychiatry. The following electronic databases, with no restrictions in terms of date, language, and type of document (e.g., full text paper, conference proceeding, or dissertation, among others): Pubmed (Medline), Ovid databases (PsycInfo, Embase+Embase classic, OVID Medline), and Web of Knowledge Databases (Web of science (science citation index expanded), Biological abstracts, Biosis, Food science and technology abstracts), from inception to 9 January, 2018. Reference lists of relevant retrieved papers were hand-searched to find any additional pertinent NMA. The quality of each included NMA was appraised using the AMSTAR-2 tool. The following NMAs were identified for ADHD medications, including methylphenidate

First author (year)	N trials	Type of included trials	Participants	Eligible treatments	Outcomes
Roskell (2014)	32	Parallel RCTs	Children and/or adolescents with ADHD, with or without comorbid ODD	MPH, LDX ATX, DEX	Efficacy: changes in ADHD-RS, CGI-I Safety: all-cause and AE discontinuations
Locatelli (2016) (conference proceeding only)	34	Parallel double blind RCTs > 2 weeks	Children and/or adolescents with ADHD; no further information	MPH (MPH-I and MPH-MR), LDX ATX, BUP	Efficacy: clinical improvement (decline in ADHD- RS questionnaire score by at least 25% or improved CGI-I)
Catala-Lopez (2017)	190	Parallel RCTs ≥ 3 weeks. (crossover included if they reported pre crossover results)	Children and/or adolescents with ADHD (< 18 y), as per DSM or ICD	Pharmacological treatments: Stimulants; Non- stimulants Antipsychotics Other unlicensed drugs Non- pharmacological interventions: Behavioral therapy Cognitive training Neurofeedback Complementary and alternative medicine interventions	Primary: treatment response (ADHD symptoms or global functioning) and all- cause treatment dis- continuation rates. Secondary outcomes: tolerability, serious AEs and specific adverse events
Joseph (2017)	017) 36 Parallel RCTs, (crossover included if they reported pre crossover results)		Children and/or adolescents aged 6-17	d-AMPH, ATX, CIR, GIR, GXR, LDX, MPH-IR, or MPH-ER/OROS	Efficacy: change in ADHD-RS, CGI-S, CPRSs, or SNAP- IV; achievement of response at the CGI Safety: all cause discontinuation and discontinuation due to AEs
Li (2017)	62	RCTs, regardless of level of blinding	Children and adolescents with ADHD aged 4-17	ATX, BUP, CLON, GXR, LDX, MPH	Efficacy: changes on validated ADHD scales

					Safety: Withdrawals due to all-cause, or AEs and lack of efficacy
Luan (2017)	73	RCTs, regardless of level of blinding, > 3 weeks	Children and adolescents with ADHD as per DSM-I, aged 6-18	ATX, CLON, GXR, BUP, LDX, MPH	Efficacy: changes on ADHD-RS Safety: all cause withdrawals, withdraw due to AEs, withdrawal due to lack of efficacy

Abbreviation for Medications: AMPH: Amphetamines; BUP: Bupropion; CLON: Clonidine; GUA: Guanfacine; GXR: Guanfacine Extended Release LDX: Lisdexamfetamine; MAS: Mixed Amphetamine Salts; MODA: Modafinil; MPH: Methylphenidate (ER: Extended release: SR: sustained release); PBO: Placebo.

Abbreviation for Comorbidity: AD: Aggression/Defiance; A/D: Abuse/Dependence; Adj Dis: Adjustment Disorder with mixed disturbance of emotions and conduct; ASD: Autism Spectrum Disorder; ASPD: Antisocial Personality Disorder; BD: Bipolar Disorder; CD: Conduct Disorder; Comm: Communications Disorder; DD: Depression Disorder; Disr Beh: Disruptive Behavior Disorder; GAD: Generalized Anxiety Disorder; LD: Learning disorder; MD: Major Depression; MOOD: Mood disorder; MSD: Motor Skills Disorder; OCD: Obsessive– Compulsive Disorder; ODD: Oppositional Defiant Disorder; PD: Personality disorder; PHO: Phobia; SAD: Separation anxiety disorder; SPD: Seasonal pattern disorders; SUD: substance use disorder; TD: Tic Disorders.

An additional NMA was published after the search date of this meta-review. The quality of the NMAs identified in the meta-review by Cortese et al. (2018) is described in the accompanying Table.

By contrast, the quality of the NMA by Cortese et al. (2018) was rated as HIGH in another recent meta-review (Boaden et al., 2020). As such, data on comparative effectiveness of methylphenidate from the network meta-analysis by (Cortese et al., 2018) are presented here as deriving from the highest quality NMA currently available.

The following table summarizes the comparative efficacy of methylphenidate on ADHD core symptoms rated by clinicians in the short term

Quality of Network Meta Analyses						
Author (Year)	AMSTAR-2 Rating					
Roskell (2014)	Low					
Catala-Lopez (2017)	Moderate					
Joseph (2017)	Critically Low					
Li (2017)	Critically Low					
Luan (2017)	Critically Low					

(average 12 weeks) in relation to placebo and other medications used to treat ADHD

	Atomoxetine		Bupropion		Clonidine	Clonidine Guanfacine			Methylphenidate		Modafinil		Placebo	
	Children	Adults	Children	Adults	Children	Adults	Children	Adults	Children	Adults	Children	Adults	Children	Adults
Amphetami	ines													
Clinicians	-0-46 (-0-65 to -0-27)*	-0-34 (-0-58 to -0-10)*	-0.06 (-0.81 to 0.68)†	-0-33 (-0-77 to 0-11)*	-0-31 (-0.81 to 0-18)*	8	-0-35 (-0-59 to-0-10)*	÷	-0-24 (-0-44 to -0-05)*	-0-29 (-0-54 to-0-05)*	-0-39 (-0-67 to -0-12)*	-0-94 (-1-43 to -0-46)1	-1-02 (-1-19 to -0-85)1	-0-79 (-0-95 to -0-58)1
Teachers	-	-	~	-	1.1	-	-	-	-	-	-	-	-	
Atomoxetin	ke .													
Clinicians		~	0.40 (-0.34 to 1.14)*	0.01 (-0.41 to 0.42)"	0-15 (-0-33 to 0-63)*	-	0-11 (-0-09 to 0 32)*		0-22 (0-05 to 0-39)*	0.04 (-0.14 to 0.23)#	0-07 (-0-17 to 0-31)*	-0-61 (-1-06 to -0-15)*	-0-56 (-0-66 to -0-45)*	-0-45 (-0-58 to -0-32)*
Teachers	2		0.00 (-0.90 to 0.90)†	-	141	- + -	0-31 (-0-79 to 1-42)†	н	0.50 (-0.11 to 1.10)"		0-44(-0-19 to 1-07)*	-	-0-32 (-0-82 to 0-18)1	-
Bupropion														
Clinicians		201	+	÷1	-0-25 (-1-12 to 0-62)†		-0-28 (-1-04 to 0-47)1	ê.	-0.18 (-0.90 to 0.54)†	0.04 (-0.38 to 0.45)*	-0-33 (-1-10 to 0-43)†	-0-62 (-1-20 to -0-03)*	-0-96 (-1-69 to -0-22)1	-0-46 (-0-8) to -0-07)*
Teachers	e		-	-	-	2	031(-092 to1-55)1		050(-017 to 1-17)*		0-44 (-0-38 to 1-26)*	-	-0-32 (-1-07 to 0-43)†	-
Clonidine														
Clinicians	4	-		-	7	ų.	-0.03(-0.53 to 0.46)1	2	0-07 (-0-42 to 0-56)1	-	-0-08 (-0-59 to 0-43)1	2	-0-71 (-1-17 to -0-24)‡	-
Guanfacine														
Clinicians	- 7	-	-	1			-	-	0-11 (-0-13 to 0-34)*		-0-05 (-0-32 to 0-23)*	5	-0-67 (-0-85 to -0-50)‡	1
Teachers	-		114	-	-	.11	-	-	0-18 (-0-86 to 1-22)†		0-12 (-0-93 to 1-18)†	-	-0-63 (-1-62 to 0-35)†	-
Methylphen	hidate													
Clinicians	10	1.00	-	~	4	4	-	÷			-0-15 (-0-41 to 0-10)*	-0-65 (-1-11 to -0-19)*	-0-78 (-0-93 to -0-62)1	-0-49 (-0-6- to-0-35)1
Teachers	14	-	-	-	3	-		-		2	-0-06 (-0-53 to 0-42)1	-	-0-82 (-1-16 to -0-48)*	-
Modafinil														
Clinicians	-				2				**	-	-	-	-0-62 (-0-84 to -0-41)*	0.16 (-0.28 to 0.59)*
Teachers	-	3	1	~	-	1	-	1	2	-	-	-	-0.76 (-1.15 to-0.37)1	-

Data are standardised mean difference (9)% CI) between treatments. Results in boid are significant. Negative values favour the treatment in the row and positive values favour the treatment in the row and positive values favour the treatment in the column. Drugs are reported in aphabetical order. Results are based on network estimates. No data for clonidine and guanfacine in adults are reported because no studies identified by our search tested these two drugs in adults. No teacher ratings were available for clonidine. ADHD+attention-deficit hyperactivity disorder. *Low quality of evidence. TVery low quality of evidence. #Moderate quality of evidence.

Table 1: Effect of ADHD drugs in children and adults at timepoints closest to 12 weeks in terms of efficacy, as rated by clinicians and teachers

In summary, methylphenidate showed higher SMDs compared with placebo and was slightly inferior to amphetamines in terms of efficacy on ADHD core symptoms rated by clinicians

The quality of the evidence from RCTs of methylphenidate, rated with the GRADE system, was deemed of moderate level for the comparison methylphenidate vs placebo, clinicians ratings.

Identification of Clinical Evidence for Longer Term Effectiveness Observational Studies

Due to lack of randomization, observational, naturalistic studies may be prone to bias. A systematic review focused on within-individual design studies, that account for confounding by indication Chang et al. (2019). They performed a systematic search in PubMed and Embase for studies that investigated the association between ADHD medications and behavioral or neuropsychiatric outcomes using population-based prescription databases between January 1, 2008, and February 1, 2019, with no language restrictions. They used terms related to ADHD (attention-deficit/hyperactivity disorder, ADHD) and medication (medication, stimulant*, treatment) and type of data (regist*, claim*, record*, population*) in combination. They followed the recommendations of the Preferred Reporting Items for Systematic Reviews and Meta-Analyses statement

Summary of Available Data for Longer Term Effectiveness from Observational Studies

These studies reviewed by Chang et al. (2019) showed a significant decrease in negative outcomes, such as unintentional physical injuries, motor vehicle accidents (among male patients), substance use disorder, and criminal acts, as well as an improvement in academic functioning. All of their results are shown in the following Figure, reproduced from their article.

Injuries and traumas

Dalsgaard et al., 2015 (39), Denmark Man et al., 2015 (41), Hong Kong Mikolajczyk et al., 2015 (43), Germany Raman et al., 2013 (44), United Kindom Motor vehicle accidents Chang et al., 2014 (49), Sweden. Males Females Chang et al., 2017 (50), United States. Males Females Criminality Lichtenstein et al., 2012 (57), Sweden, Males Females Suicidality Chen et al., 2014 (59), Sweden Man et al., 2017 (63), Hong Kong Substance use disorder Chang et al., 2014 (64), Sweden Quinn et al., 2017 (66), United States. Males Females Depression Chang et al., 2016 (67), Sweden Bipolar disorder and mania Viktorin et al, 2017 (69), Sweden. Without mood stabilizers With mood stabilizers Psychosis Man et al., 2016 (71), Hong Kong Seizures Wiggs et al., 2018 (76), United States. Prior seizure No prior seizure Brikell et al., 2019 (77), Sweden 8.0 2.0 0.5 1.0 ES (95% CI)

Favors medication

Favors no medication

Figure 1. Forest plot of within-individual studies for short-term effects of attention-deficit/hyperactivity disorder medications. Note: Studies on educational outcomes were not included because they used continuous measures of outcome. Cl, confidence interval; ES, effect size.

Reference to Methylphenidate in Existing WHO & Other Clinical Guidelines

From the pharmacological interventions section of the World Health Organization's, mhGAP Intervention Guide for mental, neurological and substance use disorders in non-specialized health settings (World Health Organization, 2018b): "Consider methylphenidate for hyperkinetic disorder only if psychosocial interventions have failed, the child has been carefully assessed and is at least 6 years old, and conditions whose management can be complicated by methylphenidate have been ruled out. Use of stimulant medication must always be part of a comprehensive treatment plan that includes psychological, behavioral and educational interventions"

Key recommendations from other recent guidelines are summarized in the table below from the New England Journal of Medicine (Cortese, 2020).

Table 2. Recommendations for ADHD	Treatment from Recent Clinical Guidelines.						
Organization and Patient Age	Treatment Recommendations						
American Academy of Pediatrics ³							
Preschool children (4-5 yr old)	First line: parental training in behavior management, behavioral classroom interventions, or both Second line: methylphenidate (off-label)						
Children 6–11 yr old	FDA-approved medications (in descending order according to strength of evidence: stimulants, atomoxetine, extended-release guanfacine, extended-release clonidine) with parental training in behavior management, behavioral classroom interventions, or preferably both; educational interventions						
Adolescents 12–17 yr old	FDA-approved medications; training or behavioral interventions, if available, or both; educational interventions						
Adults	Recommendations are not included in the guideline						
National Institute for Health and Care Excellence, United Kingdom ⁴							
Children <5 yr old	First line: ADHD-focused group training for parents Second line: medication only after second specialist opinion						
Children ≥5 yr old and young people	ADHD-focused support (e.g., education and information on the causes and effects of ADHD, advice on parenting strategies, and liaison with school) (fADHD symptoms persist in at least one area of functioning after environmental modification, start medication (in descending order of preference): methylphenidate, lisdexamfetamine (or dexam- phetamine if unacceptable side effects with lisdexamfetamine), atomoxetine or guanfacine For symptoms of oppositional defiant disorder or conduct disorder: parental training Cognitive behavioral therapy for young people if symptoms still impairing at least one area of func- tioning after pharmacologic treatment						
Adults	If ADHD symptoms persist in at least one area of functioning after environmental modification: medication (in descending order of preference): methylphenidate or lisdexamfetamine (or dex- amphetamine if lisdexamfetamine associated with unacceptable side effect profile), atomoxetine Supportive psychological intervention if medication is ineffective or associated with unacceptable side effects						
ADHD German Guidelines [±]							
Children <6 yr old	First line: ADHD-focused group or individual training for parents or teachers Second line: medication only after specialist advice for children >3 yr old						
Children ≥6 yr old and young people							
Mild-to-moderate ADHD	After psychoeducation, first line: parental training or family-based interventions; if needed, patient school-, and workplace-based interventions After psychoeducation, second line: medication (in descending order of preference): stimulants, atomoxetine or guanfacine						
Moderate-to-severe ADHD After psychoeducation, first line: medication (in descending order of preference): s oxetine or guanfacine After psychoeducation, second line: parental training or family-based interventions patient-based and school- or workplace-based interventions							
Adults	After psychoeducation, first-line: medication; nonpharmacologic treatment if patient chooses it or if medication ineffective or associated with unacceptable side effects						
10. Review of harms and toxicity: summary of evidence of safety

Estimate of Total Patient Exposure to Date

According to the 2015 report from the International Narcotics Control Board <u>http://www.incb.org/documents/Publications/AnnualReports/AR2014/English/methylphenidate.pdf</u>, the United States accounted for more than 80% of global consumption. Iceland had the highest per capita consumption of methylphenidate in the world. Other countries with high per capita use were Norway, Sweden, Australia, Belgium, Germany and Canada. Their Figure below shows total consumption has been increasing from 1990 to 2013.

Figure I. Global consumption of methylphenidate, 1990-2013



Raman et al. reported a retrospective, observational study using population-based databases from 13 countries and one Special Administrative Region: four in Asia and Australia, two in North America, five in northern Europe, and three in western Europe. They reported their results as follows: "154.5 million individuals were included in the study. ADHD medication use prevalence in 2010 (in children aged 3–18 years) varied between 0.27% and 6.69% in the countries and SAR assessed (0.95% in Asia and Australia, 4.48% in North America, 1.95% in northern Europe, and 0.70% in western Europe). The prevalence of ADHD medication use among children increased over time in all countries and regions, and the absolute increase per year ranged from 0.02% to 0.26%. Among adults aged 19 years or older, the prevalence of any ADHD medication use in 2010 varied between 0.03% and 1.48% (0.05% in Asia and Australia, 1.42% in North America, 0.47% in northern Europe, and 0.03% in western Europe). The absolute increase in ADHD medication use prevalence per year ranged from 0.02% to 0.12%. Methylphenidate was the most commonly used ADHD medication in most countries." (Raman et al., 2018)

Description of Adverse Effects/Reactions and Estimates of Frequency and Summary of Available Data

The review on this section is based on a) the relevant meta-analyses and within-subject cohort studies identified by the International Consensus Statement on ADHD (Faraone et al., 2020 Submitted),

b) a recent qualitative systematic review of studies that investigated risks and benefits of ADHD medication using linked prescription databases, including 18 within-individual designs accounting for confounding by indication (Chang et al., 2019), c) a recent large scale systematic meta-review of 78 adverse effects of psychotropic medications in children and adolescents with psychiatric disorders (Solmi et al., 2020), d) the most comprehensive network meta-analysis on the tolerability of ADHD medication (Cortese et al., 2018), e) the work of the EU-funded ADDUCE project, that investigated the long-term effects of stimulants on growth, the neurological system, psychiatric states and the cardiovascular system, and f) a systematic review of the PubMed and Cochrane databases (http://adhd-adduce.org/page/view/2/Home).

PubMed and Cochrane catalogues were searched for meta-analyses on the safety of methylphenidate using keywords "methylphenidate", "adverse" and "meta-analysis*" for PubMed and "methylphenidate" and "ADHD" for the Cochrane database search (last search, Nov 10, 2020). There were no specifications on language. A total of 75 abstracts in PubMed and 11 reviews in Cochrane databases were identified initially. Among these, 25 were relevant to comparative evidence on safety for methylphenidate in children and adolescents. Of the 25 relevant articles, 5 were excluded due to being outdated or methodological flaws.

Common side effects of methylphenidate include erythema, weight loss, decrease in appetite, loss in appetite, nausea, vomiting, headache, insomnia, mild labile mood, nasal congestion, and nasopharyngitis with loss of appetite and sleep difficulties being most common (Coghill et al., 2014; Cortese et al., 2013; Faraone et al., 2019; Graham and Coghill, 2008; UpToDate, 2018).

Adverse Effects in Randomized Controlled Clinical Trials

a. In an comprehensive systematic review and network meta-analysis on the tolerability (study drop-outs) of medications for ADHD comparing amphetamines (including lisdexamfetamine), atomoxetine, bupropion, clonidine, guanfacine, methylphenidate, and modafinil with each other or placebo at timepoints closest to 12 weeks, 26 weeks, and 52 weeks, (Cortese et al., 2018) included 82 published and unpublished double-blind randomised controlled trials (11,018 children and adolescents). Summary odds ratios (ORs) and standardised mean differences (SMDs) were estimated using pairwise and network meta-analysis with random effects. Risk of bias of individual studies was assessed with the Cochrane risk of bias tool and confidence of estimates with the Grading of Recommendations Assessment, Development, and Evaluation approach for network meta-analyses. With respect to tolerability, methylphenidate was not statistically different from placebo (OR 1.44, 95% CI 0.90-2.31). Use of methylphenidate was associated with a significantly increased diastolic blood pressure (SMD: 0.24, CI: 0.14–0.33) and decreased weight (SMD: -0.77, CI: -1.09 to -0.45). There was no significant increase in systolic blood pressure (SMD: 0.09, CI: -0.01-0.19).

b. A Cochrane review by (Storebø et al., 2018) on adverse events of methylphenidate to treat ADHD concluded, in contrast to all other meta-analyses, that methylphenidate may be associated with psychotic disorders and arrhythmia. This conclusion was based on two non-randomised comparative studies. One was a Taiwanese cohort study conducted by Shyu et al. (Shyu et al., 2015), which reported that the risk for any psychotic disorder (RR 1.36; CI 1.17 to 1.57; 71,771 participants) was increased. The other study by (Shin et al., 2016) reported increased risk for arrhythmia (RR 1.61, 95% CI 1.48 to 1.74; 1 study, 1224 participants) compared with no intervention. However, according to (Storebø et al., 2018), both studies had serious (Shin et al., 2016) or critical (Shyu et al., 2015) risk for bias due to confounding factors, such as confound by indication to treatment or comorbid disorders. In contrast, two large population-based cohort studies using within-person designs from Swedish and Hong-Kong registries by (Hollis et al., 2019) and (Man et al., 2016) and found no evidence that methylphenidate was associated with psychotic disorders and the Cochrane review on the efficacy of methylphenidate by (Storebø et al.,

2015) found no evidence for an increase in serious adverse events. These latter studies are more convincing because the use of a within-person design eliminates confounding by indication.

c. According to a more recent, comprehensive meta-review on network meta-analyses and meta-analyses of randomized controlled trials (RCTs), individual RCTs, and cohort studies reporting on 78 a priori selected adverse events across 19 categories of 80 psychotropic medications in children and adolescents with mental disorders including data from nine network meta-analyses, 39 meta-analyses, 90 individual RCTs, and eight cohort studies with a total of 337,686 children and adolescents included (Solmi et al., 2020), methylphenidate was associated with significantly worse anorexia (RR: 3.21; 95% confidence interval [CI] 2.61-3.94; (Holmskov et al., 2017), insomnia (OR: 4.66; CI 1.99-10.9; (Ching et al., 2019), weight loss (standard mean difference [SMD] -0.77;CI -1.09 to -0.45; (Cortese et al., 2018), nausea (RR: 1.38; CI 1.04-1.84; (Holmskov et al., 2017)) and abdominal pain (RR: 1.50; CI = 1.26-1.79; (Holmskov et al., 2017)) than placebo. Details are in the following Table from Solmi et al. (2020) (reference citations in the table are in their published paper).

Medication	Adverse events covered by literature	Adverse events worse than placebo	Adverse event	Type of effect size	Effect	95% CI	Source	Quality	N
Mined anti A DUD	10 (24 49/)	7 (0.00/)	A h d a min a 1 main 155	DD	1.44	1.02.2.00	14		2.155
medications	19 (24.4%)	7 (9.0%)	Abdominal pain	DD	6.31	2 58 15 5	MA	п	2,155
			Discontinuation due to adverse event ¹⁴⁴	OR	2.30	1.36-3.89	NMA	н	14,346
			Hypertension ¹⁴⁴	SMD	0.09	0.01-0.18	NMA	н	14,346
			Insomnia ¹⁵⁵	RR	3.80	2.12-6.83	MA	н	2,429
			Nausea/vomiting ¹⁵⁵	RR	1.63	1.04-2.56	MA	н	1,579
			Weight loss ¹⁴⁴	SMD	-0.71	-1.15 to -0.27	NMA	н	14,346
Mixed α -2 agonists	5 (6.4%)	1 (1.3%)	Discontinuation due to adverse event ⁴⁹	Log OR	-29.6	-95.5 to -2.6	NMA	М	2,623
Atomoxetine	20 (25.6%)	5 (6.4%)	Anorexia ¹⁴⁷	RR	2.51	1.77-3.57	MA	М	2,179
			Gastrointestinal symptoms147	RR	1.76	1.51-2.07	MA	М	3,712
			Hypertension ¹⁴⁴	SMD	0.12	0.02-0.22	NMA	н	14,346
			Nausea/vomiting ¹⁵⁶	RR	1.91	1.24-2.94	MA	L	193
			Weight loss ¹⁴⁴	SMD	-0.84	-1.16 to -0.52	NMA	н	14,346
Clonidine	10 (12.8%)	2 (2.6%)	Hypotension ¹⁴⁹	Hedges' g	0.52	0.15-0.89	MA	М	119
			Sedation ¹⁶⁴	OR	7.67	2.92-20.1	RCT	М	230
d-amphetamine	6 (7.7%)	3 (3.8%)	Anorexia ¹⁷⁰	NA	Sig	Sig	RCT	L	81
			Insomnia ¹⁷⁰	NA	Sig	Sig	RCT	L	81
			Irritability ¹⁷⁰	NA	Sig	Sig	RCT	L	81
Guanfacine	16 (20.5%)	4 (5.1%)	Abdominal pain ¹⁶⁶	OR	4.51	1.34-15.2	RCT	М	455
			Discontinuation due to adverse event ¹⁴⁴	OR	2.64	1,20-5,81	NMA	н	14,346
			QT prolongation ¹⁴⁹	Hedges' g	0.33	0.12-0.54	MA	М	785
			Sedation ¹⁴⁹	RR	2.43	1.06-5.58	MA	М	1,059
Lisdexamphetamine	14 (17.9%)	5 (6.4%)	Anorexia ¹⁵⁵	RR	9.83	5.08-19.0	MA	н	1,081
			Discontinuation due to adverse event ¹⁴⁵	RR	3.11	1.20-3.76	NMA	М	6,931
			Dry mouth ¹⁶⁹	OR	8.63	1.13-66.0	RCT	н	547
			Hypertension ¹⁴⁴	SMD	0.14	0.03-0.25	NMA	н	14,346
			Insomnia ¹⁵⁵	RR	5.91	2.84-12.3	MA	н	1,081
Methylphenidate	25 (32.1%)	5 (6.4%)	Abdominal pain ¹⁵⁴	RR	1.50	1.26-1.79	MA	М	5,983
			Anorexia ¹⁵⁴	RR	3.21	2.61-3.94	MA	М	5,983
			Insomnia ¹⁴⁸	OR	4.66	1.99-10.9	MA	М	749
			Nausea/vomiting ¹⁵⁴	RR	1.38	1.04-1.84	MA	М	2,630
			Weight loss ¹⁴⁴	SMD	-0.77	-1.09 to -0.45	NMA	н	14,346
Modafinil	13 (16.7%)	3 (3.8%)	Anorexia ¹⁵³	RR	5.02	2.55-9.89	MA	М	921
			Insomnia ¹⁵³	RR	6.16	3.40-11.2	MA	М	921
			Weight loss ¹⁴⁴	SMD	-0.93	-1.59 to -0.26	NMA	н	14,346

Table 3 Safety of anti-attention-deficit/hyperactivity (ADHD) medications in children and adolescents with any mental illness (adverse events significantly worse than with placebo/controls)

OR - odds ratio, RR - risk ratio, Log OR - log odds ratio, SMD - standardized mean difference, NMA - network meta-analysis, MA - meta-analysis, RCT - randomized controlled trial, NA - not available, H - high quality, M - medium quality, L - low quality (lower score of either AMSTAR or AMSTAR-Content), Sig - significant difference between medication and placebo without effect size available

Adverse Effects in Observational Studies: Somatic Effects

Much of the following comes from the International Consensus Statement on ADHD (Faraone et al., 2020 Submitted).

a. Children treated with stimulants may show delays in expected height gains averaging two centimeters over one or two years. These sometimes attenuate over time and often reverse when treatment is stopped (Faraone et al., 2008). A medical records study from the USA comparing 32,999 stimulant-treated ADHD children with 11,515 controls found continuing declines in expected height over a four-year period.

b. Carucci et al. (Carucci et al., 2020) conducted a meta-analysis of association of long-term (> six months) methylphenidate exposure with height, weight and timing of puberty, including 18 studies (n = 4868). methylphenidate was associated with consistent statistically significant pre-post difference for both height (SMD = 0.27, CI= 0.16-0.38) and weight (SMD = 0.33, CI= 0.22-0.44) Z scores, with prominent impact on weight during the first 12 months and on height within the first 24-30 months. No significant effects of dose, formulation, age and drug-naive condition as clinical moderators were found.

c. A study using Danish national registers followed over 700,000 individuals for an average period of almost a decade. Looking at 8,300 people with ADHD, stimulant users had more than twice the rate of cardiovascular events (primarily hypertension) than nonusers. These events were rare (Dalsgaard et al., 2014).

d. A recent meta-analysis by Liang et al. (Liang et al., 2018a) found that children and adolescents treated with methylphenidate had more significant post- vs. pretreatment increases in heart rate (11 studies; SMD: 1.56, CI: 0.71-2.41, z = 3.59, p < 0.001) and systolic blood pressure (10 studies; SMD: 1.61, 95% CI: 0.81-2.41, z = 3.96, p < 0.001) than those treated by placebo.

e. In a meta-analysis of three studies with over 1.4 million people of all ages methylphenidate was not associated with a higher risk of all-cause death, heart attack or stroke (three studies, over half a million people) (Liu et al., 2019).

f. A cohort study of over 1.8 million pregnancies in the United States and over 2.5 million pregnancies in the health registries of Denmark, Finland, Sweden, Norway, and Iceland reported that use of methylphenidate (but not amphetamines) by pregnant woman was associated with a higher risk for cardiac malformations from 12.9 per thousand infants to 16.5 per thousand infants (Huybrechts et al., 2018). A meta-analysis of four studies of three million women also found that intrauterine exposure to methylphenidate was associated with a higher risk of cardiac malformations (Koren et al., 2020).

Adverse Effects in Observational Studies: Other Psychiatric and Neurological Effects

a. The Hong Kong Clinical Data Analysis & Reporting System, a population-based, electronic medical records database, was used to examine over 25,000 people receiving methylphenidate for ADHD. During the 90-day period prior to initiation of treatment, individuals with ADHD were greater than six times more likely to attempt suicide than after treatment. After ongoing treatment, the risk for attempted suicide was no longer elevated among patients with ADHD (Man et al., 2017).

b. In line with this, a Swedish cohort study examining including 37,936 patients with ADHD found no evidence for an increased risk of suicidal events, regardless of sex or type of medication. Among stimulant users, a reduced within patient rate of suicide related events was seen during treatment periods (0.81, 0.70 to 0.94) (Chen et al., 2014).

c. Another nationwide Swedish longitudinal cohort study including 38,752 patients with ADHD found that ADHD medication was associated with a reduced long-term risk (i.e., 3 years later) for

depression (hazard ratio = 0.58; 95% confidence interval, 0.51-0.67) and 20% reduced rate of unplanned hospital visits due to depression (Chang et al., 2016).

d. Studying children and youths newly diagnosed with ADHD (n=71,080) and age-and gender-matching controls (n=71,080) chosen from Taiwan's National Health Insurance database during the period of January 200 to December 201, Lee and colleagues investigated whether methylphenidate and atomoxetine influence the risk of depression (Lee et al., 2016a). ADHD patients who received longer methylphenidate treatment were found to be at a lower risk for developing any depressive disorder (aOR, 0.91; 99% CI, 0.88–0.94), dysthymic disorder (aOR, 0.89; 99% CI, 0.85–0.94) or major depressive disorder (aOR, 0.82; 99% CI, 0.73–0.93). However, treatment duration with atomoxetine was not significantly correlated with the probability of developing a depressive disorder. Regarding treatment with methylphenidate, a longer duration of methylphenidate use demonstrates significant protective effects against developing a depressive disorder.

e. Using the Hong Kong Clinical Data Analysis & Reporting System, the risk for psychosis did not differ between periods when patients were on and off methylphenidate treatment (Man et al., 2016). A Swedish registry study of over 23,000 adolescents and young adults treated with methylphenidate for ADHD found no evidence for an association between psychosis and methylphenidate treatment. A year after initiation of methylphenidate treatment, the incidence of psychotic events was 36% lower in in those with a history of psychosis and 18% lower in those without a history of psychosis relative to the period immediately before the beginning of treatment (Hollis et al., 2019).

f. Two studies investigating short-term effects reported that ADHD medication was associated with up to 35% reduced risk of substance use disorder (Chang et al., 2014; Quinn et al., 2017). Using Swedish national registers, Chang and colleagues studied all individuals born between 1960 and 1998 and diagnosed with ADHD (38,753 patients) concerning an association between stimulant ADHD medication in 2006 and substance abuse during 2009 and found that ADHD medication was not associated with increased rate of substance abuse (hazard ratio: 0.69; CI=0.57-0.84).

g. The other study adopted a within-individual design using commercial health care claims from 2,993,887 patients (2005-2014) and found statistically significant negative associations for previous treatment and treatment duration with the risk of substance-related events during months in which patients received medication (Quinn et al., 2017). In adjusted within-individual comparisons, relative to periods in which patients did not receive ADHD medication, male patients had 35% lower odds of concurrent substance-related events when receiving medication (odds ratio=0.65, CI=0.64-0.67), and female patients had 31% lower odds of concurrent substance-related events (odds ratio=0.69, 95% CI=0.67-0.71). Moreover, male patients had 19% lower odds of substance-related events 2 years after medication periods (odds ratio=0.81, CI=0.78-0.85), and female patients had 14% lower odds of substance-related events 2 years after medication periods (odds ratio=0.86, 95% CI= 0.82-0.91). If anything, the data suggested a long-term protective effect on substance abuse.

Summary of comparative safety against comparators

a. In the comprehensive systematic review and network meta-analysis on the tolerability, Cortese et al. (2018) no statistically significant differences in tolerability, were noted between active drugs, although amphetamines (odds ratio [OR] 2.30, 95% CI 1.36-3.89) and guanfacine were less well tolerated than placebo (2.64, 1.20-5.81) and tolerability for methylphenidate was not statistically different from placebo (OR 1.44, 95% CI 0.90-2.31). No statistically significant differences were found between methylphenidate and other active drugs regarding effects on systolic blood pressure, diastolic blood pressure (except more increase than modafinil (SMD: 0.09, CI: 0.26-0.45)) and weight (except more loss than guanfacine (SMD: 0.86, CI: 0.26-1.47)).

b. A systematic review and meta-analysis (Hennissen et al., 2017) compared the effects of methylphenidate, amphetamines, and atomoxetine on diastolic and systolic blood pressure (DBP, SBP) and heart rate (HR). Based on 18 clinical trials (n=5837) the investigators found small, but statistically significant pre-post increase of SBP (methylphenidate: SMD 0.25, CI 0.08-0.42, p < 0.01; amphetamine: SMD 0.09, 95% CI 0.03-0.15, p < 0.01; atomoxetine: SMD 0.16, 95% CI 0.04-0.27, p = 0.01) for all medications. methylphenidate did not have a pre-post effect on DBP and HR. amphetamine treatment was associated with a small but statistically significant pre-post increase of DBP (SMD 0.16, CI 0.03-0.29, p = 0.02), as was atomoxetine treatment (SMD 0.22, CI 0.10-0.34, p < 0.01). amphetamine and atomoxetine were associated with a small to medium statistically significant pre-post increase of HR (amphetamine: SMD 0.37, CI 0.13-0.60, p < 0.01; atomoxetine: SMD 0.43, CI 0.26-0.60, p < 0.01).

c. The meta-analysis by (Liang et al., 2018a) compared the effects of atomoxetine and methylphenidate on heart rate, systolic blood pressure, and a number of adverse cardiac events. Children and adolescents treated with atomoxetine had more significant post- vs. pre-treatment increases in heart rate (4 studies; 0.86, 95% CI: 0.11–1.62, z = 2.24, p = 0.025) and systolic blood pressure (3 studies; SMD: 0.366, 95% CI: 0.23–0.51, z = 5.09, p < 0.001) than those treated with methylphenidate. There was no difference in the number of adverse cardiac events between the participants treated with methylphenidate and atomoxetine (5 studies; OR = 0.88, 95% CI: 0.51–1.51, z = -0.47, p = 0.64).

d. In a fixed-effects meta-analysis of all double-blind, randomized, placebo-controlled trials examining the risk ratio of irritability reported as an adverse event in children treated with stimulants compared with placebo (32 trials, 3,664 children), the relative risk of irritability significantly differed between stimulant classes (Stuckelman et al., 2017). Methylphenidate derivatives was associated with a significantly decreased risk of irritability compared with placebo (risk ratio [RR] = 0.89 [95% CI, 0.82 to 0.96], z = -2.87, P = .004, k = 32, I(2) = 50%), whereas amphetamine derivatives were associated with a significantly increased risk of irritability (RR = 2.90 [95% CI, 1.26 to 6.71], z = 2.5, P = .01, k = 5, I(2) = 0%).

e. A meta-analysis of ten studies and more than 2,500 participants found that methylphenidate was more than twice as likely to induce insomnia as atomoxetine, but about half as likely to cause nausea and vomiting, and about a sixth as likely to cause drowsiness (Liu et al., 2017).

f. The umbrella systematic review by Solmi et al. (2020) concluded: "Among anti-ADHD medications with '20% of adverse events covered, methylphenidate had the best safety/coverage ratio (5/25 adverse events covered significantly worse), while guanfacine and atomoxetine had the worst safety/coverage ratio (4/16 and 5/20, respectively). Five anti-ADHD medications were associated with significantly worse anorexia (atomoxetine, d-amphetamine, lisdexamphetamine, methylphenidate, modafinil), four with insomnia (d-am-phetamine, lisdexamphetamine, methylphenidate, modafinil), three with weight loss (atomoxetine, methylphenidate, modafinil), two each with abdominal pain (methylphenidate, guanfacine), discontinuation due to adverse event (lisdexamphetamine, guanfacine), hypertension (atomoxetine, lisdexamphetamine), and sedation (clonidine, guanfacine), and one with QT prolongation (guanfacine). (page 218)"

Identification of variation in safety that may relate to health systems and patient factors

ADHD & tic disorder

a. A Cochrane review on the safety of various pharmacological treatments in children with ADHD and a comorbid chronic tic disorder (n=500; 443 boys and 67 girls) with regard to cardiovascular effects and weight changes included eight randomized controlled trials (Osland et al., 2018). Risk of bias of included studies was low for blinding; low or unclear for random sequence generation, allocation concealment, and attrition bias; and low or high for selective outcome reporting. The authors found

appetite suppression or weight loss in association with methylphenidate, dextroamphetamine, atomoxetine, and desipramine, insomnia associated with methylphenidate and dextroamphetamine, and sedation associated with clonidine.

b. Another fixed effects meta-analysis of 22 double-blind, randomized, placebo-controlled trials involving 2,385 children with ADHD examined the risk ratio of new onset or worsening tics in children treated with stimulants compared with placebo (Cohen et al., 2015). The risk of new onset or worsening of tics associated with psychostimulant treatment was similar to that observed with placebo (risk ratio = 0.99, 95% CI = 0.78-1.27, z = -0.05, p = .962). Type of psychostimulant, dose, duration of treatment, recorder, and participant age did not affect risk of new onset or worsening of tics.

ADHD & epilepsy

a. Results from two studies on seizures that used a within-individual design suggest a possible protective short-term effect of ADHD medication in individuals both with and without a history of seizures. Wiggs and colleagues (Wiggs et al., 2018) followed a sample of 801,838 patients with ADHD who had prescribed drug claims from the Truven Health MarketScan Commercial Claims and Encounters databases. In adjusted within-individual comparisons, ADHD medication was associated with lower odds of seizures among patients with (OR = 0.71, 95% CI = 0.60-0.85) and without (OR = 0.71, 95% CI = 0.62-0.82) prior seizures. Long-term within-individual comparisons suggested no evidence of an association between medication use and seizures among individuals with (OR = 0.87, 95% CI = 0.59-1.30) and without (OR = 1.01, 95% CI = 0.80-1.28) a seizure history.

b. Using Swedish population registers including a total of 21 557 individuals with a seizure history (Brikell et al., 2019) found that ADHD medication periods were associated with a reduced rate of acute seizures (hazard ratio [HR] 0.73, 95% confidence interval [CI] 0.57-0.94), compared with non-medication periods within the same individual.

ADHD & autism spectrum disorder

a. A Cochrane review on randomised controlled trials including four cross-over studies (Sturman et al., 2017), with a total of 113 children diagnosed with ASD or pervasive developmental disorder (aged 5 to 13 years) found no evidence that methylphenidate worsens the core symptoms of ASD or benefits social interaction. The only adverse effect that was significantly more likely with treatment was reduced appetite as rated by parents (risk ratio 8.28, 95% CI 2.57 to 26.73; 2 studies, 74 participants; P < 0.001; very low-quality evidence).

b. A more recent systematic review and meta-analysis by Rodrigues et al. (Rodrigues et al., 2020) pooling evidence from four randomized controlled trials children and youth with autism spectrum disorder found a non-significant elevated risk of dropout due to adverse events associated with methylphenidate.

ADHD & intellectual impairment

a. There is a paucity of data on tolerability of methylphenidate in children with intellectual impairment (ID). The most recent meta-analysis of 8 studies (average Jadad score = 2.5) by Sun et al. (Sun et al., 2019a) on children with ADHD and borderline intellectual functioning or intellectual disability (242 participants receiving methylphenidate, 181 participants receiving placebo) did not find a significant difference in drop-out rate [odds ratio (OR) = 1.679, p = 0.260] or rate of treatment discontinuation due to adverse events (OR = 4.815, p = 0.053) between subjects receiving methylphenidate (N=242) and those taking placebos (n=181), but due to sample size statistical power was limited.

ADHD & bipolar disorder

a. Retrospective studies have indicated a high prevalence of ADHD comorbidity among the bipolar disorder (BD) population. A nationwide cohort of patients (children and youth) newly diagnosed with ADHD (n-144,920) and age-and gender-matching controls (n=144,920) were found in Taiwan's National Health Insurance database from January 2000 to December 2011 (Wang et al., 2016). compared with ADHD patients that had never taken methylphenidate, patients with long-term use of methylphenidate (> 365 days) were less likely to be diagnosed with BD. However, the duration of exposure to atomoxetine did not have a significant relationship to a BD diagnosis, suggesting that methylphenidate has protective effects.

Summary of Available Estimates of Comparative Safety of Methylphenidate

The adverse effect profiles of methylphenidate and amphetamine-based medication are similar, with decreased appetite and sleep difficulties being most common. Stimulants and atomoxetine can be associated with slight, but in subgroups potentially clinically meaningful increases in systolic and diastolic blood pressure and heart rate, as well as weight loss and delays in expected height gains. Evidence suggests that, for most patients, differences in growth tend to attenuate after stimulant discontinuation (Faraone et al., 2008). Tic development or worsening has been linked to methylphenidate use, but meta-analyses do not support this claim on a group level. Overall, studies suggest that the frequency and severity of adverse events may be somewhat less with methylphenidate products. There is no evidence for an increased risk for serious adverse events for methylphenidate compared with other pharmacologic treatments for ADHD.

A systematic review of all literature on the nonmedical use and diversion of prescription stimulants including a total of 111 studies (most studies examined college students) found a high prevalence of nonmedical use and diversion of stimulants(Faraone et al., 2020). NMU and diversion are highly prevalent; self-reported rates among population samples range from 2.1% to 58.7% and from 0.7% to 80.0%, respectively. The majority of nonmedical use is associated with no, or minor, medical effects; however, adverse medical outcomes, including death, occur in some individuals, particularly when administered by non-oral routes. The issue of misuse has been investigated across the various governing medical bodies and the consensus has been that the benefits of methylphenidate continue to outweigh the risks when used to treat children aged six years and above and adolescents with ADHD. Instead, governing bodies have opted to revise prescribing information for these medicines to make them consistent and in order to maximize their safe usage.

11.Summary of Available Data on Comparative Cost and Cost-Effectiveness of Methylphenidate within its Pharmacological Class/Therapeutic Group

Year Reported	Source	Package	Package Price	Unit Price
2015	OECS/PPS*	100 Tab-cap (Tablets)	\$4.68	0.0468/tab-cap
2015	SAFRICA	30 Tab-cap (Tablets)	\$2.01	0.0670/tab-cap
2015	PERU	1 Tab-cap (Tablets)	\$0.31	0.3112/tab-cap
2014	CRSS**	100 Tab-cap	\$5.14	0.0514/tab-cap

Range of Costs

2013	BDS***	100 Tab-cap	\$ 6.29	0.0629/tab-cap
2013	NAMIBIA	30 Tab-cap	\$ 11.13	0.3710/tab-cap
Note: Data e *OECS/PPS Rica Social ***BDS=Ba	extracted from the Organization of I Security arbados Drug Serv	International Medical Products Eastern Caribbean States Pharma ices	Price Guide <u>https://msh</u> aceutical Procurement S	oriceguide.org/en/home/ ervices **CRSS=Costa

Comparative Cost-Effectiveness

A systematic review of the cost-effectiveness literature on methylphenidate was conducted (last search, Nov 10th 2020). A PubMed search using the keywords "methylphenidate cost effectiveness" yielded 44 articles. Of these, 30 were deemed relevant based on criteria that they expressed cost-effectiveness as a range of cost per routine outcome. 18 of the relevant articles were excluded based on small sample size and/or poor study design. A search of the Cochrane Database of Systematic Reviews using the same keywords yielded 5 articles, all of which were deemed irrelevant based on analyses that only mentioned methylphenidate but did not include as a comparator therapy.

The overall evidence suggests that methylphenidate can be recommended from a costeffectiveness standpoint as it is at worst cost-neutral compared with other stimulant and non-stimulant medications for the treatment of ADHD in youth.

A Markov model was constructed to compare immediate release methylphenidate to no treatment from the perspective of the Brazilian Unified Health System as payer, and the time horizon was 6 years (Maia et al., 2016). Considering the immediate release methylphenidate monthly cost of I\$38, the incremental cost-effectiveness ratio (ICER) of treatment was I\$9,103/QALY for children and I\$11,883/QALY for adolescents. In two-way sensitivity analysis, considering one Gross National Product per capita (I\$11,530) as willingness-to-pay, a cost of no-treatment lower than I\$45/month would render immediate release methylphenidate a cost-saving strategy.

A systematic review of the literature was to describe the cost-effectiveness analyses of medications launched in Spain for the treatment of ADHD (Catalá-López et al., 2013). A search was made in PubMed/MEDLINE, SCOPUS, databases of the Centre for Reviews and Dissemination, and the websites of technology assessment agencies from Canada, the United Kingdom and the Spanish Platforms AUnETS. Eleven studies that considered at least methylphenidate or atomoxetine as pharmacological treatment alternatives in children/adolescents with ADHD were examined. Both methylphenidate and atomoxetine were presented as cost-effective alternatives over placebo or no treatment in all studies. However, the incremental cost-effectiveness reasons varied greatly in the various studies. The few direct comparisons between methylphenidate and atomoxetine presented contradictory results according to the source of funding for the study: atomoxetine was shown to be cost-effective over methylphenidate in 2 evaluations associated with the manufacturer or atomoxetine, while MPH-ER was cost-effective over atomoxetine in the evaluation associated with the manufacturer of methylphenidate.

A systematic literature review of economic evaluations of pharmacotherapies for ADHD was conducted in MEDLINE, the National Health Services (NHS) Economic Evaluation database and EMBASE (Wu et al., 2012). For inclusion in this review, studies had to compare two or more ADHD interventions with at least one pharmacotherapy, assess both costs and outcomes, and be conducted between 1990 and 2011 in North America, Europe, Australia or New Zealand. Thirteen papers met the inclusion/exclusion criteria and were included in the review. Identified pharmacotherapies including methylphenidate were found to be cost-effective compared with no treatment, placebo, behavioral therapy or community care among children and adolescents with ADHD. When comparing stimulants with stimulants, there were varied results. A Zupancic et al. study showed that methylphenidate dominated dexamfetamine (with \$Can 7 lower costs, i.e. \$US8 in 2010 and a 2-point decrease in CTRS) and pemoline (with \$Can29 lower costs, i.e. \$US35 in 2010, and a 2.7- point decrease in CTRS) (Miller et al., 1998). Finally, a Marchetti et al. study found that branded methylphenidate had the lowest annual expected cost per patient among all medications considered (\$US1487/patient in 2001) and branded SA amphetamine/dexamphetamine salts had the highest expected cost (\$US2232/patient in 2001) (Marchetti et al., 2001).

An economic model with Markov processes was developed to estimate the costs and benefits of atomoxetine versus other current ADHD treatment options for the perspective of the United Kingdom (Cottrell et al., 2008). For stimulant-naïve patients, the incremental cost per QALY gained for the atomoxetine algorithm compared with the immediate-release methylphenidate hydrochloride was \pounds 15,224 (\pounds 13,241 compared with extended- release methylphenidate).

A systematic review with a total of 65 papers that met inclusion criteria were examined to assess the clinical and cost-effectiveness of oral methylphenidate, dexamfetamine and atomoxetine in children and adolescents diagnosed with ADHD (King et al., 2006). Given the lack of available evidence for statistically significant differences in efficacy between the alternative drugs, the results of the economic model were largely driven by drug cost, in which there are marked differences. The economic evaluation clearly suggests an optimal treatment strategy that is dexampletamine first-line, followed by IR-MPH for treatment failures followed by atomoxetine for repeat treatment failures. If dexampletamine is considered not suitable as a first-line therapy, the optimal strategy is IR-MPH first-line, followed by dexampletamine as second-line and atomoxetine again as third-line.

In a multi-modal treatment study, five hundred seventy-nine children with ADHD were assigned to 14 months of medication management (including methylphenidate), behavioral treatment, both combined or community care (Jensen et al., 2005). In summary, findings suggest that carefully monitored medication treatment, although not quite as effective as combination of medication and behavioral treatment, is likely to be more cost-effective in routine treatments for children with ADHD, particularly those without comorbid disorders.

A literature search was performed using MEDLINE to identify all published articles on the economic implications of ADHD, and in total, 22 relevant items were located including published original studies, economic review articles, conference presentations, and reports available on the internet (Matza et al., 2005). Three published studies utilized decision-analytic modeling techniques to assess the cost-effectiveness of drug therapy, methylphenidate, for ADHD. Overall, results of the three modeling analyses indicated that methylphenidate is a cost-effective treatment option for children with ADHD. The cost per QALY gained ranged from \$15,509 to \$19,281 when considering short- and medium-term benefits of methylphenidate.

A comprehensive literature review was conducted using HEALTHSTAR and MEDLINE regarding the use of amphetamine/dexamphetamine mixed salts, methylphenidate and dexamphetamine in the treatment of ADHD, as well as relevant ADHD studies on cost-effectiveness and quality of life (Narayan and Hay, 2004). A cost-effectiveness model was constructed from a societal perspective encompassing both direct and indirect cost, and using a cost per quality-adjusted life year outcomes metric. Decision-tree analysis was utilized to construct a 1-year model using probability-weighted utility and cost outcomes for each outcome branch. The results showed that methylphenidate treatment is dominated by amphetamine/dextroamphetamine therapy in the base case, yet when varying response rates, it can be seen that amphetamine/dexamphetamine no longer remains the dominant strategy. It is difficult to generalize about incremental cost effectiveness between stimulant therapies given the essentially equal efficacy and similar-side effect profiles between the agents. Thus, treatment with either amphetamine/dextroamphetamine or methylphenidate is quite cost effective compared with no treatment. Stimulant therapy is estimated to have an incremental cost per quality-adjusted life year ranging from US\$14,758 to 73,162/QALY.

A meta-analysis of randomized controlled trials was performed from a health sector perspective in Australia to determine cost-effectiveness of dexamphetamine and methylphenidate interventions to treated childhood ADHD (Donnelly et al., 2004). Effect sizes were translated into utility values and a simulation modelling technique was used to present a 95% uncertainty interval around the incremental cost-effectiveness ratio (ICER) which is calculated in cost per DALY averted. The findings found that methylphenidate and dexamphetamine are cost-effective interventions for childhood ADHD. The ICER For dexamphetamine is A\$4100/DALY saved and for methylphenidate is A\$15,000/DALY saved. dexamphetamine is more costly than methylphenidate for the government but much less costly for the patient. Therefore, dexamphetamine is more cost-effective than methylphenidate, although if methylphenidate were listed at a lower price as it is in Canada, then it would become more cost-effective.

A comprehensive literature search was undertaken in 1997 to identify randomized controlled or crossover trials that evaluated effects of methylphenidate in children (Gilmore and Milne, 2001). The cost-utility analysis was performed from NHS rather than a societal perspective according to methodology developed by the former South and West Development Evaluation Committee. The number of Quality Adjusted Life Years (QALYs) gained was estimated by using the Index of Health-Related Quality of Life to model treatment effects. Evidence from good and medium quality randomized controlled trials shows benefits of methylphenidate over weeks and months respectively. Evidence beyond 6 months is poorer and it is uncertain whether effects of methylphenidate persist into adolescence and adulthood. Methylphenidate is of reasonable cost-effectiveness when considering short- and medium-term benefits with an estimated cost per QALY of £7,400 to £9,200 at 1997 prices.

According to the review papers identified, the comparative cost-effectiveness literature all but one paper favor methylphenidate or is at least cost-neutral relative to both stimulant and non-stimulant treatments among treatments for ADHD.

12. Summary of the Regulatory Status and Availability of Methylphenidate

Methylphenidate is approved for use in various jurisdictions as follows:

US Food and Drug Administration (FDA)

Methylphenidate Immediate Release

Liquid Preparation

• Methylin Solution

Chewable

• Methylin Chewable

Tablets

- Ritalin
- Focalin

Methylphenidate Intermediate and long acting

Oral

Liquid Preparation

• Quillivant XR liquid)

Disintegrating tablets

• Cotempla-XR-ODT

Chewable

• Quilichew ER

Caplet

Concerta

Sprinkles

- Metadate CD/ER
- Ritalin LA
- Focalin XR
- Aptensio XR
- Adhansia XR
- Jornay PM

Transdermal Patch

• Daytrana

European Medicines Agency (EMA) (Agency, 2018)

The availability of methylphenidate in European Union countries is given in Appendix B.

United Kingdom Medicines and Healthcare Products Regulatory Agency https://tinyurl.com/owt629g

Methylphenidate hydrochloride – generic immediate release 10mg and several brand name counterparts are licensed in Australia for the treatment of ADHD. These are IR methylphenidate 10mg; Medikinet tablets 5, 10, 20 mgs Ritalin tablets 10mg; Generic methylphenidate 10, 20mgs; Concerta XL 18, 27, 36, 54mgs; Xaggitin XL 18, 27, 36, 54mgs; Matoride XL 18, 27, 36, 54mgs; Delmosart 18, 27, 36, 54mgs; Xenidata XL 18, 27, 36, 54mgs.

<u>Australian Government, Department of Health, Therapeutic Goods Administration (Australian</u> Government Department of Health, 2018)

Methylphenidate hydrochloride – generic immediate release 10mg and several brand name counterparts are licensed in Australia for the treatment of ADHD. These are Ritalin 10mg; Ritalin LA 10, 20, 30, &40 mgs, OROS methylphenidate 18, 27, 36, & 54mgs.

Japanese Pharmaceuticals and Medical Devices Agency (Pharmaceuticals and Medical Devices Agency, 2018)

Methylphenidate hydrochloride, immediate release 10mg and brand name counterparts are licensed in Japan for the treatment of ADHD.

Health Canada (Government of Canada Indigenous Services, 2017)

Methylphenidate hydrochloride, immediate release 5mg, 10mg, 20mg and brand name counterparts are licensed in Canada for the treatment of ADHD.

Chinese National Medical Products Administration http://english.nmpa.gov.cn/

Immediate release methylphenidate (10mg) and OROS methylphenidate (18mg, 36mg) are licensed in China for the treatment of ADHD.

South African Medicines Control Council https://www.sahpra.org.za/

Ritalin 10mg; Methylphenidate Douglas 10mg (generic); Ritalin LA 10mg, 20g, 30mg, 40mg; OROS methylphenidate (branded): 18mg, 27mg, 36mg, 54mg (Lilly); OROS methylphenidate (generic): 18mg, 27mg, 36mg, 54mg (clone - Sanofi); MUPS technology: Contramyl 18mg, 27mg, 36mg, 54mg

Israeli Ministry of Health Pharmacology Department https://www.gov.il/en/service/israelidrug-inde

Ritalin IR. Ritalin LA (8 hours) and OROS methylphenidate are approved for doses up to 90 mg (no matter which formula) for all prescribers. Specialists can be authorized to prescribe up to 120mg.

<u>Central Drugs Standard Control Organization (CDSCO)</u>—Directorate General of Health Services <u>Ministry of Health & Family Welfare, Government of India</u>

https://cdscoonline.gov.in/CDSCO/Drugs

Methylphenidate hydrochloride Extended release tablet- each extended release contains: methylphenidate HCL USP-18mg, 36 mg, 54 mg

National Administration on of Drugs, Foods, and Medical Devices (ANMAT)-Argentina

http://www.anmat.gov.ar/webanmat/EspecMed/febrero/especmed_monodrogas06.asp

Methylphenidate hydrochloride-20 mg

Ministry of Food and Drug Safety- South Korea

https://synapse.koreamed.org/articles/1111906

Methylphenidate Instant release (Penid, Perospin) 10-60 mg; Extended Release (Metadate CD, Medikinet retard, Bisphentin controlled release) 20- 60 mg; OROS (Concerta OROS) 18-72

<u>Ministry of Health-Singapore https://www.moh.gov.sg/cost-financing/healthcare-</u> schemes-subsidies/drug-subsidies-schemes

Methylphenidate Hydrochloride Extended Release tablet 18 mg, 27mg, 36 mg, 54 mg; Long acting tablet 20 mg; Modified-release capsule (Medikinet) 5 mg, 10 mg, 20 mg, 30 mg, 40 mg; Sustained-release tablet 20 mg; Tablet 10 mg.

National Agency for Food and Drug Administration and Control, Nigeria

<u>https://www.nafdac.gov.ng/wp-content/uploads/Publications/Narcotics/1-NATIONAL-</u> <u>GUIDELINES-ON-ESTIMATION-OF-PSYCHOTROPIC-SUBSTANCES-AND-PRECURSORS.pdf</u>

Methylphenidate tablet 10 mg, 18 mg, 36 mg

The Norwegian Medical Agency

<u>https://legemiddelverket.no/nyheter/tilbakekalling-av-batch-med-methylphenidate-teva-10-mg-kapsler</u>

Methylphenidate tablet 10 mg

Methylphenidate is also available in the following countries under different brand names

Brand Name	Country
Adaphen	South Africa
Addwize	India
Artige	Australia
Attenta	Australia
Cognil	Paraguay
Concentra	Bangladesh
Equasym	Belgium, Switzerland, Spain, Ireland
Inspiral	India
Medikinet	Belgium, Switzerland, Germany, Denmark, Estonia, Great Britain, Ireland,
	Norway, Poland, Sweden
Methylin	Argentina
Nebapul	Chile
Penid	Republic of Korea
Phenida	Pakistan
Prohiper	Indonesia
Ritaline	Luxembourg
Ritalin	United Arab Emirates, Austria, Australia, Barbados, Burkina Faso, Bahrain,
	Benin, Switzerland, Cote D'Ivoire, Chile, Colombia, Cyprus, Czech Republic,
	Germany, Denmark, Ethiopia, Great Britain, Ghana, Gambia, Guinea, Hong
	Kong, Indonesia, Ireland, Israel, Iraq, Iran, Iceland, Jordan, Japan, Kenya,
	Kuwait, Lebanon, Sri Lanka, Liberia, Libya, Morocco, Mali, Mauritania, Malt,
	Mauritius, Malawi, Mexico, Malaysia, Niger, Nigeria, Norway, New Zealand,
	Oman, Peru, Pakistan, Qatar, Saudi Arabia, Seychelles, Sudan, Sweden,
	Singapore, Slovenia, Sierra Leone, Senegal, Syria, Tunisia, Taiwan, Tanzania,
D'4.1'	Uganda, venezuela, vemen, Zamola, Zimbabwe
Ritalina D'talia	Argentina, Brazil, Paraguay, Oruguay
Ritaline	Belgium, France, Greece
Kubilen	Argenuna, Spain, Sri Lanka, Malaysia, New Zealand, Portugal, Singapore,
Tradaa	Inanana, Uruguay
Iradea	Costa Kica, Dominican Republic, Guatemaia, Honduras, Mexico, Nicaragua,
	ranama, El Salvador

13. Availability of Pharmacopeial Standards for Methylphenidate

British Pharmacopoeia: Yes, https://www.pharmacopoeia.com

European Pharmacopoeia: Yes, https://www.edqm.eu/en/european-pharmacopoeia-ph-eur-9th-edition

Indian Pharmacopeia: Yes, <u>https://www.indianpharmacopoeia.in</u> International Pharmacopeia: No, <u>http://apps.who.int/phint/en/p/docf/</u> United States Pharmacopeia: Yes, <u>http://www.usp.org</u> Australian Pharmacopeia: Yes, <u>https://www.tga.gov.au/pharmacopoeias</u> Japanese Pharmacopeia: Yes, <u>https://www.pmda.go.jp/english/index.html</u> South Africa (observer, European Pharmacopoeia) China: Yes, see Appendix C

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APPENDICES

Appendix A: Letters of Support

Appendix B: Methylphenidate Formulations Approved in European Union Countries

Appendix C: Chinese Pharmacopeia

Appendix A: Letters of Support



Professor Stephen Faraone

President World Federation of ADHD Upstate Medical University 505 Irving Avenue Syracuse New York

November 13, 2020

Dear Prof. Faraone:

On behalf of patients in Spain who receive treatment for ADHD I am writing to support your application for including methylphenidate on the World Health Organization's List of Essential Medicines. Methylphenidate is a first line treatment for Attention Deficit Hyperactivity Disorder.

Patients with ADHD include children and adolescents as well as adults. Attention deficit hyperactivity disorder is a developmental disorder with an age onset prior to 12 years. Children with ADHD have a significantly lower ability to focus and sustain attention and score higher on impulsivity and hyperactivity.

Untreated ADHD is not a benign condition and pharmacological interventions such as methylphenidate have wide ranging beneficial effects for Spanish patients. For most patients, the impairing symptoms of ADHD persist into adulthood. Because ADHD is a common neurodevelopment disorder in childhood affecting 5% of children and 2.8% of adults worldwide, limiting access to methylphenidate will have profound repercussions. It also does not consider the many mental and somatic health risks associated with failure to treat ADHD such as accidents, injuries, suicide, and premature death, which have been documented by large population studies or meta-analyses.

This medication has been a lifeline for so many thousands of children allowing them to access their education and very importantly to enjoy a positive family life. It has given them the opportunity to complete their education and move on into further education, university, and employment. All these experiences are crucial to a productive and secure future.

Excluding methylphenidate from the List of Essential Medicines undermines the confidence of prescribers and impacts decisions made by prescribers. Ultimately it is the patient who then suffers.

Including methylphenidate on the List of Essential Medicines will go a long way to destigmatize a very real treatable condition and it will improve access to this very effective treatment which, in turn, will improve the quality of life of many people with ADHD and their relatives.

Yours sincerely

Josefina Rodriguez Sastre

President ARPANIH

ARPANIH

Asociación Riojana de Padres de Niños Hiperactivos Avda. de La Rioja, 12, 2º, 26001 Logroño (La Rioja) Spain www.arpanih.org 608 692 614 - arpanih@arpanih.or

Professor Stephen Faraone President World Federation of ADHD Upstate Medical University 505 Irving Avenue Syracuse New York

12 November 2020

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Untreated ADHD is not a benign condition and pharmacological interventions such as methylphenidate have wide ranging beneficial effects for patients Spanish wide. For most patients, the impairing symptoms of ADHD persist into adulthood. Because ADHD is a common neurodevelopmental disorder in childhood affecting 5% of children and 2.8% of adults worldwide, limiting access to methylphenidate will have profound repercussions. It also does not consider the many mental and somatic health risks associated with failure to treat ADHD such as accidents, injuries, suicide, and premature death, which have been documented by large population studies or meta-analyses.

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Presidenta de ADAHIMAR

ADAHIMAR - Asociación de Ayuda al TDAH (Trastorno por Déficit de Atención/ Hiperactividad) C/ Fernando VII, Nº 44, Blq 5, 1º A. 29601. Marbella. (Málaga, España) Tlf. : +34 653590729 adahimar_tdah@yahoo.es https://es-la.facebook.com/adahimar.sanpedro adahimar.es



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www.facebook.com/ADHDMalta

11th November 2020

Dear Prof. Faraone,

On behalf of ADHD MALTA, I am writing to support your application for including methylphenidate on the World Health Organization's List of Essential Medicines for Children. Methylphenidate is a first line treatment for attention deficit hyperactivity disorder in MALTA. Excluding methylphenidate from the List of Essential Medicines undermines the confidence of prescribers and impacts decisions made by the insurance programs that pay for medications. Including methylphenidate on the List of Essential Medicines will improve access to this very effective treatment which, in turn, will improve the quality of life of many children with ADHD and the parents that care for them.

Yours Singerel 00

Carola Stivala Honorary Secretary ADHD Malta (VO 41)



ASOCIACIÓN DE PERSONAS CON DEFICIT DE ATENCION E HIPERACTIVIDAD DE BIZKAIA

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Professor Stephen Faraone

President World Federation of ADHD Upstate Medical University

505 Irving Avenue Syracuse

New York

13 November 2020

Dear Prof. Faraone:

On behalf of patients in Europe who receive treatment for ADHD I am writing to support your application for including methylphenidate on the World Health Organization's List of Essential Medicines. Methylphenidate is a first line treatment for Attention Deficit Hyperactivity Disorder in all Bizkaia

Patients with ADHD includes children and adolescents as well as adults. Attention deficit hyperactivity disorder is a developmental disorder with an age onset prior to 12 years. Children with ADHD have significantly lower ability to focus and sustain attention and score higher on impulsivity and hyperactivity.

Untreated ADHD is not a benign condition and pharmacological interventions such as methylphenidate have wide ranging beneficial effects for patients European wide. For most patients, the impairing symptoms of ADHD persist into adulthood. Because ADHD is a common neurodevelopmental disorder in childhood affecting 5% of children and 2.8% of adults worldwide, limiting access to methylphenidate will have profound repercussions. It also does not consider the many mental and somatic health risks associated with failure to treat ADHD such as accidents, injuries, suicide, and premature death, which have been documented by large population studies or meta-analyses.

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Including methylphenidate on the List of Essential Medicines will go a long way to destigmatize a very real treatable condition and it will improve access to this very effective treatment which, in turn, will improve the quality of life of many people with ADHD and their relatives.

Yours sincerely

Dr. Itziar Orive President AHIDA Bizkai

Inscrita en el Registro de Asociaciones, con Núm. AS/B/07970/1999- CIF G 95041521



Professor Stephen Faraone

President World Federation of ADHD Upstate Medical University

505 Irving Avenue Syracuse

New York

12 November 2020

Dear Prof. Faraone:

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Yours sincerely

40924913R MIRIAM GALINDO (R: G43891019) determined and a constraint of the second seco

Miriam Galindo Gómez President AHIDA-TTE

> Ajuda per la hiperactivitat i déficit d'atenció Terres de l'Ebre (AHIDA-TTE) AV Catalunya 103-109 Amposta 43870 Inscrita n 33966 de la Secció 1a del Registre de Tarragona



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Dear Prof. Faraone:

I would like to express my strong support for the inclusion of methylphenidate on the World Health Organization's List of Essential Medicines for Children. ADHD causes significant morbidity for children and adolescents across the world. Methylphenidate is an extremely effective and first line treatment for ADHD, and is recognized as such by Canadian national guidelines, physician and healthcare organizations, the federal government and all provincial governments. If methylphenidate is not included on the List of Essential Medicine, this could affect decisions made by insurance companies and governmental agencies. It's essential for child mental health and quality of life that methylphenidate be included on the List of Essential Medicines; otherwise this will reduce access and cause significant health issues to the children and families affected by this disorder. I thank you for you consideration of this important matter.

Doron Almagor MD FRCPC Child and Adolescent Psychiatrist Director, Possibilities Clinic


8 November 2020

Professor Stephen Faraone President World Federation of ADHD Upstate Medical University 505 Irving Avenue Syracuse New York

Dear Prof. Faraone:

On behalf of parents and children in the UK who receive treatment for ADHD I am writing to support your application for including methylphenidate on the World Health Organization's List of Essential Medicines for Children. Methylphenidate is a first line treatment for Attention Deficit Hyperactivity Disorder in the United Kingdom as recommended in the NICE Guidelines (National Institute of Health and Clinical Excellence). This medication has been a lifeline for so many thousands of children allowing them to access their education and very importantly to enjoy a positive family life. It has given them the opportunity to complete their education and move on into further education, university and employment. All these experiences are crucial to a productive and secure future.

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Including methylphenidate on the List of Essential Medicines will go a long way to destigmatise a very real treatable condition and it will improve access to this very effective treatment which, in turn, will improve the quality of life of many children with ADHD and the parents that care for them.

Yours sincerely

Ander Ell

Mrs Andrea Bilbow OBE Founder and CEO of ADDISS Vice President of ADHD Europe ADDISS 10th Floor, Hyde House The Hyde, Colindale London NW9 6LH

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12 November 2020

Professor Stephen Faraone President World Federation of ADHD Upstate Medical University 505 Irving Avenue Syracuse New York

Dear Prof. Faraone:

On behalf of patients in Spain who receive treatment for ADHD I am writing to support your application for including methylphenidate on the World Health Organization's List of Essential Medicines. Methylphenidate is a first line treatment for Attention Deficit Hyperactivity Disorder.

Patients with ADHD includes children and adolescents as well as adults. Attention deficit hyperactivity disorder is a developmental disorder with an age onset prior to 12 years. Children with ADHD have significantly lower ability to focus and sustain attention and score higher on impulsivity and hyperactivity.

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Yours sincerely

María Parra Calderón President ADAHIGI

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ASOCIACIÓN TINERFEÑA DE MADRES Y PADRES DE NIÑOS Y ADOLESCENTES CON DÉFICIT DE ATENCIÓN E HIPERACTIVIDAD

Professor Stephen Faraone President World Federation of ADHD Upstate Medical University 505 Irving Avenue Syracuse New York

13th November 2020

Dear Prof. Faraone:

On behalf of patients in Spain who receive treatment for ADHD I am writing to support your application for including methylphenidate on the World Health Organization's List of Essential Medicines. Methylphenidate is a first line treatment for Attention Deficit Hyperactivity Disorder.

Patients with ADHD includes children and adolescents as well as adults. Attention deficit hyperactivity disorder is a developmental disorder with an age onset prior to 12 years. Children with ADHD have significantly lower ability to focus and sustain attention and score higher on impulsivity and hyperactivity.

Untreated ADHD is not a benign condition and pharmacological interventions such as methylphenidate have wide ranging beneficial effects for patients Spanish wide. For most patients, the impairing symptoms of ADHD persist into adulthood. Because ADHD is a common neurodevelopmental disorder in childhood affecting 5% of children and 2.8% of adults worldwide, limiting access to methylphenidate will have profound repercussions. It also does not consider the many mental and somatic health risks associated with failure to treat ADHD such as accidents, injuries, suicide, and premature death, which have been documented by large population studies or meta-analyses.

This medication has been a lifeline for so many thousands of children allowing them to access their education and very importantly to enjoy a positive family life. It has given them the opportunity to complete their education and move on into further education, university, and employment. All these experiences are crucial to a productive and secure future.

Excluding methylphenidate from the List of Essential Medicines undermines the confidence of prescribers and impacts decisions made by prescribers. Ultimately it is the patient who then suffers.

Including methylphenidate on the List of Essential Medicines will go a long way to destigmatize a very real treatable condition and it will improve access to this very effective treatment which, in turn, will improve the quality of life of many people with ADHD and their relatives.

Yours sincerely

Marina Pérez Acosta President ATIMANA-DAH

> ATIMANA-DAH Avda. La Libertad, Ed. Araucaria 15 Local E 4 – Los Majuelos Tfno, 922 645 715 E-mail: secretariaatimana@gmail.com







October 18th 2020

Support Letter

Dear Prof. Faraone:

I am writing to support your application for including methylphenidate on the World Health Organization's List of Essential Medicines for Children. Methylphenidate is a first line treatment for attention deficit hyperactivity disorder in Kingdome of Saudi Arabia (KSA). Excluding methylphenidate from the List of Essential Medicines undermines the confidence of prescribers and impacts decisions made by the insurance programs that pay for medications. Including methylphenidate on the List of Essential Medicines will improve access to this very effective treatment which, in turn, will improve the quality of life of many children with ADHD and the parents that care for them.

Ayman Shawqi Alhazmi, MD

Developmental & behavioral Pediatric consultant HOD developmental pediatrics, King Saud Medical City. MOH, Riyadh KSA



Email: admin@aadpa.com.au ABN: 85 616 076 049

www.aadpa.com.au

Professor Steven V. Faraone President World Federation of ADHD

2 October 2020

Dear Professor Faraone,

I write to provide my strong support for your application for including methylphenidate on the World Health Organization's List of Essential Medicines for Children. Methylphenidate is a first line treatment for attention deficit hyperactivity disorder (ADHD) in Australia. ADHD affects around 800,000 people in Australia and is associated with a huge economic and social cost. Excluding methylphenidate from the List of Essential Medicines undermines the confidence of prescribers and impacts decisions made by the insurance programs that pay for medications. Including methylphenidate on the List of Essential Medicines will improve access to this very effective treatment which, in turn, will improve the quality of life of many children with ADHD and the parents that care for them.

Yours sincerely,

Professor Mark A. Bellgrove, President The Australian ADHD Professionals Association (AADPA) www.aadpa.com.au



Asociación TDAH Bahía de Cádiz

639 066 625

asociaciontdahbahiadecadiz@gmail.com

@asociaciónTDAHCadiz

Professor Stephen Faraone

President World Federation of ADHD Upstate Medical University 12 November 2020

505 Irving Avenue Syracuse . New York

Dear Prof. Faraone:

On behalf of patients in Spain who receive treatment for ADHD I am writing to support your application for including methylphenidate on the World Health Organization's List of Essential Medicines. Methylphenidate is a first line treatment for Attention Deficit Hyperactivity Disorder.

Patients with ADHD includes children and adolescents as well as adults. Attention deficit hyperactivity disorder is a developmental disorder with an age onset prior to 12 years. Children with ADHD have significantly lower ability to focus and sustain attention and score higher on impulsivity and hyperactivity.

Untreated ADHD is not a benign condition and pharmacological interventions such as methylphenidate have wide ranging beneficial effects for patients Spanish wide. For most patients, the impairing symptoms of ADHD persist into adulthood. Because ADHD is a common neurodevelopmental disorder in childhood affecting 5% of children and 2.8% of adults worldwide, limiting access to methylphenidate will have profound repercussions. It also does not consider the many mental and somatic health risks associated with failure to treat ADHD such as accidents, injuries, suicide, and premature death, which have been documented by large population studies or meta-analyses.

This medication has been a lifeline for so many thousands of children allowing them to access their education and very importantly to enjoy a positive family life. It has given them the opportunity to complete their education and move on into further education, university, and employment. All these experiences are crucial to a productive and secure future.

Excluding methylphenidate from the List of Essential Medicines undermines the confidence of prescribers and impacts decisions made by prescribers. Ultimately it is the patient who then suffers.



Including methylphenidate on the List of Essential Medicines will go a long way to destigmatize a very real treatable condition and it will improve access to this very effective treatment which, in turn, will improve the quality of life of many people with ADHD and their relatives.

Yours sincerely,

Vanesa Clavaín

Presidenta Asociación Bahía de Cádiz

Núm. Registro Asociaciones de Andalucía: 12953 . CIF: G72328560



October 2, 2020

Stephen V. Faraone, Ph.D. Distinguished Professor and Vice Chair for Research Department of Psychiatry, SUNY Upstate Medical University

Dear Dr. Faraone,

I am writing to support your application for including methylphenidate on the World Health Organization's List of Essential Medicines for Children. CHADD – the U.S. national organization that supports children and adults with ADHD, their parents, educators and professionals, supports evidencebased science and information regarding ADHD. Results from numerous studies, and direct reports from parents and adults, show that methylphenidate is a first line treatment for attention deficit hyperactivity disorder in the United States. Excluding methylphenidate from the List of Essential Medicines undermines the confidence of prescribers and impacts decisions made by the insurance programs that pay for medications. It is CHADD's position that all individuals with diagnosed ADHD should have access to the full range of safe and effective prescription medications indicated to treat ADHD. In light of the rampant misconceptions about ADHD treatment, the stigma surrounding the disorder, and other external pressures, individuals with ADHD often face significant barriers to accessing prescribed medications. This important medication will improve the quality of life of many children and those that care for them. We respectfully urge the World Health Organization to include methylphenidate on the List of Essential Medicines for Children.

Very truly yours,

Robert Cattoi Chief Executive Officer CHADD – Children and Adults with ADHD

Children and Adults with Attention-Deficit/Hyperactivity Disorder (CHADD) 4221 Forbes Blvd., Suite 270 Lanham, MD 20706; www.chadd.org DGKJP - Deutsche Gesellschaft für Kinder- und Jugendpsychiatrie, Psychosomatik und Psychotherapie e.V. Geschäftsstelle • Reinhardtstraße 27 B • 10117 Berlin

Stephen V. Faraone, PhD President, World Federation of ADHD Board Member, American Professional Society of ADHD and Related Disorders Distinguished Professor of Psychiatry, SUNY Upstate Medical University, Syracuse NY, USA <u>sfaraone@childpsychresearch.org</u>

Letter of Support

Dear Prof. Faraone,

I am writing to support your point to include methylphenidate on the World Health Organization's List of Essential Medicines for Children. ADHD is one of the most frequent psychiatric disorders in childhood and adolescence. There is strong evidence for the effectiveness of methylphenidate in the treatment of ADHD. Both the German National Guideline for Diagnostics and Treatment of ADHD (AWMF S3-Leitlinie ADHS bei Kindern, Jugendlichen und Registernummer Erwachsenen. 028-045. https://www.awmf.org/leitlinien/detail/ll/028-045.html) and other guidelines (like NICE) recommend MPH as a safe treatment option within child and adolescent psychiatry. There are numerous studies about effects and safety, and there is sound evidence about positive effects to prevent severe negative consequences of ADHD on our patients' later lives (e.g. school performance). In Germany MPH is licensed for the treatment of ADHD. Furthermore, it is an economic choice.

Excluding methylphenidate from the List of Essential Medicines undermines the confidence of prescribers, as it might impact decisions made by the insurance programs that pay for medications. Including methylphenidate on the List of Essential Medicines will improve access to this very effective treatment which, in turn, will improve the quality of life of many children with ADHD and the parents who care for them.

Kind regards

Prof. Michael Kölch President DGKJP



Präsident Prof. Dr. med. Michael Kölch Direktor der Klinik für Psychiatrie, Neurologie, Psychosomatik und Psychotherapie im Kindesund Jugendalter Universitätsmedian Rostock

Stellvertretender Präsident und Schatzmeister Prof. Dr. med. Marcel Romanos Direktor der Klink und Polikinik für Kinder- und Jugendpsychiatrie, Psychosomatik und Psychotherapie Universitätsklinikum Würzburg

Stellvertretender Präsident und Kongresspräsident Prof. Dr. med. Hans-Henning Flechtner Direktor der Universitätskillnik für Psychiatrie, Psychotherapie und Psychosomatische Medizin des Kindes- und Jugendalters Otto von Guericke Universität Magdeburg

October 30, 2020

Schriftführerin Prof. Dr. med. Dipl.-Theol. Christine M. Freitag Direktorin der Klink für Psychiatrie, Psychosomatik und Psychotherapie des Kindes- und Jugendalters Universitätsklinikum Frankfurt

Beisitzerin Prof. Dr. med. Renate Schepker Regionaldirektorin ZIP Südwürttemberg, Ravensburg

Beisilzerin Prof. Dr. rer. nat. Kerstin Konrad Leitung des Lehr- und Forschungsgebietes Klinische Neuropsychologie des Kindes- u. Jugendalters Klinik für Psychiatrie, Psychosomatik und Psychichterapie des Kindes- und Jugendalters Universitätsklinikum Aachen

Beisitzer Prof. Dr. med. Tobias Renner Direktor der Abteilung Psychiatrie, Psychosomatik und Psychotherapie im Kindes- und Jugendalter Universitätsklinikum Tübingen

Ehrenpräsidenten Prof. em. Dr. med. Dr. phil. Helmut Remschmidt Marburg

Prof. em. Dr. med. Dr. rer. nat. Martin H. Schmidt Mannheim

Kooptierte Mitglieder Dr. med. Martin Jung Vorsitzender der BAG KJPP

Or. med. Gundolf Berg Vorsitzender des BKJPP

Geschäftsstelle Dr. Mareike Alscher, DipL-Soz. Antie Rößler, DipL Betriebswirtin (BA) Reinhardtstraße 27 B 10117 Berlin **27** 030 / 28 09 43 86, 10 30 / 27 58 15 38 E-mail: geschaeftsstellesdelking.de Internet: http://www.dekjn.de

Deutsche Apotheker- und Ärztebank BLZ 300 606 01 Klo-Nr.: 0006788564 IBAN Nr.: DE67 3006 0601 0006 7885 64 BIC (Swift Code): DAAEDEDD

VR 27791 B Amtsgericht Berlin Charlottenburg

Prof. Dr. med. Dominique Eich-Höchli FMH Psychiatrie und Psychotherapie Turnerstrasse 26 8006 Zürich

Fon 0041-43 243 35 35

Zürich, October 30th, 2020

Dear Prof. Faraone

I am writing to support your application for including methylphenidate on the World Health Organization's List of Essential Medicines for Children.

Methylphenidate is a first line treatment for attention deficit hyperactivity disorder in Switzerland.

Excluding methylphenidate from the List of Essential Medicines undermines the confidence of prescribers and impacts decisions made by the insurance programs that pay for medications. Including methylphenidate on the List of Essential Medicines will improve access to this very effective treatment which, in turn, will improve the quality of life of many children with ADHD and the parents that care for them.

Dominique Eich-Höchli, MD, Prof. Co-President of the Swiss Society for ADHD



Schweizerische Fachgeselischaft ADHS Société suisse pour le TDAH Società svizzera per l'ADHD Swiss Society for ADHD Prof. Dr. med. Dominique Eich FMH Psychiatrie & Psychotherapie Turnerstrasse 26 CH-8006 Zürich W 133501



For the science and treatment of disorders of the brain

Cagliari, Madrid, October 27th, 2020

Prof. Stephen V. Faraone, PhD President, World Federation of ADHD Distinguished Professor of Psychiatry, SUNY Upstate Medical University, Syracuse NY, USA

Dear Prof. Faraone,

I am writing to strongly support your application for including methylphenidate on the World Health Organization's List of Essential Medicines for Children.

Methylphenidate is a first line treatment for attention deficit hyperactivity disorder in Italy, Spain and the other 10 countries represented at the European Network of Child Adolescent Neuropsychopharmacology (at the European College of Neuropsychopharmacology-ECNP).

Excluding methylphenidate from the List of Essential Medicines undermines the confidence of, prescribers, the compliance of parents and young children and impacts decisions made by the insurance programs that pay for medications.

Including methylphenidate on the List of Essential Medicines will improve access to this very effective treatment which, in turn, will improve the quality of life of many children and adolescents with ADHD and the parents that care for them.

Kind regards

Alessandro Zuddas, MD Chair of ECNP Network of Child Adolescent Neuropsychopharmacology Professor of Child Neuropsychiatry Dept. Biomedical Sciences, Sect. Neuroscience & Clinical Pharmacology University of Cagliari, Cagliari, Italy

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Carmen Moreno, MD, PhD Co-Chair of ECNP Network of Child Adolescent Neuropsychopharmacology Child and Adolescent Psychiatry Department Institute of Psychiatry and Mental Health Hospital General Universitario Gregorio Marañón, Madrid, Spain

SECRETARIAT ECNP OFFICE T: +31 88 75 69 555 F. +31 88 75 59 900 E. secretariat@ecnp.eu POSTAL ADDRESS PO BOX 85410 3508 AK Utrecht The Netherlands www.ecnp.eu VISITING ADDRESS Bolognalaan 28 3584CJ Utrecht The Netherlands



Athens, 12/11/2020

The ESCAP Board:

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Dear Prof. Faraone,

Email: danagnostopoulos@escap.eu or On behalf of the European Society for Child and Adolescent Psychiatry (ESCAP), I am writing to support your application for including methylphenidate on the World Health Organization's List of Essential Medicines for Children.

> Methylphenidate is a first-choice pharmacological treatment for children suffering with ADHD. The safety and efficacy of methylphenidate has been strongly demonstrated based on extended research and clinical evidences. Like in other disorders e.g. hypertension or diabetes everyone should have access to a medication that has shown effectiveness and is recommended in all international and European guidelines. Including methylphenidate on the List of Essential Medicines will improve access to this effective treatment which, in turn, will improve the quality of life of many children with ADHD and the parents that care for them.

Wishing that your application will be successful.

Kind regards,

ESCAP

Dimitris Anagnostopoulos

Dimitris C. Anagnostopoulos MD, PhD Professor of Child and Adolescent Psychiatry, National & Kapodistrian University of Athens President, European Society for Child and Adolescent Psychiatry danagnost@med.uoa.gr, danagnostopoulos@escap.eu Mobile: 00306973303375, FT, WhatsApp, Viber



European Society for Child and Adolescent Psychiatry - ESCAP **ESCAP** Online E-mail: info@escap.eu



Professor Stephen Faraone President World Federation of ADHD Upstate Medical University 505 Irving Avenue Syracuse New York

12 November 2020

Dear Prof. Faraone:

On behalf of patients in Castilla y León who receive treatment for ADHD I am writing to support your application for including methylphenidate on the World Health Organization's List of Essential Medicines. Methylphenidate is a first line treatment for Attention Deficit Hyperactivity Disorder.

Patients with ADHD includes children and adolescents as well as adults. Attention deficit hyperactivity disorder is a developmental disorder with an age onset prior to 12 years. Children with ADHD have significantly lower ability to focus and sustain attention and score higher on impulsivity and hyperactivity.

Untreated ADHD is not a benign condition and pharmacological interventions such as methylphenidate have wide ranging beneficial effects for patients Spanish wide. For most patients, the impairing symptoms of ADHD persist into adulthood. Because ADHD is a common neurodevelopmental disorder in childhood affecting 5% of children and 2.8% of adults worldwide, limiting access to methylphenidate will have profound repercussions. It also does not consider the many mental and somatic health risks associated with failure to treat ADHD such as accidents, injuries, suicide, and premature death, which have been documented by large population studies or meta-analyses.

This medication has been a lifeline for so many thousands of children allowing them to access their education and very importantly to enjoy a positive family life. It has given them the opportunity to complete their education and move on into further education, university, and employment. All these experiences are crucial to a productive and secure future.

Excluding methylphenidate from the List of Essential Medicines undermines the confidence of prescribers and impacts decisions made by prescribers. Ultimately it is the patient who then suffers.

Including methylphenidate on the List of Essential Medicines will go a long way to destigmatize a very real treatable condition and it will improve access to this very effective treatment which, in turn, will improve the quality of life of many people with ADHD and their relatives.

Yours sincerely

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M^a Cristina E. Peña Ruiz, President FACYL-TDAH

FEDERACIÓN DE ASOCIACIONES DE CASTILLA Y LEÓN DE TDAH (FACYL-TDAH) facyl.comunicacion@gmail.com (Información central FACYL-TDAH) Teléfono 646 25 43 33



12 November 2020

Professor Stephen Faraone President World Federation of ADHD Upstate Medical University 505 Irving Avenue Syracuse New York

Dear Prof. Faraone:

On behalf of patients in Spain who receive treatment for ADHD I am writing to support your application for including methylphenidate on the World Health Organization's List of Essential Medicines. Methylphenidate is a first line treatment for Attention Deficit Hyperactivity Disorder.

Patients with ADHD includes children and adolescents as well as adults. Attention deficit hyperactivity disorder is a developmental disorder with an age onset prior to 12 years. Children with ADHD have significantly lower ability to focus and sustain attention and score higher on impulsivity and hyperactivity.

Untreated ADHD is not a benign condition and pharmacological interventions such as methylphenidate have wide ranging beneficial effects for patients Spanish wide. For most patients, the impairing symptoms of ADHD persist into adulthood. Because ADHD is a common neurodevelopmental disorder in childhood affecting 5% of children and 2.8% of adults worldwide, limiting access to methylphenidate will have profound repercussions. It also does not consider the many mental and somatic health risks associated with failure to treat ADHD such as accidents, injuries, suicide, and premature death, which have been documented by large population studies or meta-analyses.

This medication has been a lifeline for so many thousands of children allowing them to access their education and very importantly to enjoy a positive family life. It has given them the opportunity to complete their education and move on into further education, university, and employment. All these experiences are crucial to a productive and secure future.

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Including methylphenidate on the List of Essential Medicines will go a long way to destigmatize a very real treatable condition and it will improve access to this very effective treatment which, in turn, will improve the quality of life of many people with ADHD and their relatives.

Yours sincerely Firmado por 34100719E MAITE URKIZU (R: G30787261) el día Maite Urkizu Mof控/역/92020 con un President FEAABatificado emitido por AC Representación

> FEDERACIÓN ESPAÑOLA DE ASOCIACIONES DE AYUDA AL DÉFICIT DE ATENCIÓN E HIPERACTIVIDAD, FEAADAH. Inscrita en la sección segunda del Registro de Asociaciones del Ministerio del Interior con el nº F-2296 www.feaadah.org directiva@feaadah.org Teléfono 650 237 885



www.fegadah.org info@fegadah.org

Professor Stephen Faraone

505 Irving Avenue Syracuse

President World Federation of ADHD Upstate Medical University

12 November 2020

New York

Dear Prof. Faraone:

On behalf of patients in Spain who receive treatment for ADHD I am writing to support your application for including methylphenidate on the World Health Organization's List of Essential Medicines. Methylphenidate is a first line treatment for Attention Deficit Hyperactivity Disorder.

Patients with ADHD includes children and adolescents as well as adults. Attention deficit hyperactivity disorder is a developmental disorder with an age onset prior to 12 years. Children with ADHD have significantly lower ability to focus and sustain attention and score higher on impulsivity and hyperactivity.

Untreated ADHD is not a benign condition and pharmacological interventions such as methylphenidate have wide ranging beneficial effects for patients Spanish wide. For most patients, the impairing symptoms of ADHD persist into adulthood. Because ADHD is a common neurodevelopmental disorder in childhood affecting 5% of children and 2.8% of adults worldwide, limiting access to methylphenidate will have profound repercussions. It also does not consider the many mental and somatic health risks associated with failure to treat ADHD such as accidents, injuries, suicide, and premature death, which have been documented by large population studies or meta-analyses.

This medication has been a lifeline for so many thousands of children allowing them to access their education and very importantly to enjoy a positive family life. It has given them the opportunity to complete their education and move on into further education, university, and employment. All these experiences are crucial to a productive and secure future.

Excluding methylphenidate from the List of Essential Medicines undermines the confidence of prescribers and impacts decisions made by prescribers. Ultimately it is the patient who then suffers.

Including methylphenidate on the List of Essential Medicines will go a long way to destigmatize a very real treatable condition and it will improve access to this very effective treatment which, in turn, will improve the quality of life of many people with ADHD and their relatives.

Yours sincerely



Montserrat Álvarez Rodríguez

President FEGADAH

FEDERACIÓN GALEGA DE ASOCIACIÓNS DE DÉFICIT DE ATENCIÓN E HIPERACTIVIDADE ANIHDA (Vigo) - ANIHDACORUÑA (A Coruña) - ADAHPO (Pontevedra-Vilagarcía de Arousa - Ourense) - ACNH (Santiago) - BULEBULE (Lugo)R. / Rosalía de Castro, 36, Baixo. 36001 (Pontevedra) -Telfs.: 655146134 CIF: G94128469. Email: presidencia@fegadah.org





5th October 2020

Dear Prof. Faraone

Re: Inclusion of methylphenidate on WHO List of Essential Medicines for Children

I am writing to you on behalf of PANDA SA (Paediatric Neurology and Development Association of Southern Africa) as we strongly believe that methylphenidate needs to included on the World Health Organization's List of Essential Medicines for Children.

Therefore, I would like to support your application for including methylphenidate on the World Health Organization's List of Essential Medicines for Children. Methylphenidate is a first line treatment for attention deficit hyperactivity disorder in South Africa both in the public and private sectors. In the public sector there is no access to other treatments for ADHD.

We feel that excluding methylphenidate from the List of Essential Medicines undermines the confidence of prescribers and impacts decisions made by the insurance programs that pay for medications. Including methylphenidate on the List of Essential Medicines will improve access to this very effective treatment which, in turn, will improve the quality of life of many children with ADHD and their caregivers.

Kind regards

Prof Gail Scher Paediatric Neurologist Chairperson PANDA SA (Paediatric Neurology and Development Association of Southern Africa)

Department of Paediatrics and Child Health, University of the Witwatersrand P O Box 1804 Houghton Johannesburg South Africa 2041



October 1, 2020

To: Stephen V. Faraone, PhD President, World Federation of ADHD Board Member, American Professional Society of ADHD and Related Disorders Distinguished Professor of Psychiatry, SUNY Upstate Medical University, Syracuse NY, USA

RE: WHO List of Essential Medicines for Children

Dear Prof. Faraone,

I am writing to support your application for including methylphenidate on the World Health Organization's (WHO) List of Essential Medicines for Children.

The Canadian ADHD Practice Guidelines, 4.1 Edition (2020) includes methylphenidate as a first line treatment for attention deficit hyperactivity disorder in Canada. The decision of the WHO to exclude methylphenidate from its List of Essential Medicines is contrary to Canadian expert clinical consensus. Moreover, it undermines the confidence of prescribers and impacts decisions made by the insurance programs that pay for medications.

Medications are part of an integrated and multimodal treatment plan for ADHD. Including methylphenidate on the List of Essential Medicines will improve access to this very effective treatment. Research has shown that early treatment of ADHD is a strong preventive measure in the field of mental health. Furthermore, it will improve the quality of life of many children with ADHD and the parents that care for them.

Yours faithfully,

Wet of

Martin Gignac MD FRCPC Chair, CADDRA Board of Directors CADDRA – Canadian ADHD Resource Alliance Associate Professor, McGill University, Montreal, Qc, Canada

366 Adelaide St. E, Suite 221, Toronto, ON M5A 3X9 ~ P: 416-637-8583 ~ www.caddra.ca



Dear Prof. Faraone:

I am writing on behalf of the Centre for ADHD Awareness Canada (CADDAC), a national charity dedicated to improving the lives of families and individuals with ADHD, to support your application for including methylphenidate on the World Health Organization's List of Essential Medicines for Children. While we consider Methylphenidate a second line treatment for attention deficit hyperactivity disorder in Canada, due to its briefer duration of action, we do consider it to be an essential medication for the treatment of ADHD world-wide. Excluding methylphenidate from the List of Essential Medicines undermines the confidence of prescribers and impacts decisions made by governments and insurance programs that pay for medications. Including methylphenidate on the List of Essential Medicines will improve access to this treatment which, in turn, will improve the quality of life of many children with ADHD and their families.

24 Brutter

Heidi Bernhardt Founder and President Centre for ADHD Awareness Canada 366 Adelaide St E, Suite 221 Toronto, ON Canada M5A 3X9



Dear Professor Faraone,

My name is lane Kestelman; I am the president of the Brazilian Association for Attention Deficit Disorder (ABDA) - the only and largest Non-Profit Organization, an entity representing the rights of people with ADHD in Brazil.

The reason for this email is to affirm my support for the World Health Organization in order to recognize the list of essential medications for the treatment of children with ADHD and the use of methylphenidate

In my country the most used medication for the treatment of children with ADHD is methylphenidate, due to its low cost and also because the Brazilian Health Agency (ANVISA) only makes medications based on methylphenidate and Lisdexamfetamine available for ADHD.

The exclusion of Ritalin from the list of essential medications is certain to have a negative impact on an absurd number of people and will cause problems of a social nature by interrupting important health policies that are carried out with children with ADHD in Brazil.

On behalf of the association, I reaffirm the need for methylphenidate in order to improve the quality, treatment and social inclusion of all children with ADHD in my country and, on behalf of them, I request the inclusion of the medication mentioned in the list.

Yours sincerely,

lane Kestelman



lane Kestelman Presidente Fone: 55(21) 3217.75 www.tdah.org.br

www.tdah.org.br





החברה הישראלית להפרעת קשב The Israeli Society for ADHD

10-14-20

Dear Prof. Faraone:

I am writing to support your application for including methylphenidate on the World Health Organization's List of Essential Medicines for Children.

Methylphenidate is the sole first line treatment for Attention Deficit Hyperactivity Disorder (ADHD) in Israel.

Its exclusion from the List of Essential Medicines undermines the confidence of prescribers and impacts decisions made by the insurance programs that pay for medications. Including methylphenidate on the List of Essential Medicines will improve access to this very effective treatment which, in turn, will improve the quality of life of many children with ADHD and the parents that care for them.

Professor Iris Manor

Senior Child and Adolescent psychiatrist Director of the ADHD clinic, Geha MHC, Petah-Tikva, Israel Associate professor, Sackler school of medicine, Tel Aviv University, Israel Chair of the Israeli Society of ADHD



1 Helsinky St. Petach-Tikva 49100, P.O.B. 102 • Tel: 972-3-9258258 • Fax: 972-3-9241041 • www.geha.co.il





October 15, 2020

Dear Prof. Faraone:

I am writing to support your application for including methylphenidate on the World Health Organization's List of Essential Medicines for Children.

Methylphenidate is a first line treatment for attention deficit hyperactivity disorder in México, were there is more than a two million and a half of children with these disorder.

Excluding methylphenidate from the List of Essential Medicines undermines the confidence of prescribers and impacts decisions made by the programs that pay for medications.

Including methylphenidate on the List of Essential Medicines will improve access to this very effective treatment which, in turn, will improve the quality of life of many children with ADHD and the parents that care for them.

The negative impacts on children who do not receive Methylphenidate substantially affect them, their families and society in general, for which we strongly support their inclusion.

Dr. Juan Carlos Pérez Castro Vázquez

Director General



Torresco No. 6, Col. Santa Catarina, Deleg. Coyoacán, C.P. 04010, México, D.F. Tels: (55) 5658 7122 (55) 5339 5065 (55) 5339 5936 RFC: FCF000926EEA www.cerebrofeliz.org



Federació Catalana d'Associacions de Familiars i Afectats per TDAH C/.Convent, 36 08202 Sabadell

Dear Professor Faraone:

The Catalan Federation of Associations of Relatives and People Affected by ADHD (FCAFA-TDAH) supports your request to include methylphenidate in the list of essential medicines for children of the World Health Organization. In Spain, and in Catalonia specifically, methylphenidate is a first-line treatment for attention deficit hyperactivity disorder prescribed by practically the majority of mental health professionals, and is trusted by thousands of families for treatment of this disorder for its innumerable advantages. Excluding methylphenidate from the list of essential medicines would cause thousands of children in Spain to abandon treatment by affecting this decision to the public health system and a very important economic decline in Spanish families. The inclusion of methylphenidate on the essential drug list will improve access to this highly effective treatment and, in turn, improve the quality of life for many children with ADHD and the parents who care for them.

Greetings,

Hardt

Juan Pérez Caro President of the Catalan Federation of Relatives and People Affected by ADHD (FCAFA-TDAH).

FCAFA-TDAH Inscrita en el registre d'associacions de la Generalitat de Catalunya amb el número 573 C/.Convent 36, 08202 Sabadell info@federaciocatalanatdah.org



PsyQ KvK 27321697 www.psyq.nl

PsyQ is onderdeel van Parnassia Groep

Onderwerp

The Hague, 9 oktober 2020

Dear Prof. Faraone,

I am writing to support your application for including methylphenidate on the World Health Organization's List of Essential Medicines for Children.

Methylphenidate is a first line treatment for attention deficit hyperactivity disorder in the Netherlands. Excluding methylphenidate from the List of Essential Medicines undermines the confidence of prescribers and impacts decisions made by the insurance programs that pay for medications. Including methylphenidate on the List of Essential Medicines will improve access to this very effective treatment which, in turn, will improve the quality of life of many children with ADHD and the parents that care for them.

Prof. Dr. J.J.S. Kooij, psychiatrist

Amsterdam University Medical Center/VUmc, Amsterdam, the Netherlands & PsyQ, psychomedical Programs, the Hague, the Netherlands





October 15, 2020

Dear Prof. Faraone:

I am writing to support your application for including methylphenidate on the World Health Organization's List of Essential Medicines for Children.

Methylphenidate is a first line treatment for attention deficit hyperactivity disorder in México.

Excluding methylphenidate from the List of Essential Medicines undermines the confidence of prescribers and impacts decisions made by the programs that pay for medications.

Including methylphenidate on the List of Essential Medicines will improve access to this very effective treatment which, in turn, will improve the quality of life of many children with ADHD and the parents that care for them.

Mtra, María Elena Frade Rubio

President and Founder



Torresco No. 6, Col. Santa Catarina, Deleg. Coyoacán, C.P. 04010, México, D.F. **Tels:** (55) 5658 7122 (55) 5339 5065 (55) 5339 5936 **RFC:** FCF000926EEA *www.cerebrofeliz.org*



Junta Directiva	Subject: Written Support from LILAPETDAH
Dra Zuleika Morillo	Dear Prof. Faraone,
Dia. Zaiena Wormo	On behalf of all countries of Latin America that form part of the
Presidenta	Latin American League for the study and research of ADHD, we
Dr. Gastón Schmidt	join to support your application for including methylphenidate on
Vicepresidente	the World Health Organization's List of Essential Medicines for
Dr. Javier Adi	Children. Methylphenidate is a first-line treatment for attention
Secretario General	deficit hyperactivity disorder in Latin America. Maintaining
Dra. Laura Viola	methylphenidate included on the List of Essential Medicines will
Dra. Laura viola	improve the quality of life of many children living with ADHD and
Comité Científico	the parents that care for them.
Dra. Andrea Abadi	
Comité Manejo	Zuleika Morillo de Nieto, MD President of the Latinamerican Federation and Association of Child & Adolescent Psychiatrists and related professions FLAPIA
Medios y	President of the Latinamerican League for the study of ADHD, Lilapetdah. Chief Manager of the Mental Health Department Robert Reid Hospital, Santo Dgo.
Divulgación	Child & Adolescent Psychiatrist professor of the Pediatric and general Psychiatry
	Professor in the Psychology school of the Catholic University of Santo Domingo and the
	Iberoamericano University of Santo Domingo. Chair of Iaedp. International Chapter .Association of Eating Disorders Professionals Clinic Director of medical service CPE/Renovatus, special program for eating

disorders, Santo Domingo.



Asociación TDA- H PALENCIA Es miembro de: Entidad sin ánimo de lucro, G-34243832



12 November 2020

Professor Stephen Faraone

President World Federation of ADHD Upstate Medical University

505 Irving Avenue Syracuse

New York

Dear Prof. Faraone:

On behalf of patients in Spain who receive treatment for ADHD I am writing to support your application for including methylphenidate on the World Health Organization's List of Essential Medicines. Methylphenidate is a first line treatment for Attention Deficit Hyperactivity Disorder.

Patients with ADHD includes children and adolescents as well as adults. Attention deficit hyperactivity disorder is a developmental disorder with an age onset prior to 12 years. Children with ADHD have significantly lower ability to focus and sustain attention and score higher on impulsivity and hyperactivity.

Untreated ADHD is not a benign condition and pharmacological interventions such as methylphenidate have wide ranging beneficial effects for patients Spanish wide. For most patients, the impairing symptoms of ADHD persist into adulthood. Because ADHD is a common neurodevelopmental disorder in childhood affecting 5% of children and 2.8% of adults worldwide, limiting access to methylphenidate will have profound repercussions. It also does not consider the many mental and somatic health risks associated with failure to treat ADHD such as accidents, injuries, suicide, and premature death, which have been documented by large population studies or meta-analyses.

This medication has been a lifeline for so many thousands of children allowing them to access their education and very importantly to enjoy a positive family life. It has given them the opportunity to complete their education and move on into further education, university, and employment. All these experiences are crucial to a productive and secure future.

Excluding methylphenidate from the List of Essential Medicines undermines the confidence of prescribers and impacts decisions made by prescribers. Ultimately it is the patient who then suffers.

Including methylphenidate on the List of Essential Medicines will go a long way to destigmatize a very real treatable condition and it will improve access to this very effective treatment which, in turn, will improve the quality of life of many people with ADHD and their relatives.

Yours sincerely

José Antonio Hoyos Álvarez President TDA-H PALENCIA

Firmado por 12730853P JOSE ANTONIO HOYOS (R: G34243832) el día 12/11/2020 con un certificado emitido por AC Representación

Inscrita en el Rezistro de Asocíaciones de la Delegación Territorial de la Junta de Castília y León en Palencia con el nº 0002150 de la sección PRIMERA.

Inscrita en el Registro Municipal de Asociaciónes de Palencia con el nº 430. Inscrita en el Registro Municipal de Asociaciónes de Palencia con el nº 430. Inscrita en el Registro de Entidades, Servicios y Centros de Carácter Social de la Gerencia de Servicios sociales de Castilla y León con el nº de entidad 34.0397E, sección Entidades página 397, folio1. Inscrito con el nº 34.06125, sección Servicios y Centros, página 612, folio 1 el Programa de actividades destinadas a menores en rie Entrodoce pagina daz, non 21 manto on en en onocco, accesar activitos pagina daz, non 21 en regiona de activitado activit

Gerencia de Servicios sociales de Castilla y León v. Inscrita en Registro Regional de Entidades del Voluntariado de Castilla y León con el nº A-0355.

^{2: 979 110 330 / 663 803 898 🖃:} www.tdah-palencia.es @: info@tdah-palencia.es



Professor Stephen Faraone

President World Federation of ADHD Upstate Medical University

12 November 2020

505 Irving Avenue Syracuse

New York

Dear Prof. Faraone:

On behalt of patients in Spain who receive treatment for ADHD I am writing to support your application for including methylphenidate on the World Health Organization's List of Essential Medicines. Methylphenidate is a first line treatment for Attention Deficit Hyperactivity Disorder.

Patients with ADHD includes children and adolescents as well as adults. Attention deficit hyperactivity disorder is a developmental disorder with an age onset prior to 12 years. Children with ADHD have significantly lower ability to focus and sustain attention and score higher on impulsivity and hyperactivity.

Untreated ADHD is not a benign condition and pharmacological interventions such as methylphenidate have wide ranging beneficial effects for patients Spanish wide. For most patients, the impairing symptoms of ADHD persist into adulthood. Because ADHD is a common neurodevelopmental disorder in childhood affecting 5% of children and 2.8% of adults worldwide, limiting access to methylphenidate will have profound repercussions. It also does not consider the many mental and somatic health risks associated with failure to treat ADHD such as accidents, injuries, suicide, and premature death, which have been documented by large population studies or meta-analyses.

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Yours sincerely

Maria Fe Rico Nielo

President of TDAH AXARQUIA Association

Member of FEAADAH, FAHYDA AND ADHD EUROPE

ASOCIACION TDAH AXARQUIA, G93045607, VÉLEZ-MÁLAGA INSCRITA EN EL REGISTRO DE ASOCIACIONES DE ANDALUCIA, UNIDAD REGISTRAL DE MALAGA, Nº 8811 DE LA SECCION 1º. TLF. 650358939 tdahaxarguia@gmail.com Dear Prof. Faraone:

I am writing to support your application for including methylphenidate on the World Health Organization's List of Essential Medicines for Children. Methylphenidate is a first line treatment for attention deficit hyperactivity disorder in NAME OF COUNTRY. Excluding methylphenidate from the List of Essential Medicines undermines the confidence of prescribers and impacts decisions made by the insurance programs that pay for medications. Including methylphenidate on the List of Essential Medicines will improve access to this very effective treatment which, in turn, will improve the quality of life of many children with ADHD and the parents that care for them.

Yi Zheng, MD. President, Chinese Society of Child and Adolescent Psychiatry; Asian Federation of ADHD;

Add: Beijing Anding Hospital,Capital Medical University Beijing, 100088 P.R. China E-mail: yizheng@ccmu.edu.cn



October 2, 2020

Dear Dr. Faraone,

As President of the American Professional Society of ADHD and Related Disorders (APSARD), I am writing regarding your application to include methylphenidate on the list of Essential Medicines for Children by the World Health Organization (WHO). I, and my organization, strongly support the addition of methylphenidate, which is an important first line treatment for attention-deficit/hyperactivity disorder in the United States of America and also world-wide. Excluding methylphenidate from the list is not a fair representation of the importance of this medication in treating children and adolescents. Moreover, excluding it from the list could weaken confidence in this intervention for prescribers and insurance companies. It is important to emphasize that methylphenidate has a very large effect for youth with ADHD – one of the largest in psychiatry and, in fact, all of medicine. It has a major impact on the quality of life for children with ADHD and their parents. The importance of this information cannot be overstated; ADHD is a highly prevalent and impairing disorder in children, and methylphenidate is a highly effective treatment for this condition. Including methylphenidate on the World Health Organization's List of Essential Medicines for Children will recognize the importance of this medication in the treatment of millions of children world-wide. This is a vitally important issue, and I hope the WHO will give it serious consideration.

Sincerely,

- ND

Jeffrey H. Newcorn, MD President, American Professional Society of ADHD and Related disorders (APSARD)

STICHTING

Eunethydis Foundation

Prof. Dr. Dr. T. Banaschewski Chairman

Central Institute of Mental Health Postbox: 12 21 20 D-68072 Mannheim Tobias.Banaschewski@zi-mannheim.de T: +49 / (0)621 / 1703 – 4502 F: +49 / (0)621 / 1703 - 4505

Prof. Dr. J.K. Buitelaar Secretary and Treasurer Stiching Eunethydis Foundation Pailensweg 6 NL-6523 MC Nijmegen Jan.Buitelaar@radboudumc.nl

Mannheim, 10/27/2020

Subject: Support application for including methylphenidate

Dear Prof. Faraone,

To whom it may concern

we are writing to support your application for including methylphenidate on the World Health Organization's List of Essential Medicines for Children. Methylphenidate is a first line treatment for attention deficit hyperactivity disorder in Europe. Excluding methylphenidate from the List of Essential Medicines undermines the confidence of prescribers and impacts decisions made by the insurance programs that pay for medications.

Including methylphenidate on the List of Essential Medicines will improve access to this very effective treatment which, in turn, will improve the quality of life of many children with ADHD and the parents that care for them.

Yours sincerely,

T. Banasla

Professor Tobias Banaschewski Chairman of the Eunethydis Network

Tobias Banaschewski, MD, PhD, Professor of Child and Adolescent Psychiatry

Chairman of the Eunethydis Network

Prof. Dr. J.K. Buitelaar Secretary and Treasurer

1/1

Bankaccount 56 34 46 013 ABNAMRO Bloemendaal BIC ABNANL2A IBAN NL70ABNA0563446013

KvK 34166582 Amsterdam



Professor Stephen Faraone President World Federation of ADHD Upstate Medical University 505 Irving Avenue Syracuse New York

10 November 2020

Dear Prof. Faraone:

On behalf of patients in Europe who receive treatment for ADHD I am writing to support your application for including methylphenidate on the World Health Organization's List of Essential Medicines. Methylphenidate is a first line treatment for Attention Deficit Hyperactivity Disorder in all European countries.

Patients with ADHD includes children and adolescents as well as adults. Attention deficit hyperactivity disorder is a developmental disorder with an age onset prior to 12 years. Children with ADHD have significantly lower ability to focus and sustain attention and score higher on impulsivity and hyperactivity.

Untreated ADHD is not a benign condition and pharmacological interventions such as methylphenidate have wide ranging beneficial effects for patients European wide. For most patients, the impairing symptoms of ADHD persist into adulthood. Because ADHD is a common neurodevelopmental disorder in childhood affecting 5% of children and 2.8% of adults worldwide, limiting access to methylphenidate will have profound repercussions. It also does not consider the many mental and somatic health risks associated with failure to treat ADHD such as accidents, injuries, suicide, and premature death, which have been documented by large population studies or meta-analyses.

This medication has been a lifeline for so many thousands of children allowing them to access their education and very importantly to enjoy a positive family life. It has given them the opportunity to complete their education and move on into further education, university, and employment. All these experiences are crucial to a productive and secure future.

Excluding methylphenidate from the List of Essential Medicines undermines the confidence of prescribers and impacts decisions made by prescribers. Ultimately it is the patient who then suffers.

Including methylphenidate on the List of Essential Medicines will go a long way to destigmatize a very real treatable condition and it will improve access to this very effective treatment which, in turn, will improve the quality of life of many people with ADHD and their relatives.

Yours sincerely

DI Myrious Bra

Dr. Myriam Bea President ADHD Europe

ADHD Europe

Cosigned by National organisations

K. Kilbride

Ken Kilbride, CEO, ADHD Ireland

ADHD

Elin H. Hinriksdotti

Elín Hoe Hinriksdóttir M.Ed. Chair, ADHD association Iceland. Board member of The Icelandic Disability Alliance

ADHE

Christine Javis ADHD Solutions CIC

Director/CEO ADHD Solutions CIC







Dr. Dominique Bertholdt Treffpunkt ADHS.Asbl Luxemburg

Parture Steeron

National President

Associazione Italiana Famiglie ADHD Organizzazione di Volontariato

llaurd avere

National Vice President

Associazione Italiana Famiglie ADHD Organizzazione di Volontariato



BSNON

Beverley Sinton President of ADHD, ASC & LD Belgium European Brain Ambassador

ADHD .

He hunt Gottle

Hartmut Gartzke Vorsitzender ADHS Deutschland e. V.

ADHS ADHS

- foreningen

Trish Nymark Vice President Danish ADHD Organization



Christine GETIN Présidente HyperSupers - TDAH France



ASOCIACIÓN DE AFECTADOS POR TDAH DE MADRID. C/ Molina de Segura, 33 28030 Madrid

91 3560207 (S 657371999 - 691530347 info@anshda.org www.anshda.org

12 November 2020.

Professor Stephen Faraone President World Federation of ADHD Upstate Medical University 505 Irving Avenue Syracuse New York

Dear Prof. Faraone:

On behalf of patients in Spain who receive treatment for ADHD I am writing to support your application for including methylphenidate on the World Health Organization's List of Essential Medicines. Methylphenidate is a first line treatment for Attention Deficit Hyperactivity Disorder.

Patients with ADHD includes children and adolescents as well as adults. Attention deficit hyperactivity disorder is a developmental disorder with an age onset prior to 12 years. Children with ADHD have significantly lower ability to focus and sustain attention and score higher on impulsivity and hyperactivity.

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Yours sincerely. Teresa Moras Cítores President ANSHDA.

Anshda Tda-h Madrid



Federación Andaluza de Asociaciones de Ayuda al TDAH T 693 728 555 <u>fahyda.org@qmail.com</u> http://fahyda.blogspot.com/

Professor Stephen Faraone

President World Federation of ADHD Upstate Medical University

505 Irving Avenue Syracuse

New York

12 November 2020

Dear Prof. Faraone:

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Yours sincerely

AHYD FNIF G-91720219 A Federación Andaluza de Asociaciones de Ayuda al Trastorno Hipercinético y Deficit de Atención Telf. 693 728 555

Juan Ángel Quirós Cantos President FAHYDA

> FAHYDA c/ Camino de Ronda 133, Bajo C 18003 Granada - CIF G-91720219

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Federación Andaluza de Asociaciones de Ayuda al TDAH T 693 728 555 <u>fahyda.orq@gmail.com</u> http://fahyda.blogspot.com/

FAHYDA c/ Camino de Ronda 133, Bajo C 18003 Granada - CIF G-91720219

From: "宮島祐." <<u>miyajima-t@tokyo-kasei.ac.jp</u>> Sent: Wednesday, November 18, 2020 7:38 AM To: Steve Faraone <<u>sfaraone@childpsychresearch.org</u>> Subject: Re: WHO application

Dear Prof. Faraone:

I am writing to support your application for including methylphenidate on the World Health Organization's List of Essential Medicines for Children. Methylphenidate is a first line treatment for attention deficit hyperactivity disorder in Japan. Excluding methylphenidate from the List of Essential Medicines undermines the confidence of prescribers and impacts decisions made by the insurance programs that pay for medications. Including methylphenidate on the List of Essential Medicines will improve access to this very effective treatment which, in turn, will improve the quality of life of many children with ADHD and the parents that care for them.

Tasuku Miyajima, M.D. Ph.D Professor & Chairman

Department of Education for Childcare, Tokyo Kasei University

Miyajima-t@tokyo-kasei.ac.jp

2-15-1 Inariyama, Sayama, Saitama, 350-1398, Japan TEL: +81-(0)4-2952-1621, FAX: +81-(0)4-2955-6944 President of Japanese Society of ADHD



11-11-2020

Dear Prof. Faraone:

I am writing to support your application for including methylphenidate on the World Health Organization's List of Essential Medicines for Children. Methylphenidate is a first line treatment for attention deficit hyperactivity disorder in the Netherlands. Excluding methylphenidate from the List of Essential Medicines undermines the confidence of prescribers and impacts decisions made by the insurance programs that pay for medications. Including methylphenidate on the List of Essential Medicines will improve access to this very effective treatment which, in turn, will improve the quality of life of many children with ADHD and the parents that care for them.

Rob Rodrigues Pereira, pediatrician

Chairman Impuls en Woortblind Organisation for individuals with AD(H)D and dyslexia/dyscalculia Postbus 1058, 3860 BB Nijkerk, the Netherlands Ref No..... In replying the above Number and date of this letter should be quoted



MINISTRY OF HEALTH RICHMOND HILL INSTITUTIONS C/O MT. GAY HOSPITAL MT. GAY, ST. GEORGE'S GRENADA W.I.

October 23, 2020

The Secretary of the 22nd Expert Committee on the Selection and Use of Essential Medicines Medicine Access and Rational Use (MAR) Department of Essential Medicines and Health Products (EMP) World Health Organization 20 Avenue Appia CH-1211 Geneva 27 Switzerland

Dear Secretariat,

I am writing to on behalf of the Mt. Gay Mental Hospital in support of the application being made by Dr. Craig Katz and his colleagues at Mount Sinai School of Medicine to have Methylphenidate added to the List of Essential Medications. We have collaborated with them for over 3 years on meeting mental health needs in our own country and see their decision to make this application on behalf of people around the world as showing great initiative and wisdom. We have much experience with Methylphenidate.

We believe that at least one central nervous system stimulant should be considered an essential part of any formulary, and our experience definitely supports that it should be Methylphenidate. I would like to make a special appeal that it be included in its immediate-release formulations.

Respectfully,

.....

Dr. Evlýn Spencer **MD** Hoúse Officer Mt. Gay Psychiatric Hospital

Tel: 1 (473) 440 - 3154/3272 Fax: 1 (473) 435 - 4160 mtgayhsp@health.gov.gd

Ref No..... In replying the above Number and date of this letter should be quoted



MINISTRY OF HEALTH RICHMOND HILL INSTITUTIONS C/O MT. GAY HOSPITAL MT. GAY, ST. GEORGE'S GRENADA W.I.

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Dr. Arelys Francia Vasconcelos Consultant Psychiatrist Mt. Gay Psychiatric Hospital Tel: 1 (473) 440 – 3154/3272 Fax: 1 (473) 435 – 4160 mtgayhsp@health.gov.gd Ref No..... In replying the above Number and date of this letter should be quoted



MINISTRY OF HEALTH RICHMOND HILL INSTITUTIONS C/O MT. GAY HOSPITAL MT. GAY, ST. GEORGE'S GRENADA W.I.

October 23, 2020

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Respectfully,

Dr. Doris Keens Douglas **MD, MPH** Senior Registrar Mt. Gay Psychiatric Hospital

Tel: 1 (473) 440 - 3154/3272 Fax: 1 (473) 435 - 4160 mtgayhsp@health.gov.gd

GMERS MEDICAL COLLEGE & HOSPITAL Department of Psychiatry, Room No: 204, 2nd Floor, Hospital Building, GOTRI, Vadodara - 390021

29 October 2020

The Secretary of the 22nd Expert Committee on the Selection and Use of Essential Medicines Medicine Access and Rational Use (MAR) Department of Essentail Medicines and Halth Products (EMI) World Health Organization 20 Avenue Appia CH-1211 Geneva 27 Switzerland

Dear Secretariat

I am writing to you on behalf of the GMERS Medical College and Hospital, Gotri, Vadodara, India, in support of the application being made by Dr. Craig Katz and his colleagues at the Mount Sinai School of Medicine to have Methylphenidate added to the List of Essential Medications. We have collaborated with them for over a decade on meeting mental health needs in our own country and see their decision to make this application on behalf of people around the world as showing great initiative and wisdom. We have much experience with Mehylphenidate.

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Respectfully

Dr. Sandip H. Shah MD (Psychiatry) Professor and Head Department of Psychiatry GMERS Medical College Gotri, Vadodara.

Dr Sandip H Shah MD Professor and Head of Deparment of Psychiatry GEMRS Medical College and Hospital, Gotri, Vadodara, INDIA. Email – hod.psy.gotri@gmail.com.



MINISTRY OF HEALTH

Third Floor, East Block Building Belmopan, Belize, Central America.

Phone: 501-822-2325/2363 Fax: 501-822-2942/2055 seniorsecretary@health.gov.bz

October 5, 2020

The Secretary of the 22rd Expert Committee on the Selection and Use of Essential Medicines Medicine Access and Rational Use (MAR) Department of Essential Medicines and Health Products (EMP) World Health Organization 20 Avenue Appia CH-LZII Geneva2T Switzerland

Dear Secretariat,

I am writing to you on behalf of the Ministry of Health, Belize in support of the application being made by Dr. Craig Katz and his colleagues at the Mount Sinai School of Medicine to have Methylphenidate added to the List of Essential Medications. We have collaborated with them for over 10 years on meeting mental health needs in our own country and see their decision to make this application on behalf of people around the world as showing great initiative and wisdom. We have much experience with Methylphenidate.

We believe that at least one central nervous system stimulant should be considered an essential part of any formulary, and our experience definitely supports that it should be Methylphenidate. I would like to make a special appeal that it be included in its immediate-release formulations.

Respectfully,

Iveth Quintanilla, RN, PNP, MHA Head, Mental Health Unit Belize Ministry of Health Belize, Central America



BUĐENJE – Udruga za razumijevanje ADHD-a www.budenje.hr, 098/9978-915, e-mail: budenje@gmail.com Žiro račun Zagrebačka bauka: HR4923600001102716634 MB: 1867385; OIB: 01048724725; Kačićeva 4, 10 000 Zagreb

13th November 2020

Dear Prof. Faraone,

On behalf of "Buđenje" - non profit ADHD organisation from Croatia, I am writing to support your application for including methylphenidate on the World Health Organization's List of Essential Medicines for Children.

Yours Sincerely,

Marko Ferek President





Servei de Psiquiatria Hospital Universitari Vall d'Hebron Pg. Vall d'Hebron 119-129 | 08035 Barcelona T. 93 489 42 94 jaramos@vhebron.net

Dear Prof. Faraone:

I am writing to support your application for including methylphenidate on the World Health Organization's List of Essential Medicines for Children. Methylphenidate is a first line treatment for attention deficit hyperactivity disorder (ADHD) in Spain, where around of 80% of the children under medical treatment for ADHD are taking methylphenidate. Excluding methylphenidate from the List of Essential Medicines undermines the confidence of prescribers and the families. Also, this decision impact negatively on the appropriate treatment of children with ADHD. Including methylphenidate on the List of Essential Medicines will improve access to this very effective treatment which, in turn, will improve the quality of life of many children with ADHD and the parents that care for them.

Sincerely, a

Prof. Josep Antoni Ramos Quiroga, MD, PhD Head of Psychiatry Department Hospital Universitari Vall d'Hebron Universitat Autònoma de Barcelona

Chair of the Section Neurodevelopmental Disorders Across Lifespan. European Psychiatric Association

Pg. Vall d'Hebron, 119-129 08035 Barcelona Spain

Barcelona, October 14th of 2020







UMB

Appendix B: Methylphenidate Formulations Approved in European Union Countries

ANNEX I

LIST OF THE NAMES, PHARMACEUTICAL FORMS, STRENGTHS OF THE MEDICINAL PRODUCTS, ROUTE OF ADMINISTRATION, MARKETING AUTHORISATION HOLDERS IN THE MEMBER STATES (EU/EEA)

Member State (EU/EEA)	Marketing Authorisation Holder	Invented Name	Strength	Pharmaceutical form	Route of administration
AT - Austria	Janssen-Cilag Pharma GmbH Pfarrgasse 75 A-1232 Wien	Concerta 18 mg Retardtabletten	18 mg	Prolonged-release tablet	oral use
AT - Austria	Janssen-Cilag Pharma GmbH Pfarrgasse 75 A-1232 Wien	Concerta 36 mg Retardtabletten	36 mg	Prolonged-release tablet	oral use
AT - Austria	Janssen-Cilag Pharma GmbH Pfarrgasse 75 A-1232 Wien	Concerta 54 mg Retardtabletten	54 mg	Prolonged-release tablet	oral use
AT - Austria	Janssen-Cilag Pharma GmbH Pfarrgasse 75 A-1232 Wien	Concerta 27 mg Retardtabletten	27 mg	Prolonged-release tablet	oral use
AT - Austria	UCB Pharma GmbH Jaquingasse 16-18/3 A-1030 Wien	Equasym retard 10 mg - Hartkapseln mit veränderter Wirkstofffreisetzung	10 mg	Modified-release capsule, hard	oral use
AT - Austria	UCB Pharma GmbH Jaquingasse 16-18/3 A-1030 Wien	Equasym retard 20 mg - Hartkapseln mit veränderter Wirkstofffreisetzung	20 mg	Modified-release capsule, hard	oral use
AT - Austria	UCB Pharma GmbH Jaquingasse 16-18/3 A-1030 Wien	Equasym retard 30 mg - Hartkapseln mit veränderter Wirkstofffreisetzung	30 mg	Modified-release capsule, hard	oral use
AT - Austria	Medice Arzneimittel Pütter GmbH & Co KG Kuhloweg 37 DE-58638 Iserlohn	Medikinet 10 mg - retardierte Hartkapseln	10 mg	Prolonged-release capsule, hard	oral use
AT - Austria	Medice Arzneimittel Pütter GmbH & Co KG Kuhloweg 37 DE-58638 Iserlohn	Medikinet 20 mg - retardierte Hartkapseln	20 mg	Prolonged-release capsule, hard	oral use
AT - Austria	Medice Arzneimittel Pütter GmbH & Co KG Kuhloweg 37 DE-58638 Iserlohn	Medikinet 30 mg - retardierte Hartkapseln	30 mg	Prolonged-release capsule, hard	oral use

Marketing Authorisations for medicinal products containing METHYLPHENIDATE

AT - Austria	Medice Arzneimittel Pütter GmbH & Co KG Kuhloweg 37 DE-58638 Iserlohn	Medikinet 40 mg - retardierte Hartkapseln	40 mg	Prolonged-release capsule, hard	oral use
AT - Austria	Medice Arzneimittel Pütter GmbH & Co KG Kuhloweg 37 DE-58638 Iserlohn	Medikinet 5 mg - Tabletten	5 mg	tablet	oral use
AT - Austria	Medice Arzneimittel Pütter GmbH & Co KG Kuhloweg 37 DE-58638 Iserlohn	Medikinet 10 mg - Tabletten	10 mg	tablet	oral use
AT - Austria	Medice Arzneimittel Pütter GmbH & Co KG Kuhloweg 37 DE-58638 Iserlohn	Medikinet 20 mg - Tabletten	20 mg	tablet	oral use
AT - Austria	Novartis Pharma GmbH Brunner Straße 59 A-1235 Wien	Ritalin LA 20 mg - Kapseln	20 mg	Modified-release capsule, hard	oral use
AT - Austria	Novartis Pharma GmbH Brunner Straße 59 A-1235 Wien	Ritalin LA 30 mg - Kapseln	30 mg	Modified-release capsule, hard	oral use
AT - Austria	Novartis Pharma GmbH Brunner Straße 59 A-1235 Wien	Ritalin LA 40 mg - Kapseln	40 mg	Modified-release capsule, hard	oral use
AT - Austria	Novartis Pharma GmbH Brunner Straße 59 A-1235 Wien	Ritalin 10 mg - Tabletten	10 mg	tablet	oral use
AT - Austria	Laboratorios Rubio SA C/Industria 29, Poligon Industrial Compte de Sert ES-08755 Castellbisbal (Barcelona)	RUBIFEN 5 mg -Tabletten	5 mg	tablet	oral use
AT - Austria	Laboratorios Rubio SA C/Industria 29, Poligon Industrial Compte de Sert ES-08755 Castellbisbal (Barcelona)	RUBIFEN 10 mg -Tabletten	10 mg	tablet	oral use
AT - Austria	Laboratorios Rubio SA C/Industria 29, Poligon Industrial Compte de Sert ES-08755 Castellbisbal (Barcelona)	RUBIFEN 20 mg -Tabletten	20 mg	tablet	oral use
BE - Belgium	JANSSEN CILAG N.V. Roderveldlaan, 1 B-2600 BERCHEM	CONCERTA 18 MG	18 mg	Prolonged-release tablet	oral use

BE - Belgium	JANSSEN CILAG N.V. Roderveldlaan, 1 B-2600 BERCHEM	CONCERTA 36 MG	36 mg	Prolonged-release tablet	oral use
BE - Belgium	JANSSEN CILAG N.V. Roderveldlaan, 1 B-2600 BERCHEM	CONCERTA 54 MG	54 mg	Prolonged-release tablet	oral use
BE - Belgium	JANSSEN CILAG N.V. Roderveldlaan, 1 B-2600 BERCHEM	CONCERTA 27 MG	27 mg	Prolonged-release tablet	oral use
BE - Belgium	NOVARTIS PHARMA N.V. Medialaan, 40 1800 VILVOORDE	RILATINE	10 mg	tablet	oral use
BE - Belgium	NOVARTIS PHARMA N.V. Medialaan, 40 1800 VILVOORDE	RILATINE MODIFIED RELEASE 20 MG	20 mg	Modified-release capsule, hard	oral use
BE - Belgium	NOVARTIS PHARMA N.V. Medialaan, 40 1800 VILVOORDE	RILATINE MODIFIED RELEASE 30 MG	30 mg	Modified-release capsule, hard	oral use
BE - Belgium	NOVARTIS PHARMA N.V. Medialaan, 40 1800 VILVOORDE	RILATINE MODIFIED RELEASE 40 MG	40 mg	Modified-release capsule, hard	oral use
BG - Bulgaria	Johnson & Johnson D.O.O. Smartinska 53, 1000 Ljubljana, Slovenia	Concerta	36 mg	prolonged release tablet	Oral use
BG - Bulgaria	Johnson & Johnson D.O.O. Smartinska 53, 1000 Ljubljana, Slovenia	Concerta	18 mg	prolonged release tablet	Oral use
BG - Bulgaria	Johnson & Johnson D.O.O. Smartinska 53, 1000 Ljubljana, Slovenia	Concerta	54 mg	prolonged release tablet	Oral use

CY - Cyprus	Janssen-Cilag International N.V. Turnhoutseweg 30 B-2340 Beerse Belgium	Concerta	18 mg	prolonged-release tablet	oral use
CY - Cyprus	Janssen-Cilag International N.V. Turnhoutseweg 30 B-2340 Beerse Belgium	Concerta	36 mg	prolonged-release tablet	oral use
CY - Cyprus	Janssen-Cilag International N.V. Turnhoutseweg 30 B-2340 Beerse Belgium	Concerta	54 mg	prolonged-release tablet	oral use
CS - Czech Republic	Novartis s.r.o. Nagano III. U Nákladového nádraží 10 130 00 Praha 3, Czech Republic	RITALIN	10 mg	tablet	oral use
CS – Czech Republic	Janssen-Cilag s.r.o., Karla Engliše 3201/6, 150 00 Praha 5 – Smíchov, Czech Republic	CONCERTA 18 mg	18 mg	prolonged release tablet	oral use
CS – Czech Republic	Janssen-Cilag s.r.o., Karla Engliše 3201/6, 150 00 Praha 5 – Smíchov, Czech Republic	CONCERTA 36 mg	36 mg	prolonged release tablet	oral use
CS – Czech Republic	Janssen-Cilag s.r.o., Karla Engliše 3201/6, 150 00 Praha 5 – Smichov, Czech Republic	CONCERTA 54 mg	54 mg	prolonged release tablet	oral use
DK - Denmark	Janssen-Cilag A/S Hammerbakken 19 DK-3460 Birkerød Denmark	CONCERTA	18 mg	Prolonged-release tablets	Oral use
DK-Denmark	Janssen-Cilag A/S Hammerbakken 19 DK-3460 Birkerød Denmark	CONCERTA	36 mg	Prolonged-release tablets	Oral use

DK - Denmark	Janssen-Cilag A/S Hammerbakken 19 DK-3460 Birkerød Denmark	CONCERTA	54 mg	Prolonged-release tablets	Oral use
DK - Denmark	UCB Nordic A/S Arne Jacobsen Allé 15, DK-2300 Kobenhavn S Denmark	Equasym	5 mg	Tablets	Oral
DK - Denmark	UCB Nordic A/S Arne Jacobsens Allé 15 DK-2300 Kobenhavn S Denmark	Equasym	10 mg	Tablets	Oral
DK - Denmark	UCB Nordic A/S Arne Jacobsens Allé 15 DK-2300 Kobenhavn S Denmark	Equasym	20 mg	Tablets	Oral
DK - Denmark	UCB Nordic A/S Arne Jacobsen Allé 15, DK-2300 Kobenhavn S Denmark	Equasym Depot	10, 20, 30 mg	Modified-release capsules, hard	Oral
DA	Medice Arzneimittle Kuhloweg 37-39 Iserlohn Germany	Medikinet	5, 10, 20 mg	Tablets	Oral
DA	Medice Arzneimittle Kuhloweg 37-39 Iserlohn Germany	Medikinet CR	10, 20, 30, 40 mg	Hard capsules, modified release	Oral
DA	Sandoz A/S C.F. Tietgens Boulevard 40 5220 Odense SØ Denmark	Motiron	5, 10, 20 mg	Tablets	Oral

DA	Novartis Healthcare Lyngbyvej 172 2100 Københarn Ø Denmark	Ritalin	10 mg	Tablets	Oral
DA	Novartis Healthcare Lyngbyvej 172 2100 Københam Ø Denmark	Ritalin Uno	20, 30, 40 mg	Hard capsules, modifed release	oral
ES - Spain	Laboratorios RUBIO, SA Industria 29- Polígono industrial Comte de Sert Castellbisbal 08755	RUBIFEN 10 mg comprimidos	10 mg	tablets	oral use
ES - Spain	Laboratorios RUBIO, SA Industria 29- Polígono industrial Comte de Sert Castellbisbal 08755	RUBIFEN 20 mg comprimidos	20 mg	tablets	oral use
ES - Spain	Laboratorios RUBIO, SA Industria 29- Polígono industrial Comte de Sert Castellbisbal 08755	RUBIFEN 5 mg comprimidos	5 mg	tablets	oral use
ES - Spain	JANSSEN CILAG, SA Paseo de las doce estrellas, 5-7 Madrid 28042	CONCERTA 27 mg comprimidos de liberación prolongada	27 mg	prolonged-release tablet	oral use
ES - Spain	JANSSEN CILAG, SA Paseo de las doce estrellas, 5-7 Madrid 28042	CONCERTA 36 mg comprimidos de liberación prolongada	36 mg	prolonged-release tablet	oral use
ES - Spain	JANSSEN CILAG, SA Paseo de las doce estrellas, 5-7 Madrid 28042	CONCERTA 54 mg comprimidos de liberación prolongada	54 mg	prolonged-release tablet	oral use
ES - Spain	JANSEN CILANG, SA Paseo de las doce estrellas, 5-7 Madrid 28042	CONCERTA 18 mg comprimidos de liberación prolongada	18 mg	prolonged-release tablet	oral use
ES - Spain	Laboratorios RUBIO, SA Industria 29- Polígono industrial Comte de Sert Castellbisbal 08755	OMOZIN 5 mg comprimidos	5 mg	tablets	oral use

ES - Spain	Laboratorios RUBIO, SA Industria 29- Polígono industrial Comte de Sert Castellbisbal 08755	OMOZIN 10 mg comprimidos	10 mg	tablets	oral use
ES - Spain	Laboratorios RUBIO, SA Industria 29- Polígono industrial Comte de Sert Castellbisbal 08755	OMOZIN 20 mg comprimidos	20 mg	tablets	oral use
ES - Spain	Medice Arznemitel Putter GMBH Kuhloweg, 37 D 58638 Iselohon	MEDIKINET 5 mg comprimidos	5mg	Tablets	oral use
ES - Spain	Medice Arznemitel Putter GMBH Kuhloweg, 37 D 58638 Iselohon	MEDIKINET 10 mg comprimidos	10 mg	Tablets	oral use
ES - Spain	Medice Arznemitel Putter GMBH Kuhloweg, 37 D 58638 Iselohon	MEDIKINET 20 mg comprimidos	20 mg	Tablets	oral use
ES - Spain	Medice Arznemitel Putter GMBH Kuhloweg, 37 D 58638 Iselohon	MEDIKINET 10 mg cápsulas de liberación prolongada	10 mg	prolonged release Tablets	oral use
ES - Spain	Medice Arznemitel Putter GMBH Kuhloweg, 37 D 58638 Iselohon	MEDIKINET 20 mg cápsulas liberación priongada	20 mg	prolonged release Tablets	oral use
ES - Spain	Medice Arznemitel Putter GMBH Kuhloweg, 37 D 58638 Iselohon	MEDIKINET 30 mg cápsulas liberación prolongada	30 mg	Prolonged releaseTablets	oral use
ES - Spain	Medice Arznemitel Putter GMBH Kuhloweg, 37 D 58638 Iselohon	MEDIKINET 40 mg cápsulas liberación prolongada	40 mg	Prolonged releaseTablets	oral use
ET – Estonia	Johnson & Johnson UAB, Geležinio Vilko g. 18A, LT-08104 Vilnius, Lithuania.	CONCERTA	18 mg	prolonged release tablet	oral use
ET – Estonia	Johnson & Johnson UAB, Geležinio Vilko g. 18A, LT-08104 Vilnius, Lithuania.	CONCERTA	36 mg	prolonged release tablet	oral use

ET – Estonia	Johnson & Johnson UAB, Geležinio Vilko g. 18A, LT-08104 Vilnius, Lithuania.	CONCERTA	54 mg	prolonged release tablet	oral use
FI - Finland	Janssen-Cilag Oy Metsänneidonkuja 8 02130 Espoo FINLAND	Concerta	18 mg	prolonged-release tablet	oral
FI - Finland	Janssen-Cilag Oy Metsänneidonkuja 8 02130 Espoo FINLAND	Concerta	27 mg	prolonged-release tablet	oral
FI - Finland	Janssen-Cilag Oy Metsänneidonkuja 8 02130 Espoo FINLAND	Concerta	36 mg	prolonged-release tablet	oral
FI - Finland	Janssen-Cilag Oy Metsänneidonkuja 8 02130 Espoo FINLAND	Concerta	54 mg	prolonged-release tablet	oral
FI - Finland	UCB Pharma Oy Finland Malminkaari 5 00700 Helsinki FINLAND	Equasym Retard	10 mg	Modified-release capsule, hard	oral
FI - Finland	UCB Pharma Oy Finland Malminkaari 5 00700 Helsinki FINLAND	Equasym Retard	20 mg	Modified-release capsule, hard	oral
FI - Finland	UCB Pharma Oy Finland Malminkaari 5 00700 Helsinki FINLAND	Equasym Retard	30 mg	Modified-release capsule, hard	oral
FI - Finland	Medice Arzneimittel Pütter GmbH & Co. KG Kuhloweg 37 58638 ISERLOHN GERMANY	Medikinet	5 mg	tablet	oral
FI - Finland	Medice Arzneimittel Pütter GmbH & Co. KG Kuhloweg 37 58638 ISERLOHN GERMANY	Medikinet	10 mg	tablet	oral
FI - Finland	Medice Arzneimittel Pütter GmbH & Co. KG Kuhloweg 37 58638 ISERLOHN GERMANY	Medikinet	20 mg	tablet	oral
FI - Finland	Medice Arzneimittel Pütter GmbH & Co. KG Kuhloweg 37 58638 ISERLOHN GERMANY	Medikinet CR	10 mg	prolonged-release capsule, hard	oral
FI - Finland	Medice Arzneimittel Pütter GmbH & Co. KG Kuhloweg 37 58638 ISERLOHN GERMANY	Medikinet CR	20 mg	prolonged-release capsule, hard	oral

FI - Finland	Medice Arzneimittel Pütter GmbH & Co. KG Kuhloweg 37 58638 ISERLOHN GERMANY	Medikinet CR	30 mg	prolonged-release capsule, hard	oral
FI - Finland	Medice Arzneimittel Pütter GmbH & Co. KG Kuhloweg 37 58638 ISERLOHN GERMANY	Medikinet CR	40 mg	prolonged-release capsule, hard	oral
FR - France	JANSSEN CILAG S.A. 1 rue Camille Desmoulins TSA 91003 92787 Issy-les-Moulineaux Cedex 9 France	CONCERTA LP	18mg	prolonged-release tablet	oral
FR - France	JANSSEN CILAG S.A. 1 rue Camille Desmoulins TSA 91003 92787 Issy-les-Moulineaux Cedex 9 France	CONCERTA LP	27mg	prolonged-release tablet	oral
FR - France	JANSSEN CILAG S.A. 1 rue Camille Desmoulins TSA 91003 92787 Issy-les-Moulineaux Cedex 9 France	CONCERTA LP	36mg	prolonged-release tablet	oral
FR - France	JANSSEN CILAG S.A. 1 rue Camille Desmoulins TSA 91003 92787 Issy-les-Moulineaux Cedex 9 France	CONCERTA LP	54mg	prolonged-release tablet	oral

FR - France	Laboratorios RUBIO SA c/ Industria 29, Pol.Ind.Comte de Sert 08755 Castellbisbal Barcelona SPAIN	METHYLPHENIDATE RUBIO	10mg	tablet	oral
FR - France	Laboratorios RUBIO SA c/ Industria 29, Pol.Ind.Comte de Sert 08755 Castellbisbal Barcelona SPAIN	METHYLPHENIDATE RUBIO	20mg	tablet	oral
FR - France	Laboratorios RUBIO SA c/ Industria 29, Pol.Ind.Comte de Sert 08755 Castellbisbal Barcelona SPAIN	METHYLPHENIDATE RUBIO	5mg	tablet	oral
FR - France	UCB PHARMA S.A. 21 rue de Neuilly BP 314 92003 Nanterre France	QUASYM L.P. 10MG, GELULE A LIBERATION MODIFIEE	10mg	Modified release capsule, hard	oral
FR - France	UCB PHARMA S.A. 21 rue de Neuilly BP 314 92003 Nanterre France	QUASYM L.P. 20MG, GELULE A LIBERATION MODIFIEE	20mg	Modified release capsule, hard	oral
FR - France	UCB PHARMA S.A. 21 rue de Neuilly BP 314 92003 Nanterre France	QUASYM L.P. 30MG, GELULE A LIBERATION MODIFIEE	30mg	Modified release capsule, hard	oral

FR - France	NOVARTIS PHARMA SAS 2-4 rue Lionel Terray 92500 Rueil-Malmaison France	RITALINE	10mg	tablet	oral
FR - France	NOVARTIS PHARMA SAS 2-4 rue Lionel Terray 92500 Rueil-Malmaison France	RITALINE L.P.	20mg	modified release capsule	oral
FR - France	NOVARTIS PHARMA SAS 2-4 rue Lionel Terray 92500 Rueil-Malmaison France	RITALINE L.P.	30mg	modified release capsule	oral
FR - France	NOVARTIS PHARMA SAS 2-4 rue Lionel Terray 92500 Rueil-Malmaison France	RITALINE L.P.	40mg	modified release capsule	oral
HU - Hungary	JANSSEN-CILAG Kft. 2045 Törökbálint, Tó Park	CONCERTA 18 mg	18mg	retard tabletta	oral
HU - Hungary	JANSSEN-CILAG Kft. 2045 Törökbálint, Tó Park	CONCERTA 36 mg	36mg	retard tabletta	oral
HU - Hungary	JANSSEN-CILAG Kft. 2045 Törökbálint, Tó Park	CONCERTA 54 mg	54mg	retard tabletta	oral
HU - Hungary	Novartis Hungária Kft.Pharma 1114 Budapest Bartók Béla út 43-47	RITALIN	10mg	tablet	oral
HU - Hungary	Novartis Hungária Kft.Pharma 1114 Budapest Bartók Béla út 43-47	RITALIN	20mg	prolonged release capsules	oral
HU - Hungary	Novartis Hungária Kft.Pharma 1114 Budapest Bartók Béla út 43-47	RITALIN	30mg	prolonged release capsules	oral

HU - Hungary	Novartis Hungária Kft.Pharma 1114 Budapest Bartók Béla út 43-47	RITALIN	40mg	prolonged release capsules	oral
IE - Ireland	Novartis Pharmaceuticals UK Ltd, Frimley Business Park, Frimley, Camberley GU16 7SR, UK	Ritalin	10mg	Tablet	Oral
IE - Ireland	Novartis Pharmaceuticals UK Ltd, Frimley Business Park, Frimley, Camberley GU16 7SR, UK	Ritalin LA	20mg, 30mg, 40mg	Capsules modified release	Oral
IE - Ireland	Janssen-Cilag Ltd, Saunderton, High Wycombe HP14 4HJ, Buckinghamshire, England.	Concerta XL	18mg, 27mg 36mg, 54mg	Prolonged release tablet	Oral
IE - Ireland	Ratiopharm GmbH, Graf-Arco-Strasse 3, D-	Equasym	5mg, 10mg, 20mg	Tablets	Oral
IE - Ireland	Ratiopharm GmbH, Graf-Arco-Strasse 3, D-	Equasym XL	10mg, 20mg, 30mg	Capsules modified release	Oral
IE – Ireland	UCB (Pharma) Ireland Ltd Magna Drive, Magna Business Park Citywest Road – Dublin 24 Ireland	Equasym 5 mg tablets	5mg	Tabletss	Oral
IE – Ireland	UCB (Pharma) Ireland Ltd Magna Drive, Magna Business Park Citywest Road – Dublin 24 Ireland	Equasym 10 mg tablets	10mg	Tablets	Oral
IE - Ireland	UCB (Pharma) Ireland Ltd Magna Drive, Magna Business Park Citywest Road – Dublin 24 Ireland	Equasym 20 mg tablets	30mg	Tablets	Oral

IE - Ireland	UCB (Pharma) Ireland Ltd Magna Drive, Magna Business Park Citywest Road – Dublin 24 Ireland	Equasym XL 10mg Modified-release capsules, hard	10 mg	Modified-release capsules, hard	Oral
IE - Ireland	UCB (Pharma) Ireland Ltd Magna Drive, Magna Business Park Citywest Road – Dublin 24 Ireland	Equasym XL 20mg Modified-release capsules, hard	20 mg	Modified-release capsules, hard	Oral
IE - Ireland	UCB (Pharma) Ireland Ltd Magna Drive, Magna Business Park Citywest Road – Dublin 24 Ireland	Equasym XL 30mg Modified-release capsules, hard	30 mg	Modified-release capsules, hard	Oral
LV – Latvia	UAB Johnson & Johnson, Geležinio Vilko g. 18A, LT-08104 Vilnius, Lithuania.	CONCERTA	18 mg	prolonged release tablet	oral use
LV – Latvia	UAB Johnson & Johnson, Geležinio Vilko g. 18A, LT-08104 Vilnius, Lithuania.	CONCERTA	36 mg	prolonged release tablet	oral use
LV – Latvia	UAB Johnson & Johnson, Geležinio Vilko g. 18A, LT-08104 Vilnius, Lithuania.	CONCERTA	54 mg	prolonged release tablet	oral use
LV - Latvia	Novartis Finland Oy, Metsanneidonkuja 10, , FI-02130 Espoo, Finland,	Ritalin 10 mg	10mg	tablets	oral
LT – Lithuania	UAB "Johnson & Johnson", Geležinio Vilko g. 18A, LT-08104 Vilnius, Lithuania.	CONCERTA	18 mg	prolonged release tablet	oral use
LT – Lithuania	UAB "Johnson & Johnson", Geležinio Vilko g. 18A, LT-08104 Vilnius, Lithuania.	CONCERTA	36 mg	prolonged release tablet	oral use
LT – Lithuania	UAB "Johnson & Johnson", Geležinio Vilko g. 18A, LT-08104 Vilnius, Lithuania.	CONCERTA	54 mg	prolonged release tablet	oral use

IT- Italy	Janssen- Cilag SpA Via M. Buonarroti 23 20093 Cologno Monzese (MI) - ITALY	CONCERTA	18 mg 36 mg 54 mg	Prolonged release tablet	oral
PT - Portugal	Janssen-Cilag Farmacêutica, Lda Estrada Consiglieri Pedroso, 69 A - Queluz de Baixo - 2734-503 Barcarena	Concerta	18 mg	Prolonged-release tablet	Oral use
PT - Portugal	Janssen-Cilag Farmacêutica, Lda Estrada Consiglieri Pedroso, 69 A - Queluz de Baixo - 2734-503 Barcarena	Concerta	27 mg	Prolonged-release tablet	Oral use
PT - Portugal	Janssen-Cilag Farmacéutica, Lda Estrada Consiglieri Pedroso, 69 A - Queluz de Baixo - 2734-503 Barcarena	Concerta	36 mg	Prolonged-release tablet	Oral use
PT - Portugal	Janssen-Cilag Farmacêutica, Lda Estrada Consiglieri Pedroso, 69 A - Queluz de Baixo - 2734-503 Barcarena	Concerta	54 mg	Prolonged-release tablet	Oral use
PT - Portugal	Novartis Farma - Produtos Farmacêuticos, S.A Rua do Centro Empresarial - Edificio 8 - Quinta da Beloura - 2710-444 Sintra	Ritalina LA	20 mg	Modifyed-release capsule, hard	Oral use
PT - Portugal	Novartis Farma - Produtos Farmacêuticos, S.A Rua do Centro Empresarial - Edificio 8 - Quinta da Beloura - 2710-444 Sintra	Ritalina LA	30 mg	Modifyed-release capsule, hard	Oral use
PT - Portugal	Novartis Farma - Produtos Farmacêuticos, S.A Rua do Centro Empresarial - Edificio 8 - Quinta da Beloura - 2710-444 Sintra	Ritalina LA	40 mg	Modifyed-release capsule, hard	Oral use
PT - Portugal	Laboratorios Rubió, S.A Calle Industria, 29 - Poligono Industrial	Rubifen	5 mg	Tablet	Oral use

	Comte de Sert - E-08755 Castellbisbal - Barcelona - Spain			10. m	
PT - Portugal	Laboratorios Rubió, S.A Calle Industria, 29 - Poligono Industrial Comte de Sert - E-08755 Castellbisbal - Barcelona - Spain	Rubifen	10 mg	Tablet	Oral use
PT - Portugal	Laboratorios Rubió, S.A Calle Industria, 29 - Poligono Industrial Comte de Sert - E-08755 Castellbisbal - Barcelona - Spain	Rubifen	20 mg	Tablet	Oral use
RO Romania	Janssen-Pharmaceutica N.V. Tumhoutseweg 30 2340 Beerse Belgium	Concerta XL 18 mg	18 mg	Prolonge release film-coated tablets	
RO Romania	Janssen-Pharmaceutica N.V. Tumhoutseweg 30 2340 Beerse Belgium	Concerta XL 36 mg	36 mg	Prolonge release film-coated tablets	
RO Romania	Janssen-Pharmaceutica N.V. Turnhoutseweg 30 2340 Beerse Belgium	Concerta XL 54 mg	54 mg	Prolonged release film-coated tablets	oral
SE – Sweden	Janssen-Cilag AB Box 7073 SE-192 07 Sollentuna Sweden	Concerta	18, 27 36, 54 mg	prolonged-release tablet	oral
SE – Sweden	UCB Nordic A/S Arne Jacobsens Allé 15 DK-2300 Kobenhavn S Denmark	Equasym Depot	10, 20, 30 mg	Modified-release capsules, hard	Oral
SE – Sweden	Novartis Sverige AB Box 1150 SE-183 11 Täby Sweden	Ritalin	10, 20, 30, 40 mg	10 mg – tablet 20, 30, 40 mg – modified- release capsule, hard	oral

SE - Sweden	UCB Nordic A/S Arne Jacobsens Allé 15 DK-2300 Kobenhavn S Denmark	Equasym	5, 10, 20 mg	tablet	oral
SE – Sweden	Medice Arzneimittel Pütter & Co. KG Kuhloweg 37-39 DE-58638 Iserlohn Germany	Medikinet	5, 10, 20, 30, 40 mg	5, 10, 20 mg - tablet 10, 20, 30, 40 - prolonged- release capsule, hard	oral
UK – United Kingdom	UCB PHARMA LIMITED, 208 BATH ROAD, SLOUGH, BERKSHIRE SL1 3WE UNITED KINGDOM	EQUASYM 10 MG TABLETS	10MG	TABLET	ORAL USE
UK – United Kingdom	UCB PHARMA LIMITED, 208 BATH ROAD, SLOUGH, BERKSHIRE SL1 3WE UNITED KINGDOM	EQUASYM 5 MG TABLETS	5MG	TABLET	ORAL USE
UK – United Kingdom	UCB PHARMA LIMITED, 208 BATH ROAD, SLOUGH, BERKSHIRE SL1 3WE UNITED KINGDOM	EQUASYM 20 MG TABLETS	20MG	TABLET	ORAL USE
UK – United Kingdom	UCB PHARMA LIMITED, 208 BATH ROAD, SLOUGH, BERKSHIRE SL1 3WE UNITED KINGDOM	EQUASYM XL 10 MG CAPSULES	10MG	MODIFIED-RELEASE CAPSULE, HARD	ORAL USE
UK – United Kingdom	UCB PHARMA LIMITED, 208 BATH ROAD, SLOUGH, BERKSHIRE SL1 3WE UNITED KINGDOM	EQUASYM XL 20 MG CAPSULES	20MG	MODIFIED-RELEASE CAPSULE, HARD	ORAL USE
UK – United Kingdom	UCB PHARMA LIMITED, 208 BATH ROAD, SLOUGH, BERKSHIRE SL1 3WE UNITED KINGDOM	EQUASYM XL 30 MG CAPSULES	30MG	MODIFIED-RELEASE CAPSULE, HARD	ORAL USE
UK – United Kingdom	NOVARTIS PHARMACEUTICALS UK LIMITED, FRIMLEY BUSINESS PARK, FRIMLEY, CAMBERLEY, SURREY GU16 7SR, UNITED KINGDOM	RITALIN	10MG	TABLET	ORAL USE

UK – United Kingdom	JANSSEN-CILAG LIMITED, SAUNDERTON, HIGH WYCOMBE, BUCKINGHAMSHIRE, HP14 4HJ, UNITED KINGDOM	CONCERTA® XL	18MG	PROLONGED-RELEASE TABLET	ORAL USE
UK – United Kingdom	JANSSEN-CILAG LIMITED, SAUNDERTON, HIGH WYCOMBE, BUCKINGHAMSHIRE, HP14 4HJ, UNITED KINGDOM	CONCERTA® XL	36MG	PROLONGED-RELEASE TABLET	ORAL USE
UK – United Kingdom	JANSSEN-CILAG LIMITED, SAUNDERTON, HIGH WYCOMBE, BUCKINGHAMSHIRE, HP14 4HJ, UNITED KINGDOM	CONCERTA® XL	54MG	PROLONGED-RELEASE TABLET	ORAL USE
UK – United Kingdom	JANSSEN-CILAG LIMITED, SAUNDERTON, HIGH WYCOMBE, BUCKINGHAMSHIRE, HP14 4HJ, UNITED KINGDOM	CONCERTA® XL	27MG	PROLONGED-RELEASE TABLET	ORAL USE
UK – United Kingdom	MEDICE ARZNEIMITTEL PUTTER GMBH & CO KG; KUHLOWEG 37; ISERLOHN 58638; GERMANY	MEDIKINET	5MG	TABLET	ORAL USE
UK – United Kingdorn	MEDICE ARZNEIMITTEL PUTTER GMBH & CO KG; KUHLOWEG 37; ISERLOHN 58638; GERMANY	MEDIKINET	10MG	TABLET	ORAL USE
UK – United Kingdom	MEDICE ARZNEIMITTEL PUTTER GMBH & CO KG; KUHLOWEG 37; ISERLOHN 58638; GERMANY	MEDIKINET	20MG	TABLET	ORAL USE
UK – United Kingdom	MEDICE ARZNEIMITTEL PUTTER GMBH & CO KG; KUHLOWEG 37; ISERLOHN 58638; GERMANY	MEDIKINET XL	10MG	PROLONGED-RELEASE CAPSULE, HARD	ORAL USE
UK – United Kingdom	MEDICE ARZNEIMITTEL PUTTER GMBH & CO KG; KUHLOWEG 37; ISERLOHN 58638; GERMANY	MEDIKINET XL	20MG	PROLONGED-RELEASE CAPSULE, HARD	ORAL USE

UK – United Kingdom	MEDICE ARZNEIMITTEL PUTTER GMBH & CO KG; KUHLOWEG 37; ISERLOHN 58638; GERMANY	MEDIKINET XL	30MG	PROLONGED-RELEASE CAPSULE, HARD	ORAL USE
UK – United Kingdom	MEDICE ARZNEIMITTEL PUTTER GMBH & CO KG; KUHLOWEG 37; ISERLOHN 58638; GERMANY	MEDIKINET XL	40MG	PROLONGED-RELEASE CAPSULE, HARD	ORAL USE
UK – United Kingdom	ALFRED E TIEFENBACHER GMBH & CO; VAN-DER-SMISSEN-STRASSE 1: HAMBURG D-22767: GERMANY	ELMIFITEN	10MG	TABLET	ORAL USE
UK – United Kingdom	ALFRED E TIEFENBACHER GMBH & CO; VAN-DER-SMISSEN-STRASSE 1; HAMBURG D-22767; GERMANY	TIFINIDAT	10MG	TABLET	ORAL USE
UK – United Kingdom	LABORATORIOS RUBIÓ S A, C/INDUSTRIAL 29, POLIGONO INDUSTRIAL, COMTE DE SERT, CASTELLBISBAL, BARCELONA E- 08755, SPAIN	TRANQUILYN	5MG	TABLET	ORAL USE
UK – United Kingdom	LABORATORIOS RUBIÓ S A, C/INDUSTRIAL 29, POLIGONO INDUSTRIAL, COMTE DE SERT, CASTELLBISBAL, BARCELONA E- 08755, SPAIN	TRANQUILYN	10MG	TABLET	ORAL USE
UK – United Kingdom	LABORATORIOS RUBIÓ S A, C/INDUSTRIAL 29, POLIGONO INDUSTRIAL, COMTE DE SERT, CASTELLBISBAL, BARCELONA E- 08755, SPAIN	TRANQUILYN	20MG	TABLET	ORAL USE
IS Iceland	UCB Nordic A/S c/o Vistor hf. Hörgatúni 2, 212 Garðabær, Iceland	Equasym Depot	30 mg	Modified-release capsule, hard	Oral
IS Iceland	UCB Nordic A/S c/o Vistor hf., Hörgatúni 2, 212 Garðabær, Iceland	Equasym Depot	20 mg	Modified-release capsule, hard	Oral

IS	UCB Nordic A/S, c/o Vistor hf.,	Equasym Depot	10 mg	Modified-release capsule, hard	Oral
Iceland	Horgatuni 2, 212 Gardabær, Iceland				
IS	Janssen-Cilag AB c/o Vistor hf., Hörgatún 2, 212 Garðabær, Iceland.	Concerta	54 mg	Prolonged release tablet	Oral
IS	Janssen-Cilag AB c/o Vistor hf., Hörgatún 2, 212 Garðabær, Iceland,	Concerta	27 mg	Prolonged release tablet	Oral
IS	Janssen-Cilag AB c/o Vistor hf., Hörgatún 2, 212 Garðabær, Iceland,	Concerta	36 mg	Prolonged release tablet	Oral
IS	Janssen-Cilag AB c/o Vistor hf., Hörgatún 2, 212 Garðabær, Iceland.	Concerta	18 mg	Prolonged release tablet	Oral
IS Iceland	UCB Nordic A/S, c/o Vistor hf., Hörgatúni 2, 212 Garðabær, Iceland	Equasym	20 mg	Tablet	Oral
IS Iceland	UCB Nordic A/S, c/o Vistor hf., Hörgatúni 2, 212 Garðabær, Iceland	Equasym	10 mg	Tablet	Oral
IS Iceland	UCB Nordic A/S, c/o Vistor hf., Hörgatúni 2, 212 Garðabær, Iceland	Equasym	5 mg	Tablet	Oral
IS	Novartis Healthcare A/S, c/o Vistor hf., Hörgatún 2, 212 Garðabær, Iceland	Ritalin	10 mg	Tablet	Oral
IS	Novartis Healthcare A/S, c/o Vistor hf., Hörgatún 2, 212 Garðabær, Iceland	Ritalin Uno	40 mg	Modified-release capsule, hard	Oral
IS	Novartis Healthcare A/S, c/o Vistor hf., Hörgatún 2, 212 Garðabær, Iceland	Ritalin Uno	20 mg	Modified-release capsule, hard	Oral
IS	Novartis Healthcare A/S, c/o Vistor hf., Hörgatún 2, 212 Garðabær, Iceland	Ritalin Uno	30 mg	Modified-release capsule, hard	Oral
DE – Germany	Novartis Pharma GmbH D-90327 Nuemberg	Ritalin	10. mg	Tablet	Oral
DE - Germany	Novartis Pharma GmbH D-90327 Nuernberg	MPH Novartis 20 mg Hartkapseln mit veränderter Wirkstofffreisetzung	20. mg	Modified-release capsule, hard	Oral
DE - Germany	Novartis Pharma GmbH D-90327 Nuernberg	MPH Novartis 30 mg Hartkapseln mit veränderter Wirkstofffreisetzung	30. mg	Modified-release capsule, hard	Oral
DE - Germany	Novartis Pharma GmbH D-90327 Nuernberg	MPH Novartis 40 mg Hartkapseln mit veränderter Wirkstofffreisetzung	40. mg	Modified-release capsule, hard	Oral

DE - Germany	Novartis Pharma GmbH	Ritalin LA 20 mg Hartkapseln mit	20. mg	Modified-release capsule, hard	Oral
	D-90327 Nuernberg	veränderter Wirkstofffreisetzung			
DE - Germany	Novartis Pharma GmbH	Ritalin LA 30 mg Hartkapseln mit	30. mg	Modified-release capsule, hard	Oral
	D-90327 Nuernberg	veränderter Wirkstofffreisetzung			
DE - Germany	Novartis Pharma GmbH	Ritalin LA 40 mg Hartkapseln mit	40. mg	Modified-release capsule, hard	Oral
	D-90327 Nuernberg	veränderter Wirkstofffreisetzung			
DE - Germany	Medice	Medikinet 10mg	11.56 mg	Tablet	Oral
	Postfach 2063				
	D-58634 Iserlohn				
DE - Germany	UCB GmbH	Equasym 5 mg Tabletten	5. mg	Tablet	Oral
	Alfred-Nobel-Str. 10				
	D-40789 Monheim				
	Germany				1.1.1
DE - Germany	UCB GmbH	Equasym 10 mg Tabletten	10. mg	Tablet	Oral
	Alfred-Nobel-Str. 10 D-40789				
	Monheim				
	Germany		_		
DE - Germany	UCB GmbH	Equasym 20 mg Tabletten	20. mg	Tablet	Oral
	Alfred-Nobel-Str. 10 D-40789				
	Monheim				
	Germany				
DE - Germany	Medice	Medikid 10mg	11.56 mg	Tablet	Oral
	Postfach 2063				
	D-58634 Iserlohn				
DE - Germany	Alfred E.Tiefenbacher GmbH & Co.KG	Methylphenidat TB	11.56 mg	Tablet	Oral
	Van-der-Smissen-Str. 1			10401	
	D-22767 Hamburg				
DE - Germany	HEXAL AG	Methylphenidat HEXAL 10mg	10 mg	Tablet	Oral
	Postfach 1263	Tabletten			
	D-83602 Holzkirchen				

DE - Germany	Medice Postfach 2063 D-58634 Iserlohn	Medikinet 5 mg	5. mg	Tablet	Oral
DE - Germany	Medice Postfach 2063 D-58634 Iserlohn	Medikinet 20 mg	20. mg	Tablet	Oral
DE - Germany	Janssen-Cilag GmbH 41457 Neuss or Janssen Cilag GmbH Raiffeisenstr.8 41470 Neuss, Germany	CONCERTA 18 mg Retardtabletten	18. mg	Prolonged-release tablet	Oral
DE - Germany	Janssen-Cilag GmbH 41457 Neuss or Janssen Cilag GmbH Raiffeisenstr.8 41470 Neuss, Germany	CONCERTA 27 mg Retardtabletten	27. mg	Prolonged-release tablet	Oral
DE - Germany	Janssen-Cilag GmbH 41457 Neuss or Janssen Cilag GmbH Raiffeisenstr.8 41470 Neuss, Germany	CONCERTA 36 mg Retardtabletten	36. mg	Prolonged-release tablet	Oral
DE - Germany	Janssen-Cilag GmbH 41457 Neuss or Janssen Cilag GmbH Raiffeisenstr.8 41470 Neuss, Germany	CONCERTA 54 mg Retardtabletten	54. mg	Prolonged-release tablet	Oral
DE - Germany	Medice Postfach 2063 D-58634 Iserlohn	Medikinet retard 10 mg	10. mg	Prolonged-release capsule, hard	Oral
DE - Germany	Medice Postfach 2063 D-58634 Iserlohn	Medikinet retard 20 mg	20. mg	Prolonged-release capsule, hard	Oral
DE - Germany	Medice Postfach 2063 D-58634 Iserlohn	Medikinet retard 5 mg	5. mg	Prolonged-release capsule, hard	Oral

DE - Germany	TAD Pharma GmbH Postfach 720 D-27457 Cuxhaven	METHYLPHENI TAD 5 mg Tabletten	5. mg	Tablet	Oral
DE - Germany	TAD Pharma GmbH Postfach 720 D-27457 Cuxhaven	METHYLPHENI TAD 10 mg Tabletten	10. mg	Tablet	Oral
DE - Germany	TAD Pharma GmbH Postfach 720 D-27457 Cuxhaven	METHYLPHENI TAD 20 mg Tabletten	20. mg	Tablet	Oral
DE - Germany	ratiopharm GmbH D-89070 Ulm	Methylphenidat-ratiopharm 10 mg Tabletten	10. mg	Tablet	Oral
DE - Germany	Alfred E.Tiefenbacher GmbH & Co.KG Van-der-Smissen-Str. 1 D-22767 Hamburg	Elmifiten 10 mg Tabletten	10. mg	Tablet	Oral
DE - Germany	1 A Pharma GmbH Keltenring 1 + 3 D-82041 Oberhaching	Methylphenidat - 1 A Pharma 10 mg Tabletten	10. mg	Tablet	Oral
DE - Germany	Alfred E.Tiefenbacher GmbH & Co.KG Van-der-Smissen-Str. 1 D-22767 Hamburg	Tifinidat 10 mg Tabletten	10. mg	Tablet	Oral
DE - Germany	Medice Postfach 2063 D-58634 Iserlohn	Medikinet retard 30 mg	30. mg	Prolonged-release capsule, hard	Oral
DE - Germany	Medice Postfach 2063 D-58634 Iserlohn	Medikinet retard 40 mg	40. mg	Prolonged-release capsule, hard	Oral
DE - Germany	Medice Postfach 2063 D-58634 Iserlohn	Medikid 5 mg	5. mg	Tablet	Oral
DE - Germany	Medice Postfach 2063 D-58634 Iserlohn	Medikid 20 mg	20. mg	Tablet	Oral

DE - Germany	Medice Postfach 2063 D-58634 Iserlohn	Medikid retard 10 mg	10. mg	Prolonged-release capsule, hard	Oral
DE - Germany	Medice Postfach 2063 D-58634 Iserlohn	Medikid retard 20 mg	20. mg	Prolonged-release capsule, hard	Oral
DE - Germany	Medice Postfach 2063 D-58634 Iserlohn	Medikid retard 5 mg	5. mg	Prolonged-release capsule, hard	Oral
DE - Germany	UCB GmbH Alfred-Nobel-Str. 10 D-40789 Monheim Germany	Equasym retard 10 mg Hartkapseln mit veränderter Wirkstofffreisetzung	10 mg	Modified-release capsule, hard	Oral
DE - Germany	UCB GmbH Alfred-Nobel-Str. 10 D-40789 Monheim Germany	Equasym retard 20 mg Hartkapseln mit veränderter Wirkstofffreisetzung	20. mg	Modified-release capsule, hard	Oral
DE - Germany	UCB GmbH Alfred-Nobel-Str. 10 D-40789 Monheim Germany	Equasym retard 30 mg Hartkapseln mit veränderter Wirkstofffreisetzung	30 mg	Modified-release capsule, hard	Oral
DE - Germany	Medice Postfach 2063 D-58634 Iserlohn	Medikid retard 30 mg	30. mg	Prolonged-release capsule, hard	Oral
DE - Germany	Medice Postfach 2063 D-58634 Iserlohn	Medikid retard 40 mg	40. mg	Prolonged-release capsule, hard	Oral
EL - Greece	JANSSEN-CILAG PHARMACEUTICAL S A C.I EIRINS AVENUE 56, PEFKI, 15121 Tel: +30-210-6140061 Fax: +30-210-6140072	CONCERTA®	18 MG 36 MG 54 MG	PROLONGED RELEASE TABLETS	ORAL

EL - Greece	LABORATORIOS RUBIO S.A. C/Industria 29 Pol. Compte de Sert 08755-Castellbisbal (Barcelona) SPAIN Tel:+34-93-772 25 09 Fax:+34-93-772 25 01	METHYLPHENIDATE/RUBIO	5 MG/TAB 10 MG/TAB 20 MG/TAB	TABLETS	ORAL
EL - Greece	UCB A.E. VOULIAGMENIS AVENUE 580, ARGYROUPOLIS 16452	EQUASYM XR	10, 20, 30 mg	Modified-release capsules, hard	ORAL
IT	NOVARTIS FARMA S.P.A. Largo Umberto Boccioni 1 21040 VARESE	RITALIN	10 mg	Tablet 30	Oral
Т	NOVARTIS FARMA S.P.A. Largo Umberto Boccioni 1 21040 VARESE	RITALIN	20 mg	Tablet prolongued release 30	Oral
П	NOVARTIS FARMA S.P.A. Largo Umberto Boccioni 1 21040 VARESE	RITALIN	20 mg	Tablet prolongued release 100	Oral
MT - Malta	Novartis Pharmaceuticals UK Ltd, Frimley Business Park, Frimley Camberley, Surrey GU16 7SR United Kingdom	Ritalin	10mg	tablet	oral
MT - Malta	UCB Pharma Limited, 208, Bath Road, Slough, Berkshire SL1 3WE United Kingdom	Equasym XL	10 mg	Modified release capsule, hard.	oral
MT - Malta	UCB Pharma Limited, 208, Bath Road, Slough, Berkshire SL1 3WE United Kingdom	Equasym XL	20 mg	Modified release capsule, hard.	oral
MT - Malta	UCB Pharma Limited, 208, Bath Road, Slough, Berkshire SL1 3WE United Kingdom	Equasym XL	30 mg	Modified release capsule, hard.	Oral
MT - Maita	Janssen-Cilag International N.V. Turnhoutseweg 30 B-2340 Beerse Belgium	Concerta®	18 mg	prolonged-release tablet	oral use
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MT - Malta	Janssen-Cilag International N.V. Turnhoutseweg 30 B-2340 Beerse Belgium	Concerta®	36 mg	prolonged-release tablet	oral use
MT - Malta	Janssen-Cilag International N.V. Tumhoutseweg 30 B-2340 Beerse Belgium	Concerta®	54 mg	prolonged-release tablet	oral use
NL - Netherlands	Novartis Pharma B.V.; Raapopseweg 1; 6824 DP ARNHEM/NL	Ritalin	10 mg	tablets	oral
NL - Netherlands	Ratiopharm Nederland BV; Ronde Tocht 11:1507 CC ZAANDAM/NL	Methylfenidaat HCI ratiopharm 10 mg	10 mg	tablets	oral
NL - Netherlands	U.C.B. Pharma B.V.; Lage Mosten 33 ; 4822 NK BREDA/NL	Equasym 5 mg Tabletten	5 mg	tablets	oral
NL - Netherlands	U.C.B. Pharma B.V.; Lage Mosten 33 ; 4822 NK BREDA/NL	Equasym 10 mg tabletten	10 mg	tablets	oral
NL - Netherlands	U.C.B. Pharma B.V.; Lage Mosten 33 ; 4822 NK BREDA/NL	Equasym XL 10 mg Capsule	10 mg	modified release capsules	oral
NL - Netherlands	U.C.B. Pharma B.V.; Lage Mosten 33 ; 4822 NK BREDA/NL	Equasym XL 20 mg Capsule	20 mg	modified release capsules	oral
NL - Netherlands	U.C.B. Pharma B.V.; Lage Mosten 33 ; 4822 NK BREDA/NL	Equasym XL 30 mg Capsule	30 mg	modified release capsules	oral
NL - Netherlands	Alfred Tiefenbacher (GmbH & Co. KG); Van-der-Smisse- Strasse 1; 22767 HAMBURG/ Germany	Methylfenideat HCI AET 10 mg	10 mg	tablets	oral
NL - Netherlands	Pharmachemie B.V.; Swensweg 5; 2003 RN HAARLEM/NL	Methylfenidaat HCI 10 mg PCH	10 mg	tablets	oral
NL - Netherlands	Hexal B.V.; Pastoorslaan 28; 2182 BX HILLEGOM/NL	Methylfenidaat HCI 10 mg tabletten	10 mg	tablets	oral

NL - Netherlands	Alfred Tiefenbacher (GmbH & Co. KG); Van-der-Smisse- Strasse 1; 22767 HAMBURG/ Germany	Tifinidat	10 mg	tablets	oral
NL - Netherlands	Janssen-Cilag B.V.; Dr. Paul Janssenweg 150 ; 5026 RH TILBURG/NL	Concerta 18 mg	18 mg	prolonged release tablets	oral
NL - Netherlands	Janssen-Cilag B.V.; Dr. Paul Janssenweg 150 ; 5026 RH TILBURG/NL	Concerta 27 mg	27 mg	prolonged release tablets	oral
NL - Netherlands	Janssen-Cilag B.V.; Dr. Paul Janssenweg 150 ; 5026 RH TILBURG/NL	Concerta 36 mg	36 mg	prolonged release tablets	oral
NL - Netherlands	Janssen-Cilag B.V.; Dr. Paul Janssenweg 150 ; 5026 RH TILBURG/NL	Concerta 54 mg	54 mg	prolonged release tablets	oral
NL - Netherlands	Laboratorios Rubio, S.A.; C\Industria, no. 29 Pol. Ind. Comte de Sert; 08755 CASTELLBISBAL, BARCELONA/ SPAIN	Methylfenidaat HCI 5 mg	5 mg	tablets	oral
NL - Netherlands	Laboratorios Rubio, S.A.; C\Industria, no. 29 Pol. Ind. Comte de Sert; 08755 CASTELLBISBAL, BARCELONA/ SPAIN	Methylfenidaat HCI 10 mg	10 mg	tablets	oral
NL - Netherlands	Medice Arzneimittel Pütter GmbH; Kuhloweg 37; 58638 ISERLOHN/Germany	Medikinet 5 mg	5 mg	tablets	oral
NL - Netherlands	Medice Arzneimittel Pütter GmbH; Kuhloweg 37; 58638 ISERLOHN/Germany	Medikinet 10 mg	10 mg	tablets	oral
NL - Netherlands	Medice Arzneimittel Pütter GmbH; Kuhloweg 37; 58638 ISERLOHN/Germany	Medikinet 20 mg	20 mg	tablets	oral

NL - Netherlands	Medice Arzneimittel Pütter GmbH; Kuhloweg 37; 58638 ISERLOHN/Germany	Medikinet CR 10 mg	10 mg	modified release capsules	oral
NL - Netherlands	Medice Arzneimittel Pütter GmbH; Kuhloweg 37; 58638 ISERLOHN/Germany	Medikinet CR 20 mg	20 mg	modified release capsules	oral
NL - Netherlands	Medice Arzneimittel Pütter GmbH; Kuhloweg 37; 58638 ISERLOHN/Germany	Medikinet CR 30 mg	30 mg	modified release capsules	oral
NL - Netherlands	Medice Arzneimittel Pütter GmbH; Kuhloweg 37; 58638 ISERLOHN/Germany	Medikinet CR 40 mg	40 mg	modified release capsules	oral
NO Norway	Janssen-Cilag AS Hoffsveien 1D 0275 Oslo, Norway	Concerta	18mg 36 mg 54 mg	prolonged-release tablet	oral
NO Norway	UCB Nordic A/S Arne Jacobsens Allé 15 2300 Köbenhavn S Denmark	Equasym tabletter 5 mg	5 mg	tablet	oral
NO Norway	UCB Nordic A/S Arne Jacobsens Allé 15 2300 Köbenhavn S Denmark	Equasym tabletter 10 mg	10 mg	tablet	oral
NO - Norway	UCB Nordic A/S Arne Jacobsens Allé 15 2300 Köbenhavn S Denmark	Equasym tabletter 20 mg	20 mg	tablet	oral
NO	UCB Nordic A/S Arne Jacobsens Allé 15 2300 Köbenhavn S Denmark	Equasym Depot	10 mg 20 mg 30 mg	modified-release capsule, hard	oral

NO	Novartis Norge AS Brynsalleèn 4 0667 Oslo, Norway	Ritalin	10 mg 20 mg 30 mg 40 mg	(10 mg - tablet) (20 mg, 30 mg, 40 mg - modified- release capsule, hard)	oral
NO	Medice Arzneimittel Pütter GmbH & Co KG Kuhloweg 37 58638 Iserlohn Nordrhein- Westfalen, Germany	Medikinet	10 mg 20 mg 30 mg 40 mg	prolonged-release tablet	oral
NO	Medice Arzneimittel Pütter GmbH & Co KG Kuhloweg 37 58638 Iserlohn Nordrhein- Westfalen, Germany	Medikinet	5 mg 10 mg 20 mg	tablet	oral
PL - Poland	Janssen-Cilag International N.V. Turnhoutseweg 30 B-2340 Beerse Belgium	Concerta®	18 mg	prolonged-release tablet	oraluse
PL - Poland	Janssen-Cilag International N.V. Turnhoutseweg 30 B-2340 Beerse Belgium	Concerta®	36 mg	prolonged-release tablet	oral use
PL - Poland	Janssen-Cilag International N.V. Turnhoutseweg 30 B-2340 Beerse Belgium	Concerta®	54 mg	prolonged-release tablet	oral use
PL - Poland	Medice Arzneimittel Pütter GmbH & Co. KG Kuhloweg 37 58638 Iserlohn Germany	Medikinet 5 mg	5 mg	tablet	oral use

PL - Poland	Medice Arzneimittel Pütter GmbH & Co. KG Kuhloweg 37 58638 Iserlohn Germany	Medikinet 10 mg	10 mg	tablet	oral use
PL - Poland	Medice Arzneimittel Pütter GmbH & Co, KG Kuhloweg 37 58638 Iserlohn Germany	Medikinet 20 mg	20 mg	tablet	oral use
PL - Poland	Medice Arzneimittel Pütter GmbH & Co. KG Kuhloweg 37 58638 Isertohn Germany	Medikinet CR 10 mg	10 mg	prolonged-release capsule	oral use
PL - Poland	Medice Arzneimittel Pütter GmbH & Co. KG Kuhloweg 37 58638 Iserlohn Germany	Medikinet CR 20 mg	20 mg	prolonged-release capsule	oral use
PL - Poland	Medice Arzneimittel Pütter GmbH & Co. KG Kuhloweg 37 58638 Iserlohn Germany	Medikinet CR 30 mg	30 mg	prolonged-release capsule	oral use
PL - Poland	Medice Arzneimittel Pütter GmbH & Co. KG Kuhloweg 37 58638 Iserlohn Germany	Medikinet CR 40 mg	40 mg	prolonged-release capsule	oral use

LU	Novartis Pharma Roonstrasse 25 90429 Nürnberg Germany	Ritalin	10 mg	Tablets	Oral
LU Luxembourg	Janssen Cilag N.V./S.A Roderveldlaan 1, B- 2600 Berchem	Concerta	18 mg	Prolonged release tablets	Oral use
LU Luxembourg	Janssen Cilag N.V./S.A Roderveldlaan 1, B- 2600 Berchem	Concerta	27 mg	Prolonged release tablets	Oral use
LU Luxembourg	Janssen Cilag N.V./S.A Roderveldlaan 1, B- 2600 Berchem	Concerta	36 mg	Prolonged release tablets	Oral use
LU Luxembourg	Janssen Cilag N.V./S.A Roderveldlaan 1, B- 2600 Berchem	Concerta	54 mg	Prolonged release tablets	Oral use
LU	Medice Arzneimittel Pütter GmbH & Co Kuhloweg 37 58638 Iserlohn Germany	Medikinet	5 mg	tablets	oral
LU	Medice Arzneimittel Pűtter GmbH & Co	Medikinet	10 mg	tablets	oral
LU	Medice Arzneimittel Pütter GmbH & Co	Medikinet	20 mg	Tablets	oral
LU	Medice Arzneimittel Pűtter GmbH & Co	Medikinet retard	10 mg	Capsules	Oral
LU	Medice Arzneimittel Pütter GmbH & Co	Medikinet retard	20 mg	Capsules	Oral

LU	Medice Arzneimittel Pütter GmbH & Co	Medikinet retard	30 mg	Capsules	Oral
LU	Medice Arzneimittel Pütter GmbH & Co	Medikinet retard	40 MG	Capsules	Oral
SI	Johnson & Johnson d.o.o. Smartinska 53, 1000 Ljubljana, Slovenia	Concerta 18 mg tablete s podaljšanim sproščanjem	18 mg	Prolonged release tablets	Oral use
SI	Johnson & Johnson d.o.o. Smartinska 53, 1000 Ljubljana, Slovenia	Concerta 36 mg tablete s podaljšanim sproščanjem	36 mg	Prolonged release tablets	Oral use
SI	Johnson & Johnson d.o.o. Smartinska 53, 1000 Ljubljana, Slovenia	Concerta 54 mg tablete s podaljšanim sproščanjem	54 mg	Prolonged release tablets	Oral use
SK – Slovakia	Johnson & Johnson, s. r. o. Plynárenská 7/B 824 78 Bratislava Slovak republic	Concerta 18 mg tablety s predĺženým uvoľňovaním	18 mg	Prolonged-release tablet	oral use
SK – Slovakia	Johnson & Johnson, s. r. o. Plynárenská 7/B 824 78 Bratislava Slovak republic	Concerta 36 mg tablety s predíženým uvoľňovaním	36 mg	Prolonged-release tablet	oral use
SK – Slovakia	Johnson & Johnson, s. r. o. Plynárenská 7/B 824 78 Bratislava Slovak republic	Concerta 54 mg tablety s predĺženým uvoľňovaním	54 mg	Prolonged-release tablet	oral use

Appendix C: Chinese Pharmacopeia

附件 2

2020年版《中国药典》目录

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 102 马来酸氯苯那敏滴丸 103 马来酸瘰'与谷尔 104 马来酸瘰'与谷尔片 105 马来酸瘰'与谷尔滴眼液 106 扎来普隆 107 扎来普隆片 108 扎来普隆胶囊 109 木糖醇 110 木糖醇颗粒 111 五肽胃泌素 112 五肽胃泌素 113 五氟利多 114 五氟利多片 115 厄贝沙坦 116 厄贝沙坦片 117 厄贝沙坦於囊 118 厄贝沙坦胶囊 119 比沙可啶 120 比沙可啶肠溶片 	101	马来酸氯苯那敏注射液
 103 马来酸噻吗洛尔 104 马来酸噻吗洛尔片 105 马来酸噻吗洛尔滴眼液 106 扎来普隆 107 扎来普隆片 108 扎来普隆胶囊 109 木糖醇 110 木糖醇颗粒 111 五肽胃泌素 112 五肽胃泌素注射液 113 五氟利多片 115 厄贝沙坦 116 厄贝沙坦片 117 厄贝沙坦分散片 118 厄贝沙坦胶囊 119 比沙可啶 120 比沙可啶肠溶片 	102	马来酸氯苯那敏滴丸
 104 马来酸噻吗洛尔片 105 马来酸噻吗洛尔滴眼液 106 扎来普隆 107 扎来普隆片 108 扎来普隆胶囊 109 木糖醇 110 木糖醇颗粒 111 五肽胃泌素 112 五肽胃泌素注射液 113 五氟利多 114 五氟利多片 115 厄贝沙坦 116 厄贝沙坦片 117 厄贝沙坦片 117 厄贝沙坦胶囊 119 比沙可啶 120 比沙可啶肠溶片 	103	马来酸噻吗洛尔
 105 马亲酸噻吗洛尔滴眼液 106 扎来普隆 107 扎来普隆片 108 扎来普隆胶囊 109 木糖醇 110 木糖醇颗粒 111 五肽胃泌素 112 五肽胃泌素 112 五肽胃泌素 113 五氟利多 114 五氟利多片 115 厄贝沙坦 116 厄贝沙坦片 117 厄贝沙坦片 117 厄贝沙坦於囊 118 厄贝沙坦胶囊 119 比沙可啶 120 比沙可啶肠溶片 	104	马来酸噻吗洛尔片
 106 扎来普隆 107 扎来普隆片 108 扎来普隆胶囊 109 木糖醇 110 木糖醇颗粒 111 五肽胃泌素 112 五肽胃泌素注射液 113 五氟利多片 115 厄贝沙坦 116 厄贝沙坦片 117 厄贝沙坦分散片 118 厄贝沙坦胶囊 119 比沙可啶 120 比沙可啶肠溶片 	105	马来酸噻吗洛尔滴眼液
 107 扎来普隆片 108 扎来普隆胶囊 109 木糖醇 110 木糖醇颗粒 111 五肽胃泌素 112 五肽胃泌素注射液 113 五氟利多 114 五氟利多片 115 厄贝沙坦 116 厄贝沙坦片 117 厄贝沙坦片 117 厄贝沙坦於囊 118 厄贝沙坦胶囊 119 比沙可啶 120 比沙可啶肠溶片 	106	扎来普隆
 108 扎来普隆胶囊 109 木糖醇 110 木糖醇颗粒 111 五肽胃泌素 112 五肽胃泌素注射液 113 五氟利多片 113 五氟利多片 115 厄贝沙坦 116 厄贝沙坦片 117 厄贝沙坦分散片 118 厄贝沙坦胶囊 119 比沙可啶 120 比沙可啶肠溶片 	107	扎来普隆片
 109 木糖醇 110 木糖醇颗粒 111 五肽胃泌素 112 五肽胃泌素注射液 113 五氟利多 114 五氟利多片 115 厄贝沙坦 116 厄贝沙坦片 117 厄贝沙坦分散片 118 厄贝沙坦胶囊 119 比沙可啶 120 比沙可啶肠溶片 	108	扎来普隆胶囊
 木糖醇颗粒 五肽胃泌素 五肽胃泌素注射液 五氟利多 五氟利多片 厄贝沙坦 庖贝沙坦片 厄贝沙坦分散片 尼贝沙坦胶囊 比沙可啶 比沙可啶肠溶片 	109	木糖醇
 111 五肽 買 淡素 112 五肽 胃 淡素 注射液 113 五氟利多 114 五氟利多片 115 厄贝沙坦 116 厄贝沙坦片 117 厄贝沙坦分散片 118 厄贝沙坦胶囊 119 比沙可啶 120 比沙可啶肠溶片 	110	木糖醇颗粒
 112 五肽胃泌素注射液 113 五氟利多 114 五氟利多片 115 厄贝沙坦 116 厄贝沙坦片 117 厄贝沙坦分散片 118 厄贝沙坦胶囊 119 比沙可啶 120 比沙可啶肠溶片 	111	五肽胃泌素
 113 五氟利多 114 五氟利多片 115 厄贝沙坦 116 厄贝沙坦片 117 厄贝沙坦分散片 118 厄贝沙坦胶囊 119 比沙可啶 120 比沙可啶肠溶片 	112	五肽胃泌素注射液
 114 五氟利多片 115 厄贝沙坦 116 厄贝沙坦片 117 厄贝沙坦分散片 118 厄贝沙坦胶囊 119 比沙可啶 120 比沙可啶肠溶片 	113	五氟利多
 115 厄贝沙坦 116 厄贝沙坦片 117 厄贝沙坦分散片 118 厄贝沙坦胶囊 119 比沙可啶 120 比沙可啶肠溶片 	114	五氟利多片
 116 厄贝沙坦片 117 厄贝沙坦分散片 118 厄贝沙坦胶囊 119 比沙可啶 120 比沙可啶肠溶片 	115	厄贝沙坦
 117 厄贝沙坦分散片 118 厄贝沙坦胶囊 119 比沙可啶 120 比沙可啶肠溶片 	116	厄贝沙坦片
 118 厄贝沙坦胶囊 119 比沙可啶 120 比沙可啶肠溶片 	117	厄贝沙坦分散片
 119 比沙可啶 120 比沙可啶肠溶片 	118	厄贝沙坦胶囊
120 比沙可啶肠溶片	119	比沙可啶
	120	比沙可啶肠溶片

121 比沙可啶栓

122	贝诺酯	157	双氢青蒿素片
123	贝诺酯片	158	双氢青蒿素哌喹片
124	贝敏伪麻片	159	双唑泰栓
125	牛磺酸	160	双羟萘酸噻嘧啶
126	牛磺酸片	161	双羟萘酸噻嘧啶片
127	牛磺酸胶囊	162	双羟萘酸噻嘧啶颗粒
128	牛磺酸散	163	双氯芬酸钠
129	牛磺酸颗粒	164	双氯芬酸钠肠溶片
130	牛磺酸滴眼液	165	双氯芬酸钠肠溶胶囊
131	壬苯醇醚	166	双氯芬酸钠栓
132	壬苯醇醚阴道片	167	双氯芬酸钠搽剂
133	壬苯醇醚栓	168	双氯芬酸钠滴眼液
134	壬苯醇醚膜	169	双氯芬酸钾
135	升华硫	170	双氯芬酸钾片
136	硫软膏	171	双氯芬酸钾胶囊
137	乌司他丁	172	双氯非那胺
138	乌司他丁溶液	173	双氯非那胺片
139	注射用乌司他丁	174	双嘧达莫
140	乌拉地尔	175	双嘧达莫片
141	乌拉地尔注射液	176	双嘧达莫注射液
142	乌苯美司	177	双嘧达莫缓释胶囊
143	乌苯美司片	178	水合氯醛
144	乌苯美司胶囊	179	水杨酸
145	乌洛托品	180	水杨酸软膏
146	六甲蜜胺	181	水杨酸二乙胺
147	六甲蜜胺片	182	水杨酸二乙胺乳膏
148	六甲蜜胺胶囊	183	水杨酸镁
149	巴柳氮钠	184	水杨酸镁片
150	巴氯芬	185	水杨酸镁胶囊
151	巴氯芬片	186	去乙酰毛花苷
152	双水杨酯	187	去乙酰毛花苷注射液
153	双水杨酯片	188	去氢胆酸
154	双环醇	189	去氢胆酸片
155	双环醇片	190	去氧氟尿苷
156	双氢青蒿素	191	去氧氟尿苷片

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192	去氧氟尿苷分散片	227	丙泊酚乳状治
193	去氧氟尿苷胶囊	228	丙氨酰谷氨酮
194	去羟肌苷	229	丙氨酰谷氨酮
195	去羟肌苷肠溶胶囊	230	注射用丙氨酚
196	去羟肌苷咀嚼片	231	丙氨酸
197	甘油	232	丙硫异烟胺
198	甘油栓	233	丙硫异烟胺服
199	甘油果糖氯化钠注射液	234	丙硫氧嘧啶
200	甘油磷酸钠	235	丙硫氧嘧啶片
201	甘油磷酸钠注射液	236	丙硫氧嘧啶肠
202	甘氨双唑钠	237	丙酸交沙霉素
203	注射用甘氨双唑钠	238	丙酸交沙霉素
204	甘氨酰谷氨酰胺	239	丙酸倍氯米松
205	甘氨酸	240	丙酸倍氯米机
206	甘氨酸冲洗液	241	丙酸倍氯米松
207	甘露醇	242	丙酸倍氯米机
208	甘露醇注射液	243	丙酸氟替卡根
209	艾司唑仑	244	丙酸氯倍他素
210	艾司唑仑片	245	丙酸氯倍他素
211	艾司唑仑注射液	246	丙酸睾酮
212	艾司奥美拉唑钠	247	丙酸睾酮注身
213	注射用艾司奥美拉唑钠	248	丙磺舒
214	艾司奥美拉唑镁肠溶片	249	丙磺舒片
215	本芴醇	250	左卡尼汀
216	可待因桔梗片	251	左甲状腺素钠
217	丙戊酸钠	252	左甲状腺素银
218	丙戊酸钠片	253	左炔诺孕酮
219	丙戊酸钠缓释片(I)	254	左炔诺孕酮片
220	注射用丙戊酸钠	255	左炔诺孕酮煤
221	丙戊酸镁	256	左炔诺孕酮炒
222	丙戊酸镁片	257	左氧氟沙星
223	丙谷胺	258	左氧氟沙星片
224	丙谷胺片	259	左氧氟沙星涌
225	丙谷胺胶囊	260	左旋多巴
226	丙泊酚	261	左旋多巴片

27	丙泊酚乳状注射液
28	丙氨酰谷氨酰胺
29	丙氨酰谷氨酰胺注射液
30	注射用丙氨酰谷氨酰胺
31	丙氨酸
32	丙硫异烟胺
33	丙硫异烟胺肠溶片
34	丙硫氧嘧啶
35	丙硫氧嘧啶片
36	丙硫氧嘧啶肠溶片
37	丙酸交沙霉素
38	丙酸交沙霉素颗粒
39	丙酸倍氯米松
40	丙酸倍氯米松吸入气雾剂
41	丙酸倍氯米松吸入粉雾剂
42	丙酸倍氯米松乳膏
43	丙酸氟替卡松
44	丙酸氯倍他索
45	丙酸氯倍他索乳膏
46	丙酸睾酮
47	丙酸睾酮注射液
48	丙磺舒
49	丙磺舒片
50	左卡尼汀
51	左甲状腺素钠
52	左甲状腺素钠片
53	左炔诺孕酮
54	左炔诺孕酮片
55	左炔诺孕酮炔雌醇 (三相) 片
56	左炔诺孕酮炔雌醚片
57	左氧氟沙星
58	左氧氟沙星片
59	左氧氟沙星滴眼液
60	左旋多巴

262	左旋多巴胶囊	297	布洛芬片
263	左羟丙哌嗪	298	布洛芬胶囊
264	左羟丙哌嗪片	299	布洛芬混悬滴剂
265	左羟丙哌嗪胶囊	300	布洛芬缓释胶囊
266	左奥硝唑	301	布洛芬糖浆
267	左奥硝唑氯化钠注射液	302	戊四硝酯粉
268	石杉碱甲	303	戊四硝酯片
269	石杉碱甲片	304	戊酸雌二醇
270	石杉碱甲注射液	305	戊酸雌二醇注射液
271	石杉碱甲胶囊	306	扑米酮
272	右布洛芬	307	扑米酮片
273	右布洛芬胶囊	308	卡马西平
274	右佐匹克隆	309	卡马西平片
275	右佐匹克隆	310	卡马西平胶囊
276	右酮洛芬氨丁三醇	311	卡比马唑
277	右酮洛芬氨丁三醇胶囊	312	卡比马唑片
278	右旋糖酐20	313	卡比多巴
279	右旋糖酐 20 葡萄糖注射液	314	卡比多巴片
280	右旋糖酐20氯化钠注射液	315	卡巴胆碱
281	右旋糖酐 40	316	卡巴胆碱注射液
282	右旋糖酐 40 葡萄糖注射液	317	卡托普利
283	右旋糖酐 40 氯化钠注射液	318	卡托普利片
284	右旋糖酐70	319	卡前列甲酯
285	右旋糖酐70葡萄糖注射液	320	卡前列甲酯栓
286	右旋糖酐70氯化钠注射液	321	卡莫司汀
287	右旋糖酐铁	322	卡莫司汀注射液
288	右旋糖酐铁片	323	卡莫氟
289	右旋糖酐铁注射液	324	卡莫氟片
290	布美他尼	325	卡铂
291	布美他尼片	326	卡铂注射液
292	布美他尼注射液	327	卡培他滨
293	布洛伪麻片	328	卡培他滨片
294	布洛伪麻胶囊	329	卡维地洛
295	布洛芬	330	卡维地洛片
296	布洛芬口服溶液	331	卡维地洛胶囊

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332	叶酸	367	甲硝唑阴道泡腾片
333	叶酸片	368	甲硝唑注射液
334	甲地高辛	369	甲硝唑栓
335	甲地高辛片	370	甲硝唑胶囊
336	甲芬那酸	371	甲硝唑葡萄糖注射液
337	甲芬那酸片	372	甲硝唑氯化钠注射液
338	甲芬那酸胶囊	373	甲硝唑凝胶
339	甲状腺粉	374	甲硫氨酸
340	甲状腺片	375	甲硫氨酸片
341	甲苯咪唑	376	甲硫酸新斯的明
342	甲苯咪唑片	377	甲硫酸新斯的明注射液
343	甲苯磺丁脲	378	甲紫
344	甲苯磺丁脲片	379	甲紫溶液
345	甲砜霉素	380	甲巯咪唑
346	甲砜霉素肠溶片	381	甲巯咪唑片
347	甲砜霉素胶囊	382	甲巯咪唑肠溶片
348	甲钴胺	383	甲睾酮
349	甲钴胺片	384	甲睾酮片
350	甲钴胺注射液	385	甲醛溶液
351	甲钴胺胶囊	386	甲磺酸多沙唑嗪
352	甲氧苄啶	387	甲磺酸多沙唑嗪片
353	甲氧苄啶片	388	甲磺酸多沙唑嗪胶囊
354	甲氧苄啶注射液	389	甲磺酸加贝酯
355	甲氧氯普胺	390	注射用甲磺酸加贝酯
356	甲氧氮普胺片	391	甲磺酸培氟沙星
357	盐酸甲氧氯普胺注射液	392	甲磺酸培氟沙星片
358	甲氨蝶呤	393	甲磺酸培氟沙星注射液
359	甲氨蝶呤片	394	甲磺酸培氟沙星胶囊
360	注射用甲氨蝶呤	395	甲磺酸酚妥拉明
361	甲基多巴	396	甲磺酸酚妥拉明片
362	甲基多巴片	397	甲磺酸酚妥拉明注射液
363	甲酚	398	甲磺酸酚妥拉明胶囊
364	甲酚皂溶液	399	注射用甲磺酸酚妥拉明
365	甲硝唑	400	甲磺酸瑞波西汀
366	甲硝唑片	401	甲磺酸瑞波西汀片

402	甲磺酸瑞波西汀胶囊	437	头狗克这
403	生长抑素	438	头孢克洛干混悬剂
404	注射用生长抑素	439	头孢克洛片
405	白消安	440	头孢克洛胶囊
406	白消安片	441	头孢克洛颗粒
407	他扎罗汀	442	头孢呋辛钠
408	他扎罗汀凝胶	443	注射用头孢呋辛钠
409	他唑巴坦	444	头孢呋辛酯
410	兰索拉唑	445	头孢呋辛酯片
411	兰索拉唑肠溶片	446	头孢呋辛酯胶囊
412	兰索拉唑肠溶胶囊	447	头孢盂多酯钠
413	注射用兰索拉唑	448	注射用头孢孟多酯钠
414	头孢丙烯	449	头孢拉定
415	头孢丙烯干混悬剂	450	头孢拉定干混悬剂
416	头孢丙烯片	451	头孢拉定片
417	头孢丙烯胶囊	452	头孢拉定胶囊
418	头孢丙烯颗粒	453	头孢拉定颗粒
419	头孢他啶	454	注射用头孢拉定
420	注射用头孢他啶	455	头孢泊肟酯
421	头孢尼西钠	456	头孢泊肟酯干混悬剂
422	注射用头孢尼西钠	457	头孢泊肟酯片
423	头孢地尼	458	头孢泊肟酯胶囊
424	头孢地尼胶囊	459	头孢哌酮
425	头孢地嗪钠	460	头孢哌酮钠
426	注射用头孢地嗪钠	461	注射用头孢哌酮钠
427	头孢西丁钠	462	头孢美唑钠
428	注射用头孢西丁钠	463	注射用头孢美唑钠
429	头孢曲松钠	464	头孢唑肟钠
430	注射用头孢曲松钠	465	注射用头孢唑肟钠
431	头孢米诺钠	466	头孢唑林钠
432	注射用头孢米诺钠	467	注射用头孢唑林钠
433	头孢克肟	468	头孢氨苄
434	头孢克肟片	469	头孢氨苄干混悬剂
435	头孢克肟胶囊	470	头孢氨苄片
436	头孢克肟颗粒	471	头孢氨苄胶囊

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472	头孢氨苄颗粒	507	尼莫地平胶囊
473	头孢羟氨苄	508	尼索地平
474	头孢羟氨苄片	509	尼索地平片
475	头孢羟氨苄胶囊	510	尼索地平胶囊
476	头孢羟氨苄颗粒	511	尼群地平
477	头孢替唑钠	512	尼群地平片
478	注射用头孢替唑钠	513	尼群地平软胶囊
479	头孢硫脒	514	加巴喷丁
480	注射用头孢硫脒	515	加巴喷丁片
481	头孢噻吩钠	516	加巴喷丁胶囊
482	注射用头孢噻吩钠	517	对乙酰氨基酚
483	头孢噻肟钠	518	对乙酰氨基酚片
484	注射用头孢噻肟钠	519	对乙酰氨基酚咀嚼片
485	司可巴比妥钠	520	对乙酰氨基酚泡腾片
486	司可巴比妥钠胶囊	521	对乙酰氨基酚注射液
487	司他夫定	522	对乙酰氨基酚栓
488	司他夫定胶囊	523	对乙酰氨基酚胶囊
489	司坦唑醇	524	对乙酰氨基酚颗粒
490	司坦唑醇片	525	对乙酰氨基酚滴剂
491	司帕沙星	526	对乙酰氨基酚凝胶
492	司帕沙星片	527	对氨基水杨酸钠
493	司帕沙星胶囊	528	对氨基水杨酸钠肠溶片
494	司莫司汀	529	注射用对氨基水杨酸钠
495	司奠司汀胶囊	530	矛头腹蛇血凝酶
496	尼可刹米	531	注射用矛头腹蛇血凝酶
497	尼可刹米注射液	532	丝氨酸
498	尼尔雌醇	533	丝裂霉素
499	尼尔雌醇片	534	注射用丝裂霉素
500	尼美舒利	535	吉他霉素
501	尼美舒利片	536	吉他霉素片
502	尼莫地平	537	吉非罗齐
503	尼莫地平片	538	吉非罗齐胶囊
504	尼莫地平分散片	539	地西泮
505	尼莫地平软胶囊	540	地西泮片
506	尼莫地平注射液	541	地西泮注射液

542	地红霉素	577	西咪替丁氯化钠注射液
543	地红霉素肠溶片	578	西洛他唑
544	地红霉素肠溶胶囊	579	西洛他唑片
545	地高辛	580	西洛他唑胶囊
546	地高辛口服溶液	581	灰黄霉素
547	地高辛片	582	灰黄霉素片
548	地高辛注射液	583	达那唑
549	地奥司明	584	达那唑胶囊
550	地奥司明片	585	托西酸舒他西林
551	地蔥酚	586	托西酸舒他西林片
552	地蒽酚软膏	587	托西酸舒他西林胶囊
553	地塞米松	588	托西酸舒他西林颗粒
554	地塞米松片	589	托吡卡胺
555	地塞米松磷酸钠	590	托吡卡胺滴眼液
556	地塞米松磷酸钠注射液	591	托拉塞米
557	地塞米松磷酸钠滴眼液	592	托拉塞米片
558	亚叶酸钙	593	托拉塞米胶囊
559	亚叶酸钙片	594	注射用托拉塞米
560	亚叶酸钙注射液	595	过氧苯甲酰
561	亚叶酸钙胶囊	596	过氧苯甲酰乳膏
562	亚甲蓝	597	过氧苯甲酰凝胶
563	亚甲蓝注射液	598	曲尼司特
564	亚硝酸钠	599	曲尼司特片
565	亚硫酸氢钠甲萘醌	600	曲尼司特胶囊
566	亚硫酸氢钠甲萘醌注射液	601	曲安西龙
567	西尼地平	602	曲安西龙片
568	西尼地平片	603	曲安奈德
569	西尼地平胶囊	604	曲安奈德注射液
570	西地碘含片	605	曲安奈德益康唑乳膏
571	西叱氯铵	606	曲克芦丁
572	西叱氯铵含漱液	607	曲克芦丁片
573	西咪替丁	608	吗替麦考酚酯
574	西咪替丁片	609	吗替麦考酚酯片
575	西咪替丁注射液	610	吗替麦考酚酯分散片
576	西咪替丁胶囊	611	吗替麦考酚酯胶囊
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612	吗氯贝胺	647	齐多夫定
613	吗氯贝胺片	648	齐多夫定片
614	吗氯贝胺胶囊	649	齐多夫定注射液
615	钆贝葡胺注射液	650	齐多夫定胶囊
616	钆喷酸葡胺注射液	651	齐多拉米双夫定片
617	伏立康唑	652	交沙霉素
618	伏立康唑片	653	交沙霉素片
619	伏立康唑胶囊	654	米力农
620	伏格列波糖	655	米力农注射液
621	伏格列波糖片	656	米非司酮
622	伏格列波糖胶囊	657	米非司酮片
623	华法林钠	658	米诺地尔
624	华法林钠片	659	米诺地尔片
625	伊曲康唑	660	米氮平
626	伊曲康唑胶囊	661	米氮平片
627	肌苷	662	安钠咖注射液
628	肌苷口服溶液	663	那可丁
629	肌苷片	664	那可丁片
630	肌苷注射液	665	那他霉素
631	肌苷胶囊	666	那他霉素滴眼液
632	肌苷葡萄糖注射液	667	那格列奈
633	肌苷氯化钠注射液	668	那格列奈片
634	注射用肌苷	669	那格列奈胶囊
635	多索茶碱	670	异戊巴比妥
636	多索茶碱片	671	异戊巴比妥片
637	多索茶碱注射液	672	异戊巴比妥钠
638	多索茶碱胶囊	673	注射用异戊巴比妥钠
639	多烯酸乙酯	674	异卡波肼
640	多烯酸乙酯软胶囊	675	异卡波肼片
641	多潘立酮	676	异环磷酰胺
642	多潘立酮片	677	注射用异环磷酰胺
643	色甘酸钠	678	异氟烷
644	色甘酸钠滴眼液	679	异亮氨酸
645	色氨酸	680	异烟肼
646	冰醋酸	681	异烟肼片

682	注射用异烟肼	717	克拉霉素
683	异烟腙	718	克拉霉素片
684	异烟腙片	719	克拉霉素胶囊
685	异维A酸	720	克拉霉素颗粒
686	异维 A 酸软胶囊	721	克林霉素磷酸酯
687	异维A酸凝胶	722	克林霉素磷酸酯外用溶液
688	异福片	723	克林霉素磷酸酯注射液
689	异福胶囊	724	克林霉素磷酸酯栓
690	异福酰胺片	725	克罗米通
691	异福酰胺胶囊	726	克罗米通乳膏
692	红霉素	727	克霉唑
693	红霉素肠溶片	728	克霉唑口腔药膜
694	红霉素肠溶胶囊	729	克霉唑阴道片
695	红霉素软膏	730	克霉唑阴道膨胀栓
696	红霉素眼膏	731	克霉唑乳膏
697	麦白霉素	732	克霉唑药膜
698	麦白霉素片	733	克霉唑栓
699	麦白霉素胶囊	734	克霉唑喷雾剂
700	坎地沙坦酯	735	克霉唑溶液
701	坎地沙坦酯片	736	克霉唑倍他米松乳膏
702	芬布芬	737	苏氨酸
703	芬布芬片	738	劳拉西泮
704	芬布芬胶囊	739	劳拉西泮片
705	苄达赖氨酸	740	杆菌肽
706	苄达赖氨酸滴眼液	741	杆菌肽软膏
707	苄星青霉素	742	杆菌肽眼膏
708	注射用苄星青霉素	743	更昔洛韦
709	苄氟噻嗪	744	更昔洛韦胶囊
710	苄氟噻嗪片	745	更昔洛韦氯化钠注射液
711	克拉维酸钾	746	注射用更昔洛韦
712	阿莫西林克拉维酸钾于混悬剂	747	两性霉素 B
713	阿莫西林克拉维酸钾片	748	注射用两性霉素 B
714	阿莫西林克拉维酸钾分散片	749	抑肽酶
715	阿莫西林克拉维酸钾颗粒	750	注射用抑肽酶
716	注射用阿莫西林钠克拉维酸钾	751	来曲唑

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752	来曲唑片	787	吲哚美辛
753	来氟米特	788	吲哚美辛片
754	来氟米特片	789	吲哚美辛肠溶片
755	呋喃妥因	790	吲哚美辛乳膏
756	呋喃妥因肠溶片	791	吲哚美辛贴片
757	呋喃唑酮	792	吲哚美辛栓
758	呋喃唑酮片	793	吲哚美辛胶囊
759	呋塞米	794	吲哚美辛搽剂
760	呋塞米片	795	吲哚美辛缓释片
761	呋塞米注射液	796	吲哚美辛缓释胶囊
762	吡拉西坦	797	吲哚洛尔
763	吡拉西坦口服溶液	798	吲哚菁绿
764	吡拉西坦片	799	注射用吲哚菁绿
765	吡拉西坦注射液	800	别嘌醇
766	吡拉西坦胶囊	801	别嘌醇片
767	吡拉西坦氯化钠注射液	802	利巴韦林
768	注射用吡拉西坦	803	利巴韦林口服溶液
769	吡罗昔康	804	利巴韦林片
770	吡罗昔康片	805	利巴韦林分散片
771	吡罗昔康肠溶片	806	利巴韦林含片
772	吡罗昔康软膏	807	利巴韦林注射液
773	吡罗昔康注射液	808	利巴韦林胶囊
774	吡罗昔康胶囊	809	利巴韦林颗粒
775	吡罗昔康凝胶	810	利巴韦林滴眼液
776	吡哌酸	811	利巴韦林滴鼻液
777	吡哌酸片	812	利巴韦林葡萄糖注射液
778	吡哌酸胶囊	813	利巴韦林氯化钠注射液
779	叱喹酮	814	注射用利巴韦林
780	吡喹酮片	815	利血平
781	吡嗪酰胺	816	利血平片
782	吡嗪酰胺片	817	利血平注射液
783	叱嗪酰胺胶囊	818	利培酮
784	吲达帕胺	819	利培酮口服溶液
785	吲达帕胺片	820	利培酮口崩片
786	吲达帕胺胶囊	821	利培酮片

822	利培酮胶囊	857	肝素钠乳膏
823	利鲁唑	858	肝素钠注射液
824	利鲁唑片	859	辛伐他汀
825	利福平	860	辛伐他汀片
826	利福平片	861	辛伐他汀胶囊
827	利福平胶囊	862	间苯二酚
828	注射用利福平	863	沙丁胺醇
829	利福昔明	864	沙丁胺醇吸入气雾剂
830	利福昔明于混悬剂	865	沙利度胺
831	利福昔明片	866	沙利度胺片
832	利福昔明胶囊	867	泛昔洛韦
833	佐匹克隆	868	泛昔洛韦片
834	佐匹克隆片	869	泛昔洛韦胶囊
835	佐匹克隆胶囊	870	泛酸钙
836	佐米曲普坦	871	泛酸钙片
837	佐米曲普坦片	872	泛影酸
838	佐米曲普坦分散片	873	泛影葡胺注射液
839	谷丙甘氨酸胶囊	874	泛影酸钠注射液
840	谷氨酰胺	875	尿促性素
841	谷氨酰胺胶囊	876	注射用尿促性素
842	谷氨酰胺颗粒	877	尿素
843	谷氨酸	878	尿素软膏
844	谷氨酸片	879	尿素乳膏
845	谷氨酸钠	880	尿激酶
846	谷氨酸钠注射液	881	注射用尿激酶
847	谷氨酸钾注射液	882	阿片
848	谷胱甘肽片	883	阿片粉
849	妥布霉素	884	阿片片
850	妥布霉素滴眼液	885	阿片酊
851	妥布霉素地塞米松滴眼液	886	阿桔片
852	妥布霉素地塞米松眼膏	887	阿仑膦酸钠
853	硫酸妥布霉素注射液	888	阿仑膦酸钠片
854	肝素钙	889	阿仑膦酸钠肠溶片
855	肝素钙注射液	890	阿卡波糖
856	肝素钠	891	阿卡波糖片

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892	阿卡波糖胶囊	927	阿奇霉素胶囊
893	阿立哌唑	928	阿奇霉素颗粒
894	阿立哌唑口崩片	929	注射用阿奇霉素
895	阿立哌唑片	930	阿法骨化醇
896	阿立哌唑胶囊	931	阿法骨化醇片
897	阿司匹林	932	阿法骨化醇软胶囊
898	阿司匹林片	933	阿洛西林钠
899	阿司匹林肠溶片	934	注射用阿洛西林钠
900	阿司匹林肠溶胶囊	935	阿莫西林
901	阿司匹林泡腾片	936	阿莫西林干混悬剂
902	阿司匹林栓	937	阿莫西林片
903	阿托伐他汀钙	938	阿莫西林胶囊
904	阿米卡星	939	阿莫西林颗粒
905	阿利沙坦酯	940	阿莫西林钠
906	阿利沙坦酯片	941	注射用阿莫西林钠
907	阿昔洛韦	942	阿维 A
908	阿昔洛韦片	943	阿维A胶囊
909	阿昔洛韦咀嚼片	944	阿替洛尔
910	阿昔洛韦乳膏	945	阿替洛尔片
911	阿昔洛韦胶囊	946	阿普唑仑
912	阿昔洛韦葡萄糖注射液	947	阿普唑仑片
913	阿昔洛韦滴眼液	948	阿德福韦酯
914	阿昔洛韦颗粒	949	阿德福韦酯片
915	注射用阿昔洛韦	950	阿德福韦酯胶囊
916	阿昔莫司	951	阿魏酸哌嗪
917	阿昔莫司胶囊	952	阿魏酸哌嗪片
918	阿那曲唑	953	阿魏酸钠
919	阿那曲唑片	954	阿魏酸钠片
920	阿苯达唑	955	注射用阿魏酸钠
921	阿苯达唑片	956	纯化水
922	阿苯达唑胶囊	957	环丙沙星
923	阿苯达唑颗粒	958	乳酸环丙沙星注射液
924	阿奇霉素	959	环吡酮胺
925	阿奇霉素干混悬剂	960	环吡酮胺乳膏
926	阿奇霉素片	961	环孢素

062	环海委口服液液	007	苯丙氨酸
963	环島桃熊	908	茶丙酸诺龙
964	环島桃熊胶臺	000	苯丙酸诺龙注射液
965	环磷酰胺	1000	苯丙醇
966	环磷酰胺片	1000	茶页醇软胶膏
967	注射用环磷酰胺	1001	茶田酸
968	环磁胞苷	1002	茶甲酸利扎曲萼相
969	注射用环磷腺苷	1003	茶田酸雌二醇
909	古 茶 委	1004	茶田酸雌二醇注射液
071	月 同示 書 載 妻 眠 略 上	1005	茶田醇
072	青莲球彩	1007	苯佐卡因
073	月 间 加 邮 書 董 速 彩 出	1007	本 丘 下 凶 茶 巫 茈 纳
974	內國, 前,	1000	苯妥蓝钠片
975	青霉素 V 鉀	1010	注射用茶买茧纳
976	青霉素V钾片	1011	<u></u> 苯唑西林纳
977	青霉素V钾胶囊	1012	来业西林纳片
978	青霉素钠	1012	苯唑西林纳胶囊
979	注射用青霉素钠	1014	洋射用苯唑西林钠
980	青霉素钾	1015	苯酚
981	注射用青霉素钾	1016	苯溴马隆
982	青霜胺	1017	苯溴马隆片
983	青霉胺片	1018	苯溴马隆胶囊
984	苯丁酸氮芥	1019	苯磺顺阿曲库铵
985	苯丁酸氮芥纸型片	1020	注射用苯磺顺阿由库铵
986	苯扎贝特	1021	苯磺酸左氨氯地平
987	苯扎贝特片	1022	苯磺酸左氨氯地平片
988	苯扎贝特胶囊	1023	苯磺酸氨氯地平
989	苯扎氯铵	1024	苯磺酸氨氯地平片
990	苯扎氯铵溶液	1025	苯磺酸氨氯地平胶囊
991	苯扎溴铵	1026	苯噻啶
992	苯扎溴铵溶液	1027	苯噻啶片
993	苯巴比妥	1028	林旦
994	苯巴比妥片	1029	林旦乳育
995	苯巴比妥钠	1030	拉西地平
996	注射用苯巴比妥钠	1031	拉西地平片

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1032	拉米夫定	1067	罗库溴铵注射液
1033	拉米夫定片	1068	罗通定
1034	拉氧头孢钠	1069	罗逋定片
1035	注射用拉氧头孢钠	1070	硫酸罗通定注射液
1036	奈韦拉平	1071	垂体后叶粉
1037	奈韦拉平片	1072	垂体后叶注射液
1038	奋乃静	1073	依巴斯汀
1039	奋乃静片	1074	依巴斯汀片
1040	奋乃静注射液	1075	依他尼酸
1041	软皂	1076	依他尼酸片
1042	非那雄胺	1077	依他尼酸钠
1043	非那雄胺片	1078	注射用依他尼酸钠
1044	非那雄胺胶囊	1079	依地酸钙钠
1045	非洛地平	1080	依地酸钙钠注射液
1046	非洛地平片	1081	依托红霉素
1047	非诺贝特	1082	依托红霉素片
1048	非诺贝特片	1083	依托红霉素胶囊
1049	非诺贝特胶囊	1084	依托红霉素颗粒
1050	非诺洛芬钙	1085	依托泊苷
1051	非诺洛芬钙片	1086	依托泊苷软胶囊
1052	帕司烟肼	1087	依托泊苷注射液
1053	帕米膦酸二钠	1088	依托咪酯
1054	帕米膦酸二钠注射液	1089	依托咪酯注射液
1055	肾上腺素	1090	依托度酸
1056	盐酸肾上腺素注射液	1091	依托度酸片
1057	果糖	1092	依西美坦
1058	明胶	1093	依西美坦片
1059	吸收性明胶海绵	1094	依西美坦胶囊
1060	咖啡因	1095	依达拉奉
1061	罗红霉素	1096	依达拉奉注射液
1062	罗红霉素干混悬剂	1097	依诺沙星
1063	罗红霉素片	1098	依诺沙星片
1064	罗红霉素胶囊	1099	依诺沙星乳膏
1065	罗红霉素颗粒	1100	依诺沙星胶囊
1066	罗库溴铵	1101	依诺沙星滴眼液

1102	依替膦酸二钠	1137	单硝酸异山梨酯片
1103	依替膦酸二钠片	1138	单硝酸异山梨酯注射液
1104	依普黄酮	1139	单硝酸异山梨酯胶囊
1105	依普黄酮片	1140	单硝酸异山梨酯缓释片
1106	乳果糖浓溶液	1141	单硝酸异山梨酯葡萄糖注射液
1107	乳果糖口服溶液	1142	单硝酸异山梨酯氯化钠注射液
1108	乳酶生	1143	法罗培南钠
1109	乳酶生片	1144	法莫替丁
1110	乳酸	1145	法莫替丁片
1111	乳酸依沙吖啶	1146	法莫替丁注射液
1112	乳酸依沙吖啶注射液	1147	法莫替丁胶囊
1113	乳酸依沙吖啶溶液	1148	法莫替丁颗粒
1114	乳酸钙	1149	注射用法莫替丁
1115	乳酸钙片	1150	注射用水
1116	乳酸钠溶液	1151	灭菌注射用水
1117	乳酸钠注射液	1152	注射用维库溴铵
1118	乳酸钠林格注射液	1153	注射用硫喷妥钠
1119	乳糖酸红霉素	1154	泮托拉唑钠
1120	注射用乳糖酸红霉素	1155	泮托拉唑钠肠溶胶囊
1121	鱼石脂	1156	注射用泮托拉唑钠
1122	鱼石脂软膏	1157	泼尼松
1123	鱼肝油酸钠注射液	1158	泼尼松龙
1124	放线菌素 D	1159	泼尼松龙片
1125	注射用放线菌素 D	1160	组氨酸
1126	炔孕酮	1161	细胞色素C溶液
1127	炔孕酮片	1162	细胞色素C注射液
1128	炔诺孕酮	1163	注射用细胞色素 C
1129	炔诺孕酮炔雌醚片	1164	玻璃酸酶
1130	決诺酮	1165	注射用玻璃酸酶
1131	炔诺酮片	1166	草乌甲素
1132	炔诺酮滴丸	1167	草乌甲素口服溶液
1133	決雌醇	1168	草乌甲素片
1134	炔雌醇片	1169	草酸艾司西酞普兰
1135	決雌醚	1170	草酸艾司西酞普兰片
1136	单硝酸异山梨酯	1171	茴拉西坦
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1172	茴拉西坦胶囊	1207	枸橼酸铋雷尼替丁
1173	茶苯海明	1208	枸橼酸铋雷尼替丁片
1174	茶苯海明片	1209	枸橼酸铋雷尼替丁胶囊
1175	茶碱	1210	枸橼酸喷托维林
1176	茶碱缓释片	1211	枸橼酸喷托维林片
1177	茶碱缓释胶囊	1212	枸橼酸喷托维林滴丸
1178	荧光素钠	1213	枸橼酸锌
1179	荧光素钠注射液	1214	枸橼酸锌片
1180	药用炭	1215	枸橼酸氯米芬
1181	药用炭片	1216	枸橼酸氯米芬片
1182	药用炭胶囊	1217	枸橼酸氯米芬胶囊
1183	枸橼酸乙胺嗪	1218	枸橼酸舒芬太尼
1184	枸橼酸乙胺嗪片	1219	枸橼酸舒芬太尼注射液
1185	枸橼酸他莫昔芬	1220	柳氮磺叱啶
1186	枸橼酸他莫昔芬片	1221	柳氮磺吡啶肠溶片
1187	枸橼酸托瑞米芬	1222	柳氮磺吡啶栓
1188	枸橼酸托瑞米芬片	1223	胃蛋白酶
1189	枸橼酸芬太尼	1224	胃蛋白酶片
1190	枸橼酸芬太尼注射液	1225	胃蛋白酶颗粒
1191	枸橼酸坦度螺酮	1226	含糖胃蛋白酶
1192	枸橼酸坦度螺酮胶囊	1227	哌库溴铵
1193	枸橼酸哌嗪	1228	注射用哌库溴铵
1194	枸橼酸哌嗪片	1229	哌拉西林
1195	枸橼酸哌嗪糖浆	1230	哌拉西林钠
1196	枸橼酸钠	1231	注射用哌拉西林钠
1197	抗凝血用枸橼酸钠溶液	1232	注射用哌拉西林钠他唑巴坦钠
1198	输血用枸橼酸钠注射液	1233	哈西奈德
1199	枸橼酸钙	1234	哈西奈德软膏
1200	枸橼酸钙片	1235	哈西奈德乳膏
1201	枸橼酸钾	1236	哈西奈德涂膜
1202	枸橼酸钾颗粒	1237	哈西奈德溶液
1203	枸橼酸铋钾	1238	咪达唑仑
1204	枸橼酸铋钾片	1239	咪达唑仑注射液
1205	枸橼酸铋钾胶囊	1240	咪康唑氯倍他索乳膏
1206	枸橼酸铋钾颗粒	1241	氟马西尼

1242	氟马西尼注射液	1277	氢氧化铝片
1243	氟比洛芬	1278	氢氧化铝凝胶
1244	氟他胺	1279	氢氯噻嗪
1245	氟他胺片	1280	氢氯噻嗪片
1246	氟尿苷	1281	氢溴酸山莨菪碱
1247	氟尿嘧啶	1282	氢溴酸山莨菪碱片
1248	氟尿嘧啶乳膏	1283	氢溴酸山莨菪碱注射液
1249	氟尿嘧啶注射液	1284	氢溴酸右美沙芬
1250	氟罗沙星	1285	氢溴酸右美沙芬口服溶液
1251	氟罗沙星片	1286	氢溴酸右美沙芬片
1252	氟罗沙星胶囊	1287	氢溴酸右美沙芬胶囊
1253	氟哌利多	1288	氢溴酸右美沙芬缓释片
1254	氟哌利多注射液	1289	氢溴酸右美沙芬颗粒
1255	氟哌啶醇	1290	注射用氢溴酸右美沙芬
1256	氟哌啶醇片	1291	氢溴酸东莨菪碱
1257	氟哌啶醇注射液	1292	氢溴酸东莨菪碱片
1258	氟胞嘧啶	1293	氢溴酸东莨菪碱注射液
1259	氟胞嘧啶片	1294	氢溴酸加兰他敏
1260	氟胞嘧啶注射液	1295	氢溴酸加兰他敏片
1261	氟康唑	1296	氢溴酸加兰他敏注射液
1262	氟康唑片	1297	氢溴酸西酞普兰
1263	氟康唑注射液	1298	氢溴酸西酞普兰片
1264	氟康唑胶囊	1299	氢溴酸后马托品
1265	氟康唑氯化钠注射液	1300	氢溴酸烯丙吗啡
1266	氟烷	1301	氢溴酸烯丙吗啡注射液
1267	氟氯西林钠	1302	秋水仙碱
1268	氟氯西林钠胶囊	1303	秋水仙碱片
1269	注射用氟氯西林钠	1304	重质碳酸镁
1270	氢化可的松	1305	重酒石酸去甲肾上腺素
1271	氢化可的松片	1306	重酒石酸去甲肾上腺素注射液
1272	氢化可的松乳膏	1307	重酒石酸间羟胺
1273	氢化可的松注射液	1308	重酒石酸间羟胺注射液
1274	氢化可的松琥珀酸钠	1309	复方十一烯酸锌软膏
1275	注射用氢化可的松琥珀酸钠	1310	复方己酸羟孕酮注射液
1276	氢氧化铝	1311	复方门冬维甘滴眼液

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1312 复方甘草口服溶液 1313 复方甘草片 1314 复方左炔诺孕酮片 1315 复方左炔诺孕酮滴丸 1316 复方卡比多巴片 1317 复方卡托普利片 1318 复方甲苯咪唑片 1319 复方地芬诺酯片 1320 复方克霉唑乳膏 1321 复方呋塞米片 1322 复方利血平片 1323 复方利血平氨苯蝶啶片 1324 复方泛影葡胺注射液 1325 复方乳酸钠葡萄糖注射液 1326 复方炔诺孕酮片 1327 复方炔诺孕酮滴丸 1328 复方炔诺酮片 1329 复方炔诺酮膜 1330 复方庚酸炔诺酮注射液 1331 复方氢氧化铝片 1332 复方盐酸阿米洛利片 1333 复方莪术油栓 1334 复方氨基酸(15)双肽(2)注 1335 复方氨基酸注射液 (18AA) 1336 复方氨基酸注射液(18AA-I) 1337 复方氨基酸注射液(18AA-II) 1338 复方氨基酸注射液(18AA-III) 1339 复方氨基酸注射液(18AA-IV) 1340 复方铝酸铋片 1341 复方铝酸铋胶囊 1342 复方维生素 C 钠咀嚼片 1343 复方葡萄糖酸钙口服溶液 1344 复方氮化钠注射液 1345 复方氯化钠滴眼液 1346 复方蒿甲醚片

1347 复方酮康唑乳膏 1348 复方硼砂含漱液 1349 复方新霉素软膏 1350 复方樟脑酊 1351 复方醋酸甲地孕酮片 1352 复方醋酸地塞米松乳膏 1353 复方磺胺甲有唑口服混悬液 1354 复方磺胺甲有唑片 1355 复方磺胺甲有唑注射液 1356 复方磺胺甲有唑胶囊 1357 复方磺胺甲有唑颗粒 1358 小儿复方磺胺甲有唑片 1359 小儿复方磺胺甲有唑颗粒 1360 复方磺胺嘧啶片 1361 复方磷酸萘酚喹片 1362 顺铂 1363 注射用顺铂 1364 胆茶碱 1365 胆茶碱片 1366 胆影酸 1367 胆影葡胺注射液 1368 胞磷胆碱钠 1369 胞磷胆碱钠片 1370 胞磷胆碱钠注射液 1371 胞磷胆碱钠葡萄糖注射液 1372 胞磷胆碱钠氯化钠注射液 1373 注射用胞磷胆碱钠 1374 注射用胞磷胆碱钠肌苷 1375 亮氨酸 1376 度米芬 1377 度米芬滴丸 1378 美司钠 1379 美司钠注射液 1380 美罗培南 1381 注射用美罗培南

1382	姜洛西林钠	1417	盐酸二氯埃托啡舌下片
1383	注射用美洛西林钠	1418	盐酸二氧丙嗪
1384	美洛昔康	1419	盐酸二氧丙嗪片
1385	美洛昔康片	1420	盐酸丁丙诺啡
1386	美洛昔康分散片	1421	盐酸丁丙诺啡舌下片
1387	美洛昔康胶囊	1422	盐酸丁丙诺啡注射液
1388	前列地尔	1423	盐酸丁卡因
1389	注射用前列地尔	1424	注射用盐酸丁卡因
1390	洛伐他汀	1425	盐酸丁螺环酮
1391	洛伐他汀片	1426	盐酸丁螺环酮片
1392	洛伐他汀胶囊	1427	盐酸三氟拉嗪
1393	洛伐他汀颗粒	1428	盐酸三氟拉嗪片
1394	洛莫司汀	1429	盐酸土霉素
1395	洛莫司汀胶囊	1430	盐酸土霉素片
1396	浓戊二醛溶液	1431	盐酸万古霉素
1397	稀戊二醛溶液	1432	注射用盐酸万古霉素
1398	浓过氧化氢溶液	1433	盐酸大观霉素
1399	过氧化氢溶液	1434	注射用盐酸大观霉素
1400	稀氨溶液	1435	盐酸小檗碱
1401	癸氟奋乃静	1436	盐酸小檗碱片
1402	癸氟奋乃静注射液	1437	盐酸小檗碱胶囊
1403	绒促性素	1438	盐酸川芎嗪
1404	注射用绒促性素	1439	盐酸川芎嗪注射液
1405	盐酸乙哌立松	1440	盐酸马普替林
1406	盐酸乙哌立松片	1441	盐酸马普替林片
1407	盐酸乙胺丁醇	1442	盐酸文拉法辛
1408	盐酸乙胺丁醇片	1443	盐酸文拉法辛胶囊
1409	盐酸乙胺丁醇胶囊	1444	盐酸文拉法辛缓释片
1410	盐酸二甲双胍	1445	盐酸去甲万古霉素
1411	盐酸二甲双胍片	1446	注射用盐酸去甲万古霉素
1412	盐酸二甲双胍肠溶片	1447	盐酸去氧肾上腺素
1413	盐酸二甲双胍肠溶胶囊	1448	盐酸去氧肾上腺素注射液
1414	盐酸二甲双胍胶囊	1449	盐酸去氯羟嗪
1415	盐酸二甲弗林	1450	盐酸去氯羟嗪片
1416	盐酸二氢埃托啡	1451	盐酸艾司洛尔

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1452	注射用盐酸艾司洛尔	1487	盐酸卡替洛尔
1453	盐酸可卡因	1488	盐酸卡替洛尔
1454	盐酸可乐定	1489	盐酸甲氧明
1455	盐酸可乐定片	1490	盐酸甲氧明注
1456	盐酸可乐定注射液	1491	盐酸甲氯芬酯
1457	盐酸可乐定滴眼液	1492	盐酸甲氯芬酯
1458	盐酸丙卡巴肼	1493	注射用盐酸甲
1459	盐酸丙卡巴肼肠溶片	1494	盐酸四环素
1460	盐酸丙卡特罗	1495	盐酸四环素片
1461	盐酸丙卡特罗片	1496	盐酸四环素胶
1462	盐酸丙卡特罗胶囊	1497	注射用盐酸四
1463	盐酸丙米嗪	1498	盐酸半胱氨酸
1464	盐酸丙米嗪片	1499	盐酸头孢甲肟
1465	盐酸丙帕他莫	1500	注射用盐酸头
1466	盐酸左布比卡因	1501	盐酸头孢他美
1467	盐酸左布比卡因注射液	1502	盐酸头孢他美
1468	盐酸左氧氟沙星	1503	盐酸头孢他美
1469	盐酸左氧氟沙星片	1504	盐酸头孢他美
1470	盐酸左氧氟沙星胶囊	1505	盐酸头孢吡肟
1471	盐酸左旋咪唑	1506	注射用盐酸头
1472	盐酸左旋咪唑片	1507	盐酸司来吉兰
1473	盐酸左旋咪唑肠溶片	1508	盐酸司来吉兰
1474	盐酸左旋咪唑颗粒	1509	盐酸尼卡地平
1475	盐酸左旋咪唑糖浆	1510	盐酸尼卡地平
1476	盐酸布比卡因	1511	盐酸尼卡地平
1477	盐酸布比卡因注射液	1512	盐酸尼卡地平
1478	盐酸布桂嗪	1513	盐酸吉西他滨
1479	盐酸布桂嗪片	1514	注射用盐酸吉
1480	盐酸布桂嗪注射液	1515	盐酸托烷司琼
1481	盐酸布替萘芬	1516	盐酸托烷司琼
1482	盐酸布替萘芬乳膏	1517	盐酸托烷司琼
1483	盐酸布替萘芬喷雾剂	1518	盐酸托烷司琼
1484	盐酸布替萘芬凝胶	1519	注射用盐酸托
1485	盐酸平阳霉素	1520	盐酸地匹福林
1486	注射用盐酸平阳霉素	1521	盐酸地匹福林

1487	盐酸卡赫次尔
1488	业 政 下 目 招 小 盐 酸 卡 恭 汝 尔 滴 眼 滴
1480	业政下省各小周北次
1490	盐酸甲氧明注射液
1491	盐酸甲氟芬酯
1492	盐酸甲氯芬酯胶囊
1493	注射用盐酸甲氯芬酯
1494	盐酸四环素
1495	盐酸四环素片
1496	盐酸四环素胶囊
1497	注射用盐酸四环素
1498	盐酸半胱氨酸
1499	盐酸头孢甲肟
1500	注射用盐酸头孢甲肟
1501	盐酸头孢他美酯
1502	盐酸头孢他美酯干混悬剂
1503	盐酸头孢他美酯片
1504	盐酸头孢他美酯胶囊
1505	盐酸头孢吡肟
1506	注射用盐酸头孢吡肟
1507	盐酸司来吉兰
1508	盐酸司来吉兰片
1509	盐酸尼卡地平
1510	盐酸尼卡地平片
1511	盐酸尼卡地平注射液
1512	盐酸尼卡地平葡萄糖注射液
1513	盐酸吉西他滨
1514	注射用盐酸吉西他滨
1515	盐酸托烷司琼
1516	盐酸托烷司琼片
1517	盐酸托烷司琼注射液
1518	盐酸托烷司琼胶囊
1519	注射用盐酸托烷司琼
1520	盐酸地匹福林
1521	盐酸地匹福林滴眼液

15	22	盐酸地尔硫革
15	23	盐酸地尔硫革片
15	24	盐酸地尔硫革缓释片
15	25	盐酸地芬尼多
15	26	盐酸地芬尼多片
15	27	盐酸地芬诺酯
15	28	盐酸西替利嗪
15	29	盐酸西替利嗪口服溶液
15	30	盐酸西替利嗪片
15	31	盐酸西替利嗪胶囊
15	32	盐酸西替利嗪滴剂
15	33	盐酸曲马多
15	34	盐酸曲马多片
15	35	盐酸曲马多分散片
15	36	盐酸曲马多注射液
15	37	盐酸曲马多栓
15	38	盐酸曲马多胶囊
15	39	盐酸曲马多缓释片
15	40	盐酸曲马多缓释胶囊
15	41	盐酸曲美他嗪
15	42	盐酸曲美他嗪片
15	43	盐酸曲美他嗪胶囊
15	44	盐酸曲普利啶
15	45	盐酸吗啡
15	46	盐酸吗啡片
15	47	盐酸吗啡注射液
15	48	盐酸吗啡缓释片
15	49	盐酸伐昔洛韦
15	50	盐酸伐昔洛韦片
15	51	盐酸伐昔洛韦胶囊
15	52	盐酸伪麻黄碱
15	53	盐酸伊托必利
15	54	盐酸伊托必利片
15	55	盐酸伊托必利分散片
15	56	盐酸伊托必利胶囊

1557	盐酸伊达比星
1558	注射用盐酸伊达比星
1559	盐酸多巴胺
1560	盐酸多巴胺注射液
1561	盐酸多巴酚丁胺
1562	盐酸多巴酚丁胺注射液
1563	盐酸多西环素
1564	盐酸多西环素片
1565	盐酸多西环素胶囊
1566	盐酸多沙普仑
1567	盐酸多沙普仑注射液
1568	盐酸多奈哌齐
1569	盐酸多柔比星
1570	注射用盐酸多柔比星
1571	盐酸多塞平
1572	盐酸多塞平片
1573	盐酸齐拉西酮
1574	盐酸齐拉西酮片
1575	盐酸齐拉西酮胶囊
1576	盐酸米托葱醌
1577	盐酸米托葱醌氯化钠注射液
1578	注射用盐酸米托蒽醌
1579	盐酸米多君
1580	盐酸米多君片
1581	盐酸米诺环素
1582	盐酸米诺环素片
1583	盐酸米诺环素胶囊
1584	盐酸安他唑啉
1585	盐酸安他唑啉片
1586	盐酸安非他酮
1587	盐酸安非他酮片
1588	盐酸安非他酮缓释片
1589	盐酸异丙肾上腺素
1590	盐酸异丙肾上腺素注射液
1591	盐酸异丙嗪

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1592	盐酸异丙嗪片	1627	盐酸阿糖胞苷
1593	盐酸异丙嗪注射液	1628	注射用盐酸阿糖胞苷
1594	盐酸苄丝肼	1629	盐酸纳美芬
1595	多巴丝肼片	1630	盐酸纳美芬注射液
1596	多巴丝肼胶囊	1631	盐酸纳洛酮
1597	盐酸克仑特罗	1632	盐酸纳洛酮注射液
1598	盐酸克仑特罗栓	1633	注射用盐酸纳洛酮
1599	盐酸克林霉素	1634	盐酸表柔比星
1600	盐酸克林霉素胶囊	1635	注射用盐酸表柔比星
1601	盐酸克林霉素棕榈酸酯	1636	盐酸环丙沙星
1602	盐酸克林霉素棕榈酸酯干混悬	1637	盐酸环丙沙星片
1603	盐酸克林霉素棕榈酸酯颗粒	1638	盐酸环丙沙星胶囊
1604	盐酸吡硫醇	1639	盐酸环丙沙星滴眼液
1605	盐酸吡硫醇片	1640	盐酸苯乙双胍
1606	盐酸吡硫醇胶囊	1641	盐酸苯乙双胍片
1607	盐酸利多卡因	1642	盐酸苯海拉明
1608	盐酸利多卡因注射液	1643	盐酸苯海拉明片
1609	盐酸利多卡因注射液(溶剂用)	1644	盐酸苯海拉明注射液
1610	盐酸利多卡因胶浆(I)	1645	盐酸苯海索
1611	盐酸利多卡因凝胶	1646	盐酸苯海索片
1612	盐酸妥卡尼	1647	盐酸林可霉素
1613	盐酸妥卡尼片	1648	盐酸林可霉素片
1614	盐酸妥卡尼胶囊	1649	盐酸林可霉素注射液
1615	盐酸妥拉唑林	1650	盐酸林可霉素胶囊
1616	盐酸妥拉唑林片	1651	盐酸林可霉素滴耳液
1617	盐酸妥拉唑林注射液	1652	盐酸林可霉素滴眼液
1618	盐酸阿扑吗啡	1653	盐酸奈福泮
1619	盐酸阿扑吗啡注射液	1654	盐酸奈福泮片
1620	盐酸阿米洛利	1655	盐酸奈福泮注射液
1621	盐酸阿米洛利片	1656	盐酸奈福泮胶囊
1622	盐酸阿米替林	1657	盐酸非那吡啶
1623	盐酸阿米替林片	1658	盐酸非那吡啶片
1624	盐酸阿莫地喹片	1659	盐酸昂丹司琼
1625	盐酸阿普林定	1660	盐酸昂丹司琼片
1626	盐酸阿普林定片	1661	盐酸昂丹司琼注射液

1662	盐酸罗哌卡因	1697	盐酸氟西汀
1663	盐酸罗哌卡因注射液	1698	盐酸氟西汀片
1664	注射用盐酸罗哌卡因	1699	盐酸氟西汀胶囊
1665	盐酸罗通定	1700	盐酸氟西泮
1666	盐酸罗通定片	1701	盐酸氟西泮胶囊
1667	盐酸帕罗西汀	1702	盐酸氟奋乃静
1668	盐酸帕罗西汀片	1703	盐酸氟奋乃静片
1669	盐酸依米丁	1704	盐酸氟奋乃静注射液
1670	盐酸依米丁注射液	1705	盐酸氟桂利嗪
1671	盐酸舍曲林	1706	盐酸氟桂利嗪片
1672	盐酸舍曲林片	1707	盐酸氟桂利嗪分散片
1673	盐酸舍曲林胶囊	1708	盐酸氟桂利嗪胶囊
1674	盐酸金刚乙胺	1709	盐酸度洛西汀
1675	盐酸金刚乙胺片	1710	盐酸度洛西汀肠溶片
1676	盐酸金刚乙胺颗粒	1711	盐酸度洛西汀肠溶胶囊
1677	盐酸金刚烷胺	1712	盐酸美他环素
1678	盐酸金刚烷胺片	1713	盐酸美他环素片
1679	盐酸金刚烷胺胶囊	1714	盐酸美他环素胶囊
1680	盐酸金刚烷胺颗粒	1715	盐酸美西律
1681	盐酸金刚烷胺糖浆	1716	盐酸美西律片
1682	盐酸金霉素	1717	盐酸美西律注射液
1683	盐酸金霉素软膏	1718	盐酸美西律胶囊
1684	盐酸金霉素眼膏	1719	盐酸美克洛嗪
1685	盐酸肼屈嗪	1720	盐酸美克洛嗪片
1686	盐酸肼屈嗪片	1721	盐酸美沙酮
1687	盐酸法舒地尔	1722	盐酸美沙酮口服溶液
1688	盐酸法舒地尔注射液	1723	盐酸美沙酮片
1689	盐酸组氨酸	1724	盐酸美沙酮注射液
1690	盐酸哌甲酯	1725	盐酸洛贝林
1691	盐酸哌甲酯片	1726	盐酸洛非西定
1692	盐酸哌唑嗪	1727	盐酸洛非西定片
1693	盐酸哌唑嗪片	1728	盐酸洛哌丁胺
1694	盐酸哌替啶	1729	盐酸洛哌丁胺胶囊
1695	盐酸哌替啶片	1730	盐酸洛美沙星
1696	盐酸哌替啶注射液	1731	盐酸洛美沙星片

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1732	盐酸洛美沙星胶囊	1767	盐酸萘甲唑啉滴眼液
1733	盐酸柔红霉素	1768	盐酸萘甲唑林滴鼻液
1734	注射用盐酸柔红霉素	1769	盐酸萘替芬
1735	盐酸班布特罗	1770	盐酸萘替芬软膏
1736	盐酸班布特罗片	1771	盐酸萘替芬溶液
1737	盐酸莫雷西嗪	1772	盐酸酚苄明
1738	盐酸莫雷西嗪片	1773	盐酸酚苄明片
1739	盐酸索他洛尔	1774	盐酸酚苄明注射液
1740	盐酸素他洛尔片	1775	盐酸麻黄碱
1741	盐酸格拉司琼	1776	盐酸麻黄碱注射液
1742	盐酸格拉司琼片	1777	盐酸麻黄碱滴鼻液
1743	盐酸格拉司琼注射液	1778	盐酸羟甲唑啉
1744	盐酸氨溴素	1779	盐酸羟甲唑啉喷雾剂
1745	盐酸氨溴索口服溶液	1780	盐酸羟甲唑啉滴鼻液
1746	盐酸氨溴素片	1781	盐酸羟考酮
1747	盐酸氨溴索注射液	1782	盐酸羟考酮片
1748	盐酸氨溴索胶囊	1783	盐酸羟苄唑
1749	盐酸氨溴索缓释胶囊	1784	盐酸羟苄唑滴眼液
1750	盐酸氨溴索糖浆	1785	盐酸维拉帕米
1751	盐酸特比萘芬	1786	盐酸维拉帕米片
1752	盐酸特比萘芬片	1787	盐酸维拉帕米注射液
1753	盐酸特比萘芬乳膏	1788	盐酸维拉帕米缓释片
1754	盐酸特拉唑嗪	1789	盐酸替扎尼定
1755	盐酸特拉唑嗪片	1790	盐酸替扎尼定片
1756	盐酸特拉唑嗪胶囊	1791	盐酸硫必利
1757	盐酸倍他司汀	1792	盐酸硫必利注射液
1758	盐酸倍他司汀片	1793	盐酸硫利达嗪
1759	盐酸胺碘酮	1794	盐酸硫利达嗪片
1760	盐酸胺碘酮片	1795	盐酸喹那普利
1761	盐酸胺碘酮注射液	1796	盐酸氮芥
1762	盐酸胺碘酮胶囊	1797	盐酸氮芥注射液
1763	盐酸黄酮哌酯	1798	盐酸氮革斯汀
1764	盐酸黄酮哌酯片	1799	盐酸氮革斯汀片
1765	盐酸黄酮哌酯胶囊	1800	盐酸氮革斯汀鼻喷雾剂
1766	盐酸萘甲唑啉	1801	盐酸氯丙那林

1802	盐酸氮丙那林片	1837	盐酸溴己新片
1803	盐酸氯丙嗪	1838	盐酸罂粟碱
1804	盐酸氯丙嗪片	1839	盐酸罂粟碱片
1805	盐酸氯丙嗪注射液	1840	盐酸罂粟碱注射液
1806	盐酸氯米帕明	1841	盐酸精氨酸
1807	盐酸氯米帕明片	1842	盐酸精氨酸片
1808	盐酸氯米帕明注射液	1843	盐酸精氨酸注射液
1809	盐酸氯胺酮	1844	盐酸赛庚啶
1810	盐酸氯胺酮注射液	1845	盐酸赛庚啶片
1811	盐酸奥布卡因	1846	盐酸赛洛唑啉
1812	盐酸奥布卡因滴眼液	1847	盐酸赛洛唑啉滴鼻液
1813	盐酸奥昔布宁	1848	盐酸噻氯匹定
1814	盐酸奥昔布宁片	1849	盐酸噻氯匹定片
1815	盐酸普罗帕酮	1850	盐酸噻氯匹定胶囊
1816	盐酸音罗帕酮片	1851	桂利嗪
1817	盐酸音罗帕酮注射液	1852	桂利嗪片
1818	盐酸普罗帕酮胶囊	1853	桂利嗪胶囊
1819	盐酸普萘洛尔	1854	格列本脲
1820	盐酸普萘洛尔片	1855	格列本脲片
1821	盐酸谙萘洛尔注射液	1856	格列齐特
1822	盐酸普鲁卡因	1857	格列齐特片(II)
1823	盐酸音鲁卡因注射液	1858	格列吡嗪
1824	注射用盐酸普鲁卡因	1859	格列吡嗪片
1825	盐酸音鲁卡因胺	1860	格列吡嗪胶囊
1826	盐酸普鲁卡因胺片	1861	格列吡嗪缓释胶囊
1827	盐酸音鲁卡因胺注射液	1862	格列美脲
1828	盐酸瑞芬太尼	1863	格列美脲片
1829	注射用盐酸瑞芬太尼	1864	格列美脲胶囊
1830	盐酸赖氨酸	1865	格列喹酮
1831	盐酸雷尼替丁	1866	格列喹酮片
1832	盐酸雷尼替丁片	1867	格隆溴铵
1833	盐酸雷尼替丁泡腾颗粒	1868	格隆溴铵片
1834	盐酸雷尼替丁注射液	1869	核黄素磷酸钠
1835	盐酸雷尼替丁胶囊	1870	核黄素磷酸钠注射液
1836	盐酸溴己新	1871	恩曲他滨

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1872	恩曲他滨胶囊	1907	氨茶碱注射液
1873	恩氟烷	1908	氨茶碱氯化钠注射液
1874	氧	1909	氨茶碱缓释片
1875	氧化亚氮	1910	氨基己酸
1876	氧化淀粉	1911	氨基己酸注射液
1877	氧化锌	1912	氨酚待因片 (I)
1878	氧化锌软膏	1913	氨酚待因片 (II)
1879	氧化镁	1914	氨鲁米特
1880	氧氟沙星	1915	氨鲁米特片
1881	氧氟沙星片	1916	氨糖美辛肠溶片
1882	氧氟沙星胶囊	1917	氨糖美辛肠溶胶囊
1883	氧氟沙星眼育	1918	特非那定
1884	氧氟沙星氯化钠注射液	1919	特非那定片
1885	氧氟沙星滴耳液	1920	胸腺五肽
1886	氧氟沙星滴眼液	1921	胸腺五肽注射液
1887	氧烯洛尔	1922	注射用胸腺五肽
1888	氧烯洛尔片	1923	胸腺法新
1889	氨力农	1924	注射用胸腺法新
1890	注射用氨力农	1925	倍他米松
1891	氨甲环酸	1926	倍他米松片
1892	氨甲环酸片	1927	倍他米松乳膏
1893	氨甲环酸注射液	1928	倍他米松磷酸钠
1894	氨甲环酸胶囊	1929	倍他米松磷酸钠注射液
1895	氨曲南	1930	胰岛素
1896	注射用氨曲南	1931	胰岛素注射液
1897	氨苄西林	1932	精蛋白锌胰岛素注射液
1898	氨苄西林丙磺舒颗粒	1933	精蛋白锌胰岛素注射液(30R)
1899	氨苄西林钠	1934	胰蛋白酶
1900	注射用氨苄西林钠	1935	注射用胰蛋白酶
1901	氨苯砜	1936	胰酶
1902	氨苯砜片	1937	胰酶肠溶片
1903	氨苯蝶啶	1938	胰酶肠溶胶囊
1904	氨苯蝶啶片	1939	胰激肽原酶
1905	氨茶碱	1940	胰激肽原酶肠溶片
1906	氨茶碱片	1941	胱氨酸
1942	胱氨酸片	1977	消旋山莨菪碱片
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1943	脂肪乳注射液(C14~24)	1978	盐酸消旋山莨菪碱注射液
1944	胶体果胶铋	1979	消旋卡多曲
1945	胶体果胶铋胶囊	1980	消旋卡多曲颗粒
1946	高三尖杉酯碱	1981	诺氟沙星
1947	高三尖杉酯碱注射液	1982	诺氟沙星片
1948	高锰酸钾	1983	诺氟沙星软膏
1949	高锰酸钾外用片	1984	诺氟沙星乳膏
1950	烟酰胺	1985	诺氟沙星胶囊
1951	烟酰胺片	1986	诺氟沙星滴眼液
1952	烟酰胺注射液	1987	培哚普利叔丁胺
1953	烟酸	1988	培哚普利叔丁胺片
1954	烟酸片	1989	黄体酮
1955	烟酸注射液	1990	黄体酮注射液
1956	烟酸占替诺	1991	萘丁美酮
1957	烟酸占替诺注射液	1992	萘丁美酮片
1958	烟酸占替诺氯化钠注射液	1993	萘丁美酮胶囊
1959	酒石酸长春瑞滨	1994	萘哌地尔
1960	酒石酸长春瑞滨注射液	1995	萘哌地尔片
1961	酒石酸双氢可待因	1996	萘敏维滴眼液
1962	酒石酸双氢可待因片	1997	萘普生
1963	酒石酸布托啡诺	1998	萘普生片
1964	酒石酸布托啡诺注射液	1999	萘普生栓
1965	酒石酸麦角胺	2000	萘普生胶囊
1966	麦角胺咖啡因片	2001	萘普生颗粒
1967	酒石酸美托洛尔	2002	萘普生钠
1968	酒石酸美托洛尔片	2003	萘普生钠片
1969	酒石酸美托洛尔注射液	2004	萘普待因片
1970	酒石酸美托洛尔胶囊	2005	萘磺酸右丙氧芬
1971	酒石酸美托洛尔缓释片	2006	萝巴新
1972	酒石酸唑吡坦	2007	酞丁安
1973	酒石酸唑吡坦片	2008	酞丁安乳膏
1974	酒石酸溴莫尼定	2009	酞丁安搽剂
1975	酒石酸溴莫尼定滴眼液	2010	酞丁安滴眼液
1976	消旋山莨菪碱	2011	酚咖片
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2012	酚酞	2047	维生素 B2
2013	酚酞片	2048	维生素 B2片
2014	酚磺乙胺	2049	维生素 B2 注射液
2015	注射用酚磺乙胺	2050	维生素 B6
2016	辅酶 Q10	2051	维生素 B6片
2017	辅酶 Q10 片	2052	维生素 B6 注射液
2018	辅酶 Q10 软胶囊	2053	维生素 B12
2019	辅酶 Q10 注射液	2054	维生素 B12 注射液
2020	辅酶 Q10 胶囊	2055	维生素 B12 滴眼液
2021	铝酸铋	2056	维生素 C
2022	铝碳酸镁	2057	维生素C片
2023	铝碳酸镁咀嚼片	2058	维生素C泡腾片
2024	铝镁司片	2059	维生素 C 泡腾颗粒
2025	脯氨酸	2060	维生素C注射液
2026	麻醉乙醚	2061	维生素C颗粒
2027	羟丁酸钠	2062	维生素C钙
2028	羟丁酸钠注射液	2063	维生素C钠
2029	羟甲香豆素	2064	维生素 D2
2030	羟甲香豆素片	2065	维生素 D2 软胶囊
2031	羟甲香豆素胶囊	2066	维生素 D2 注射液
2032	羟苯磺酸钙	2067	维生素 D3
2033	羟苯磺酸钙胶囊	2068	维生素 D3 注射液
2034	羟基脲	2069	维生素 E
2035	羟基脲片	2070	维生素E片
2036	液状石蜡	2071	维生素E软胶囊
2037	维A酸	2072	维生素 E 注射液
2038	维A酸片	2073	维生素E粉
2039	维A酸乳膏	2074	维生素 K1
2040	维生素 A	2075	维生素 K1 注射液
2041	维生素A软胶囊	2076	琥乙红霉素
2042	维生素 AD 软胶囊	2077	琥乙红霉素片
2043	维生素 AD 滴剂	2078	琥乙红霉素分散片
2044	维生素 B1	2079	琥乙红霉素胶囊
2045	维生素 B1 片	2080	琥乙红霉素颗粒
2046	维生素 B1 注射液	2081	琥珀氯霉素

2082	注射用琥珀氯霉素	2117	葡萄糖氯化钠注射液
2083	琥珀酸舒马普坦片	2118	葡萄糖酸亚铁
2084	替加氟	2119	葡萄糖酸亚铁片
2085	替加氟片	2120	葡萄糖酸亚铁胶囊
2086	替加氟注射液	2121	葡萄糖酸亚铁糖浆
2087	替加氟胶囊	2122	葡萄糖酸钙
2088	替考拉宁	2123	葡萄糖酸钙口服溶液
2089	注射用替考拉宁	2124	葡萄糖酸钙片
2090	替米沙坦	2125	葡萄糖酸钙含片
2091	替莫唑胺	2126	葡萄糖酸钙注射液
2092	替莫唑胺胶囊	2127	葡萄糖酸钙氯化钠注射液
2093	替硝唑	2128	葡萄糖酸钙颗粒
2094	替硝唑片	2129	葡萄糖酸锌
2095	替硝唑阴道片	2130	葡萄糖酸锌口服溶液
2096	替硝唑阴道泡腾片	2131	葡萄糖酸锌片
2097	替硝唑含片	2132	葡萄糖酸锌颗粒
2098	替硝唑栓	2133	葡萄糖酸锑钠
2099	替硝唑胶囊	2134	葡萄糖酸锑钠注射液
2100	替硝唑葡萄糖注射液	2135	葡萄糖酸氯己定溶液
2101	替硝唑氯化钠注射液	2136	稀葡萄糖酸氯己定溶液
2102	联苯双酯	2137	葡萄糖酸氯己定含漱液
2103	联苯双酯滴丸	2138	棓丙酯
2104	联苯苄唑	2139	注射用棓丙酯
2105	联苯苄唑乳膏	2140	棕榈氯霉素
2106	联苯苄唑栓	2141	棕榈氯霉素混悬液
2107	联苯苄唑溶液	2142	棕榈氯霉素(B型)片
2108	联磺甲氧苄啶片	2143	棕榈氯霉素(B型)颗粒
2109	葛根素	2144	硬脂酸红霉素
2110	葛根素注射液	2145	硬脂酸红霉素片
2111	注射用葛根素	2146	硬脂酸红霉素胶囊
2112	葡甲胺	2147	硬脂酸红霉素颗粒
2113	葡萄糖	2148	硝西泮
2114	无水葡萄糖	2149	硝西泮片
2115	葡萄糖注射液	2150	硝苯地平
2116	葡萄糖粉剂	2151	硝苯地平片

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2152	·明本地十 · · · · · · · · · · · · · · · · · · ·	2187	航马票令
2153	明本地十成襄	2188	航与宗令万
2154	帕首钠	2189	航空宗令
2155	汪羽用朝首羽 湖歐王里女天成	2190	航空乐堂月
2150	明政七末云谷城	2191	航政小佑母系
2157	朝政七米云省嚬凋眼波	2192	航政小话每条口服冷放
2158	明政日油谷波	2193	航政小话母亲月
2159	明政日油气务们	2194	航政小市每条注射波
2160	明政百油月	2195	航政大春地车
2161	朝政日油注新波	2196	注射用
2162	明政开山采酮	2197	师政下春初领
2105	明政开山禾酮月 瑞士尼山利弗的原	2198	江州爪號敗下各別機
2164	明政升山米阳孔面 湖歌巴山和船沿自流	2199	机胶下香烟
2105	明政开山采明江州放	2200	江州爪叽败飞春飘
2100	明胶开山采丽葡萄裙汪别放	2201	1911 敗 L 化每条 広 於 田 长 雪 孝 山
2107	們政开山米館"负务州	2202	%% 做 口 化 每 条 月
2108	明政开山采丽须伴放襄	2203	师政从 册 出 祭
2109	注剂用朝酸开山采酮 磺酚唑 唐 啦	2204	· 败队///出祭月
2170	明政休康空	2205	5000下加每系 広歌上那雪季计目流
2171	明胶木康兰的退力	2200	11. 收下加每条江划 仪 広歌上那雪麦海胆流
2172	明政休康空的追扒放義	2207	· 10 0 小 加 每 赤 间 収 次
2175	明酸味康空防退泡胸月	2208	江別八凱政下加每系
2174	明政休康空孔貫	2209	师政业状
2175	明政休康空住	2210	弧欧亚铁石
2170	明敗休康空欣義	2211	%% 敗业 沃坂 样 月
2177	明政休康空徐州	2212	· 10 00 系不生
2178	明政定成空	2215	弧酸四聚不生江剂液
2179	明敗血尿空的退膨瓜住	2214	加政可非
2180	明政並康生扎貫	2215	机胶可非仁剂胶
2101	明敗血尿生住	2210	弧政·刁·升级杆力 広聯名和英考 D
2182	阳收血尿空贝牙刑 醋酚头库吸浓油	2217	1ml取罗郑困赤 D 注目田磁齡名科苗本 D
2183	阳欧亚尿生化液	2218	江初川叽睨夕郊图系 D 広歌庄上讀書
2104	2月月久 9月1 月又 1日	2219	1911 取八八母系
2185	现代现政的	2220	11. 取仄八母系 月 広歌庄上雪書 计 山法
2186	航飞航酸钠注射液	2221	师政庆大每系壮州次

2222	硫酸庆大霉素缓释片	22
2223	硫酸庆大霉素颗粒	22
2224	硫酸庆大霉素滴眼液	22
2225	硫酸异帕米星	22
2226	硫酸异帕米星注射液	22
2227	硫酸沙丁胺醇	22
2228	硫酸沙丁胺醇片	22
2229	硫酸沙丁胺醇吸入气雾剂	22
2230	硫酸沙丁胺醇吸入粉雾剂	22
2231	硫酸沙丁胺醇注射液	22
2232	硫酸沙丁胺醇胶囊	22
2233	硫酸沙丁胺醇缓释片	22
2234	硫酸沙丁胺醇缓释胶囊	22
2235	硫酸阿托品	22
2236	硫酸阿托品片	22
2237	硫酸阿托品注射液	22
2238	硫酸阿托品眼膏	22
2239	硫酸阿米卡星	22
2240	硫酸阿米卡星注射液	22
2241	注射用硫酸阿米卡星	22
2242	硫酸软骨素钠	22
2243	硫酸软骨素钠片	22
2244	硫酸软骨素钠胶囊	22
2245	硫酸茚地那韦胶囊	22
2246	硫酸奈替米星	22
2247	硫酸奈替米星注射液	22
2248	硫酸依替米星	22
2249	硫酸依替米星注射液	22
2250	注射用硫酸依替米星	22
2251	硫酸鱼精蛋白	22
2252	硫酸鱼精蛋白注射液	22
2253	硫酸卷曲霉素	22
2254	注射用硫酸卷曲霉素	22
2255	硫酸奎宁	22
2256	硫酸奎宁片	22

2257	硫酸奎尼丁
2258	硫酸奎尼丁片
2259	硫酸钡(I型)
2260	硫酸钡(I型)干混悬剂
2261	硫酸钡(Ⅱ型)
2262	硫酸钡(Ⅱ型)干混悬剂
2263	硫酸氢氯吡格雷
2264	硫酸氢氯吡格雷片
2265	硫酸胍乙啶
2266	硫酸胍乙啶片
2267	硫酸核糖霉素
2268	注射用硫酸核糖霉素
2269	硫酸特布他林
2270	硫酸特布他林片
2271	硫酸特布他林吸入气雾剂
2272	硫酸链霉素
2273	注射用硫酸链霉素
2274	硫酸锌
2275	硫酸锌口服溶液
2276	硫酸锌片
2277	硫酸锌颗粒
2278	硫酸普拉睾酮钠
2279	注射用硫酸普拉睾酮钠
2280	硫酸新霉素
2281	硫酸新霉素片
2282	硫酸新霉素滴眼液
2283	硫酸镁
2284	硫酸镁注射液
2285	硫酸黏菌素
2286	硫酸黏菌素片
2287	硫糖铝
2288	硫糖铝口服混悬液
2289	硫糖铝分散片
2290	硫糖铝咀嚼片
2291	硫糖铝胶囊

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2292	紫杉醇	2327	氯烯雌醚
2293	紫杉醇注射液	2328	氯烯雌醚滴丸
2294	氯贝丁酯	2329	氯硝西泮
2295	氯贝丁酯胶囊	2330	氯硝西泮片
2296	氯化钙	2331	氯硝西泮注射液
2297	氯化钙注射液	2332	氯硝柳胺
2298	氯化钠	2333	氯硝柳胺片
2299	生理氯化钠溶液	2334	氯氮平
2300	氯化钠注射液	2335	氯氮平片
2301	浓氯化钠注射液	2336	氯氮革
2302	氯化钾	2337	氯氮革片
2303	氯化钾片	2338	氯普噻吨
2304	氯化钾注射液	2339	氯普噻吨片
2305	氯化钾葡萄糖注射液	2340	氯普噻吨注射液
2306	氯化钾氯化钠注射液	2341	氯碘羟喹
2307	氯化钾缓释片	2342	氯碘羟喹乳膏
2308	氯化铵	2343	氯雷他定
2309	氯化铵片	2344	氯雷他定片
2310	氯化琥珀胆碱	2345	氯雷他定胶囊
2311	氯化琥珀胆碱注射液	2346	氯雷他定颗粒
2312	氯化筒箭毒碱	2347	氯霉素
2313	氯化简箭毒碱注射液	2348	氯霉素片
2314	氯芬待因片	2349	氯霉素胶囊
2315	氯沙坦钾	2350	氯霉素眼膏
2316	氯沙坦钾片	2351	氯霉素滴耳液
2317	氯沙坦钾胶囊	2352	氯霉素滴眼液
2318	氯法齐明	2353	氯磺丙脲
2319	氯法齐明软胶囊	2354	氯磺丙脲片
2320	氯唑西林钠	2355	氯噻酮
2321	氯唑西林钠胶囊	2356	氯噻酮片
2322	氯唑西林钠颗粒	2357	氯膦酸二钠
2323	注射用氯唑西林钠	2358	氯膦酸二钠注射液
2324	氯诺昔康	2359	氯膦酸二钠胶囊
2325	氯诺昔康片	2360	奥扎格雷
2326	注射用氯诺昔康	2361	奥扎格雷钠

2362	奥卡西平	2397	普罗布考
2363	奥卡西平片	2398	音罗布考片
2364	奥沙西泮	2399	音罗碘铵
2365	奥沙西泮片	2400	普罗碘铵注射液
2366	奥沙利铂	2401	音鲁卡因青霉素
2367	注射用奥沙利铂	2402	注射用普鲁卡因青霉素
2368	奥沙音秦	2403	富马酸比索洛尔
2369	奥沙音秦肠溶片	2404	富马酸比索洛尔片
2370	奥沙音秦肠溶胶囊	2405	富马酸比索洛尔胶囊
2371	奥美拉唑	2406	富马酸亚铁
2372	奥美拉唑肠溶片	2407	富马酸亚铁片
2373	奥美拉唑肠溶胶囊	2408	富马酸亚铁咀嚼片
2374	奥美拉唑钠	2409	富马酸亚铁胶囊
2375	奥美拉唑钠肠溶片	2410	富马酸亚铁颗粒
2376	注射用奥美拉唑钠	2411	富马酸喹硫平
2377	奥美拉唑镁肠溶片	2412	富马酸喹硫平片
2378	奥硝唑	2413	富马酸氯马斯汀
2379	奥硝唑片	2414	富马酸氯马斯汀干混悬剂
2380	奥硝唑阴道泡腾片	2415	富马酸氯马斯汀片
2381	奥硝唑阴道栓	2416	富马酸酮替芬
2382	奥硝唑注射液	2417	富马酸酮替芬口服溶液
2383	奥硝唑胶囊	2418	富马酸酮替芬片
2384	奥氮平	2419	富马酸酮替芬胶囊
2385	奥氮平片	2420	富马酸酮替芬滴眼液
2386	舒巴坦钠	2421	富马酸酮替芬滴鼻液
2387	注射用舒巴坦钠	2422	富马酸福莫特罗
2388	注射用头孢哌酮钠舒巴坦钠	2423	富马酸福莫特罗片
2389	注射用氨苄西林钠舒巴坦钠	2424	巯嘌呤
2390	舒必利	2425	巯嘌呤片
2391	舒必利片	2426	瑞格列奈
2392	舒林酸	2427	瑞格列奈片
2393	舒林酸片	2428	蒿甲醚
2394	普伐他汀钠	2429	蒿甲醚胶囊
2395	普伐他汀钠片	2430	蒙脱石
2396	普伐他汀钠胶囊	2431	蒙脱石分散片

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2432	蒙脱石散	2467	碘香酸
2433	赖氨匹林	2468	碘番酸片
2434	注射用赖氨匹林	2469	碘解磷定
2435	赖诺普利	2470	碘解磷定注射液
2436	赖诺音利片	2471	碘酸钾
2437	赖诺普利胶囊	2472	碘酸钾片
2438	酮咯酸氨丁三醇	2473	碘酸钾颗粒
2439	酮咯酸氨丁三醇注射液	2474	硼砂
2440	酮洛芬	2475	硼酸
2441	酮洛芬肠溶胶囊	2476	硼酸软膏
2442	酮洛芬搽剂	2477	硼酸溶液
2443	酮康唑	2478	雷贝拉唑钠
2444	酮康唑乳膏	2479	雷贝拉唑钠肠溶片
2445	酮康唑洗剂	2480	雷贝拉唑钠肠溶胶囊
2446	酪氨酸	2481	雷米普利
2447	硖	2482	雷米普利片
2448	硖甘油	2483	腺苷
2449	碑酊	2484	腺苷注射液
2450	碘化油	2485	腺苷钴胺
2451	碘化油软胶囊	2486	腺苷钴胺片
2452	碘化油注射液	2487	羧甲司坦
2453	碘化钠	2488	羧甲司坦口服溶液
2454	碘化钾	2489	羧甲司坦片
2455	碘化钾片	2490	羧甲司坦颗粒
2456	碘他拉酸	2491	羧苄西林钠
2457	碘他拉葡胺注射液	2492	注射用羧苄西林钠
2458	碘佛醇	2493	澳丙胺太林
2459	碘佛醇注射液	2494	澳丙胺太林片
2460	碑苷	2495	溴吡斯的明
2461	碘苷滴眼液	2496	溴吡斯的明片
2462	碘苯酯	2497	澳新斯的明
2463	碘苯酯注射液	2498	澳新斯的明片
2464	碘帕醇注射液	2499	塞克硝唑
2465	碘海醇	2500	塞克硝唑片
2466	碘海醇注射液	2501	塞克硝唑胶囊

2502	塞替派	2537	醋氨己酸锌
2503	塞替派注射液	2538	醋氨己酸锌胶囊
2504	福尔可定	2539	醋氨苯砜
2505	福尔可定片	2540	醋氨苯砜注射液
2506	聚维酮碘	2541	醋氯芬酸
2507	聚维酮碘乳膏	2542	醋氯芬酸片
2508	聚维酮碘栓	2543	醋氯芬酸胶囊
2509	聚维酮碘溶液	2544	醋酸去氧皮质酮
2510	聚维酮碘凝胶	2545	醋酸去氨加压素
2511	碱式碳酸铋	2546	去氨加压素片
2512	碱式碳酸铋片	2547	去氨加压素注射液
2513	碳酸利多卡因注射液	2548	注射用去氨加压素
2514	碳酸钙	2549	醋酸可的松
2515	碳酸钙咀嚼片	2550	醋酸可的松片
2516	碳酸钙颗粒	2551	醋酸可的松注射液
2517	碳酸氢钠	2552	醋酸丙氨瑞林
2518	碳酸氢钠片	2553	注射用醋酸丙氨瑞林
2519	碳酸氢钠注射液	2554	醋酸甲地孕酮
2520	碳酸锂	2555	醋酸甲地孕酮片
2521	碳酸锂片	2556	醋酸甲地孕酮分散片
2522	碳酸锂缓释片	2557	醋酸甲地孕酮胶囊
2523	罂粟果提取物	2558	醋酸甲萘氢醌
2524	罂粟果提取物粉	2559	醋酸甲萘氢醌片
2525	堆二醇	2560	醋酸甲羟孕酮
2526	堆二醇缓释贴片	2561	醋酸甲羟孕酮片
2527	鲑降钙素	2562	醋酸甲羟孕酮分散片
2528	鲑降钙素注射液	2563	醋酸甲羟孕酮胶囊
2529	注射用鲑降钙素	2564	醋酸甲羟孕酮混悬注射液
2530	精氨酸	2565	醋酸地塞米松
2531	熊去氧胆酸	2566	醋酸地塞米松片
2532	熊去氧胆酸片	2567	醋酸地塞米松乳膏
2533	缩宫素注射液	2568	醋酸地塞米松注射液
2534	注射用缩宫素	2569	醋酸曲安奈德
2535	樟脑 (天然)	2570	醋酸由安奈德乳膏
2536	樟脑(合成)	2571	醋酸由安奈德注射液

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2572	醋酸曲普瑞林	2607	磺胺甲有唑片
2573	醋酸曲普瑞林注射液	2608	磺胺多辛
2574	醋酸泼尼松	2609	磺胺多辛片
2575	醋酸泼尼松片	2610	磺胺异有唑
2576	醋酸泼尼松眼膏	2611	磺胺异有唑片
2577	醋酸泼尼松龙	2612	磺胺嘧啶
2578	醋酸泼尼松龙片	2613	磺胺嘧啶片
2579	醋酸泼尼松龙乳膏	2614	磺胺嘧啶软膏
2580	醋酸泼尼松龙注射液	2615	磺胺嘧啶眼膏
2581	醋酸氟轻松	2616	磺胺嘧啶混悬液
2582	醋酸氟轻松乳膏	2617	磺胺嘧啶钠
2583	醋酸氟氢可的松	2618	磺胺嘧啶钠注射液
2584	醋酸氟氢可的松乳膏	2619	注射用磺胺嘧啶钠
2585	醋酸氢化可的松	2620	磺胺嘧啶银
2586	醋酸氢化可的松片	2621	磺胺嘧啶银软膏
2587	醋酸氢化可的松乳膏	2622	磺胺嘧啶银乳膏
2588	醋酸氢化可的松注射液	2623	磺胺嘧啶锌
2589	醋酸氢化可的松眼膏	2624	磺胺嘧啶锌软膏
2590	醋酸氢化可的松滴眼液	2625	磺胺醋酰钠
2591	醋酸氯己定	2626	磺胺醋酰钠滴眼液
2592	醋酸氯己定软膏	2627	噻苯唑
2593	醋酸氯地孕酮	2628	噻苯唑片
2594	醋酸奥曲肽	2629	凝血酶冻干粉
2595	醋酸奥曲肽注射液	2630	糖精钠
2596	注射用醋酸奥曲肽	2631	磷酸二氢钠
2597	醋酸赖氨酸	2632	磷酸川芎嗪
2598	醋酸磺胺米隆	2633	磷酸川芎嗪片
2599	缬沙坦	2634	磷酸川芎嗪胶囊
2600	缬沙坦片	2635	磷酸可待因
2601	缬沙坦胶囊	2636	磷酸可待因片
2602	缬氨酸	2637	磷酸可待因注射液
2603	薄荷麝香草酚搽剂	2638	磷酸可待因糖浆
2604	磺苄西林钠	2639	磷酸丙吡胺
2605	注射用磺苄西林钠	2640	磷酸丙吡胺片
2606	磺胺甲有唑	2641	磷酸丙吡胺注射液

2642	磷酸肌酸钠
2643	磷酸伯氨喹
2644	磷酸伯氨喹片
2645	磷酸苯丙哌林
2646	磷酸苯丙哌林口服溶液
2647	磷酸苯丙哌林片
2648	磷酸苯丙哌林胶囊
2649	磷酸苯丙哌林颗粒
2650	磷酸组胺
2651	磷酸组胺注射液
2652	磷酸哌喹
2653	磷酸哌喹片
2654	磷酸哌嗪
2655	磷酸哌嗪片
2656	磷酸咯萘啶
2657	磷酸咯萘啶肠溶片
2658	磷酸咯萘啶注射液
2659	磷酸氟达拉滨
2660	注射用磷酸氟达拉滨
2661	磷酸氢钙
2662	磷酸氢钙片
2663	磷酸氯喹
2664	磷酸氯喹片
2665	磷酸氯喹注射液
2666	磷酸奥司他韦
2667	磷酸奥司他韦胶囊
2668	磷酸腺嘌呤
2669	磷酸腺嘌呤片
2670	磷霉素钙
2671	磷霉素钙片
2672	磷霉素钙胶囊
2673	磷霉素钙颗粒
2674	磷霉素钠
2675	注射用磷霉素钠
2676	磷霉素氨丁三醇

2677	磷霉素氨丁三醇散
2678	螺内酯
2679	螺内酯片
2680	螺内酯胶囊
2681	糜蛋白酶
2682	注射用糜蛋白酶
品种正	E文 第二部分
2683	来昔决南钐[¹⁵³ Sm]注射液
2684	氙 [¹³³ Xe] 注射液
2685	邻碘 [131] 马尿酸钠注射液
2686	注射用亚锡亚甲基二膦酸盐
2687	注射用亚锡依替菲宁
2688	注射用亚锡喷替酸
2689	注射用亚锡植酸钠
2690	注射用亚锡焦磷酸钠
2691	注射用亚锡聚合白蛋白
2692	枸橼酸镓 [67Ga] 注射液
2693	氟 [¹⁸ F] 脱氧葡糖注射液
2694	胶体磷 [³² P] 酸铬注射液
2695	高锝 [99mTc] 酸钠注射液
2696	铬 [⁵¹ Cr] 酸钠注射液
2697	氯化亚铊 [²⁰¹ Tl] 注射液
2698	氯化锶[⁸⁹ Sr]注射液
2699	碘[¹²⁵]]密封籽源
2700	碘 [¹³¹ I] 化钠口服溶液
2701	诊断用碘 [¹³¹ I] 化钠胶囊
2702	锝[99mTc]双半胱乙酯注射液
2703	锝[99mTc]双半胱氨酸注射液
2704	锝[99mTc]甲氧异腈注射液
2705	得 [99mTc] 亚甲基二膦酸盐注
2706	锝 [99mTc] 依替菲宁注射液
2707	锝[^{99m} Tc] 植酸盐注射液
2708	锝 [99mTc] 喷替酸盐注射液
2709	锝[^{99m} Tc] 焦磷酸盐注射液
2710	锝 [^{99m} Tc] 聚合白蛋白注射液

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2711 磷 [³²P] 酸钠盐口服溶液 2712 磷 [³²P] 酸钠盐注射液