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**ASSESSMENT OF THE PAEDIATRIC NEEDS
PSYCHIATRY**

DISCLAIMER

The Paediatric Working Party (PEG) is working to identify the needs in the different therapeutic areas where there should be research and development of medicinal products for children, either old (i.e. off patent) or new ones (including those under development). Products on the list are not in any order of priority.

The lists should not be viewed as a prescription tool nor as recommendations for treatment. Accuracy of data including in particular authorised doses cannot be guaranteed.

Information on existing marketing authorisations is very limited and therefore information under “authorised” includes the indication in broad term, the lower age group authorised in at least one Member State, the authorised dose(s) (if authorised for use in patients less than 18 years of age) and formulation(s) in at least in one Member State.

Please refer to the EMEA/PEG procedure for identifying the paediatric needs for further information.

Comments from third parties are expected especially to complete and or update the list as necessary.

AGREED BY PAEDIATRIC WORKING PARTY (PEG)	25 May 2007
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END OF CONSULTATION (DEADLINE FOR COMMENTS)	31 January 2008

Comments should be provided using this [template](#) to PDCO Secretariat:
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HYPNOTICS	
CHLORAL HYDRATE (REFER ALSO TO LIST OF PAEDIATRIC NEEDS ANAESTHESIOLOGY)	
<i>Authorised indication</i>	Sedation during diagnostic procedures and in intensive care units Short term treatment of insomnia, night sedation
<i>Authorised age group</i>	Authorised only for short term insomnia (<i>United Kingdom</i>) Authorized only for sedation during diagnostic procedures (<i>France</i>)
<i>Authorised dose</i>	1 month-1 year: 25-30 mg/kg 1-5 years: 250-500 mg 6-12 years: 0.5-1 g 12-18 years 1-2 g
<i>Authorised formulation</i>	Oral solution 500 mg/5 ml; 200 mg/5ml; rectal solution (<i>France</i>) Tablets
<i>Needs</i>	Data on PK, efficacy and safety in children (all age groups) in insomnia and sedation Age appropriate oral and rectal formulation Availability in all Member States
MELATONIN	
<i>Authorised indication</i>	Not authorised
<i>Authorised age group</i>	-
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	-
<i>Needs</i>	Data on PK, efficacy and safety in autism and insomnia in children. Required for children with neurological impairment, blindness, ADHD, and to re-establish sleep patterns in infants and children. Age appropriate formulation, including slow release formulation
ANTI-HISTAMINES	
HYDROXYZINE HYDROCHLORIDE	
<i>Authorised indication</i>	Insomnia in allergy
<i>Authorised age group</i>	> 1 year (<i>Finland</i>)
<i>Authorised dose</i>	1-5 years 1-2,5 mg/kg/day 6-15 years 1-2 mg/kg/day
<i>Authorised formulation</i>	Tablets 10 mg, 25 mg Oral solution 2mg/ml Solution for iv injection 50 mg/ml Syrup
<i>Needs</i>	Availability in all Member States
PROMETHAZINE HYDROCHLORIDE	
<i>Authorised indication</i>	Treatment of agitation in psychiatric disorders
<i>Authorised age group</i>	Children and adolescents (<i>Germany</i>)
<i>Authorised dose</i>	Starting dose 0.5 ml (=10 mg) Maximum daily dose 0,5 mg/kg
<i>Authorised formulation</i>	Solution for injection Oral solution Tablets
<i>Needs</i>	Define lower age limit and investigate where needed (PK, safety and efficacy in younger children)

BENZODIAZEPINE-LIKE SUBSTANCES	
ZOPICLONE	
<i>Authorised indication</i>	Insomnia
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	-
Needs	Data on PK, efficacy and safety in children >13 years in insomnia and sedation
ZALEPLON	
<i>Authorised indication</i>	Sleep disorders
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	-
Needs	Data on efficacy, safety, and dose in children >13 years in insomnia and sedation
ZOLPIDEM	
<i>Authorised indication</i>	Sleep disorders
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	-
Needs	Data on PK, efficacy, safety in children >13 years in insomnia and sedation
ANXIOLYTICS	
BENZODIAZEPINES	
LORAZEPAM	
<i>Authorised indication</i>	Premedication, status epilepticus, acute anxiety, acute excitement
<i>Authorised age group</i>	Acute anxiety and premedication: Not recommended < 12 years (<i>United Kingdom</i>) Status epilepticus: No age limit specified
<i>Authorised dose</i>	Status epilepticus: 2mg iv Acute anxiety: 0.025-0.03mg/kg
<i>Authorised formulation</i>	Tablets Solution for injection (iv, im)
Needs	Safety and efficacy of i.m. route in acute agitation and self harm in children ≥ 13 years
MIDAZOLAM (REFER ALSO TO LIST OF PAED NEEDS ANAESTHESIOLOGY)	
<i>Authorised indication</i>	Premedication, sedation for procedures and during intensive care
<i>Authorised age group</i>	> 6 months for premedication (<i>France</i>)
<i>Authorised dose</i>	See list of paed needs anaesthesiology
<i>Authorised formulation</i>	Solution for injection iv, im, oral solution
Needs	Safety and efficacy of i.m. route in acute agitation and self harm in children ≥ 13 years Age appropriate formulation: oral, nasal, and rectal routes
ANTIPSYCHOTIC	
CHLORPROMAZINE HYDROCHLORIDE	
<i>Authorised indication</i>	Childhood schizophrenia and other psychoses, neonatal abstinence

	syndrome, aggression disorder
<i>Authorised age group</i>	All age groups
<i>Authorised dose</i>	Oral: Neonate: 0.5-1 mg/kg 3-4 times daily (max. 6 mg/kg daily) Child 1-6 years: 500 µg/kg every 4-6 hours (max. 40 mg daily); 6-12 years: 10 mg 3 times daily (max. 75 mg daily) Adolescent 12-18 years: 25 mg 3 times daily (or 75 mg at night) (max. 1 g daily) Intramuscular: Child 1-12 years: 500 µg/kg every 6-8 hours Adolescent 12-18 years: 25-50 mg every 6-8 hours
<i>Authorised formulation</i>	Tablets: 10 mg, 25 mg, 50 mg, 100 mg Oral solution: 25 mg/5 ml, 100 mg/5 ml Solution for injection: 25 mg/ml
<i>Needs</i>	IV formulation and suitable liquid concentration for neonatal use
HALOPERIDOL	
<i>Authorised indication</i>	Motor tics (including Gilles de La Tourette syndrome), schizophrenia and other psychoses, mania, short-term adjunctive management of psychomotor agitation, violent impulsive behaviour
<i>Authorised age group</i>	> 2 years
<i>Authorised dose</i>	2-12 years: 12.5-25 µg/kg twice daily (max. 10 mg daily) 12-18 years: 0.5-3 mg 2-3 times daily or 3-5 mg 2-3 times daily
<i>Authorised formulation</i>	Tablets Capsules Oral liquid Solution for injection 5mg/ml
<i>Needs</i>	Safety and efficacy of i.m. route in acute agitation and threat of self harm in children ≥ 13 years Long-term safety data: growth, sexual maturation, cognitive, emotional, and behavioural development
AMISULPRIDE	
<i>Authorised indication</i>	Acute psychotic episode, schizophrenia
<i>Authorised age group</i>	15-18 years
<i>Authorised dose</i>	200-400 mg twice daily (max. 1.2 g daily)
<i>Authorised formulation</i>	Tablets Solution
<i>Needs</i>	Data on PK, efficacy and safety in early onset schizophrenia in children ≥ 13 years Age appropriate formulation (lower strength tablets) Long-term safety data: growth, sexual maturation, cognitive, emotional, and behavioural development
CLOZAPINE	
<i>Authorised indication</i>	Schizophrenia in patients unresponsive or intolerant to conventional antipsychotic drugs
<i>Authorised age group</i>	Not licensed for use in children < 16 years
<i>Authorised dose</i>	12.5 mg once or twice daily increased gradually in steps of 25-50 mg daily (up to 300 mg daily)
<i>Authorised formulation</i>	Scored tablets 25 mg and 100 mg
<i>Needs</i>	Data on PK, safety and efficacy in children ≥13 years unresponsive or intolerant to conventional antipsychotic drugs Age-appropriate formulation (lower strength tablets)

	Long-term safety data: growth, sexual maturation, cognitive, emotional, and behavioural development
OLANZAPINE	
<i>Authorised indication</i>	Schizophrenia, mania
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	-
Needs	Data on PK, efficacy and safety in early onset schizophrenia, bipolar impulsive aggressive behaviour with emotional impairment and mood swings, autism and conduct disorder in children ≥ 13 years Age appropriate formulation (lower strength tablets) Long-term safety data: growth, sexual maturation, cognitive, emotional, and behavioural development
QUETIAPINE	
<i>Authorised indication</i>	Schizophrenia
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	-
Needs	Data on PK, efficacy and safety in early onset schizophrenia, impulsive aggressive behaviour with emotional impairment and mood swings, autism and conduct disorder in children ≥ 13 years Age appropriate formulation (lower strength tablets) Long-term safety data: growth, sexual maturation, cognitive, emotional, and behavioural development
ARIPIPRAZOLE	
<i>Authorised indication</i>	Schizophrenia
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	Tablets, orodispersible tablets, solution for i.m. inj., oral solution 1 mg/ml
Needs	Data on PK, efficacy and safety in early onset schizophrenia in children ≥ 13 years Age appropriate formulation (lower strength tablets) Long-term safety data: growth, sexual maturation, cognitive, emotional, and behavioural development
RISPERIDONE	
<i>Authorised indication</i>	Acute and chronic psychosis, impulsive behaviour, pervasive disorders in children with autism, behavioural problems (aggression, irritability, social isolation), impulsivity or self-injurious behaviour (SIB), anxiety, depression, manic episodes in bipolar disorders
<i>Authorised age group</i>	> 5 years in behaviour disorders, autism, and mental retardation (<i>France, Portugal</i>)
<i>Authorised dose</i>	Acute and chronic psychosis: 4-6 mg daily Impulsive behaviour: 1- 2 mg in 1-2 divided doses Autism > 20 kg: 1,0-2,5 mg, < 20 kg: 0,5-1,5 mg (<i>Finland</i>)
<i>Authorised formulation</i>	Tablets: 500 μ g, 1 mg, 2mg, 3 mg, 4 mg, 6 mg; Orodispersible tablets: 500 μ g, 1 mg, 2mg; Liquid (1 mg/ml). Solution for i.m. depot injection

Needs	Data on PK, efficacy and safety in impulsive and aggressive behaviour and autism in children > 5 years Data on PK, efficacy and safety in schizophrenia, depression, manic episodes and conduct disorder in children ≥ 13 years Long-term safety data: growth, sexual maturation, cognitive, emotional, and behavioural development
ZIPRASIDONE	
<i>Authorised indication</i>	Schizophrenia
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	-
Needs	Data on PK, efficacy and safety in early onset schizophrenia, impulsive aggressive behaviour with emotional impairment and mood swings, autism and conduct disorder in children > 13 years Age appropriate formulation (lower strength tablets) Long-term safety data: growth, sexual maturation, cognitive, emotional, and behavioural development
ANTIMANIC DRUGS	
VALPROIC ACID (REFER ALSO TO LIST OF PAEDIATRIC NEEDS EPILEPSY)	
<i>Authorised indication</i>	Treatment of manic episodes associated with bipolar disorders
<i>Authorised age group</i>	Age group not specified (<i>Finland</i>)
<i>Authorised dose</i>	15-30 mg/kg/day
<i>Authorised formulation</i>	Depot tablet 200 mg sodiumvalproate + 87 mg valproic acid Depot tablet 333mg sodiumvalproate + 145 mg valproic acid Valproic acid 250 mg tab (<i>United Kingdom</i>)
Needs	Data on PK, efficacy and safety in children > 12 years in bipolar and behavioural disorders Long-term safety data
SODIUM VALPROATE	
<i>Authorised indication</i>	Treatment of manic episodes associated with bipolar disorders
<i>Authorised age group</i>	Age group not specified
<i>Authorised dose</i>	15-30 mg/kg/day for children
<i>Authorised formulation</i>	Enterotablet (100 mg-600 mg) Oral mixture 60mg/ml, drops (liquid) 200 mg/ml Oral depot granules Depot tablet Sprinkles Suppositories Solution for injection
Needs	Data on efficacy and safety in children > 12 years in bipolar and behavioural disorders Long-term safety data
LITHIUM	
<i>Authorised indication</i>	Treatment and prophylaxis of mania, bipolar disorder, recurrent depression, aggressive or self-mutilating behaviour
<i>Authorised age group</i>	> 12 years
<i>Authorised dose</i>	Treatment: 1-1.5 g daily Prophylaxis: 300-400 mg daily

<i>Authorised formulation</i>	Tablets 250 mg, 400 mg Effervescent granules (<i>France</i>) Liquid (adults only)
<i>Needs</i>	Age-appropriate formulation Long-term safety data
ANTIEPILEPTICS	
CARBAMAZEPINE (REFER ALSO TO LIST OF PAEDIATRIC NEEDS EPILEPSY)	
<i>Authorised indication</i>	Anxiety in children with learning disabilities (<i>Finland</i>), prophylaxis of bipolar disorder unresponsive to lithium (<i>United Kingdom</i>)
<i>Authorised age group</i>	> 20 kg body weight (<i>Finland</i>)
<i>Authorised dose</i>	> 20 kg: starting dose 400 mg/day, maintenance 15-30 mg/kg/day (<i>Finland</i>)
<i>Authorised formulation</i>	Solution for i.v. injection Oral suspension Tablets, chewable tablets, sustained release tablets, Suppositories
<i>Needs</i>	Data on PK, efficacy and safety in bipolar disorder in children unresponsive to lithium, and in aggressive behaviour in children >13 years Long-term safety data Age appropriate slow release formulation
TOPIRAMATE	
<i>Authorised indication</i>	Epilepsy, migraine Not authorised in bipolar depressive disorders, bulimia
<i>Authorised age group</i>	-
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	-
<i>Needs</i>	Data on efficacy and safety in bulimia in children > 13 years
PREGABALINE	
<i>Authorised indication</i>	Generalized anxiety disorder (GAD), epilepsy, neuropathic pain
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	-
<i>Needs</i>	Data on PK, efficacy and safety in GAD in children \geq 13 years Age appropriate formulation
ANTIDEPRESSANTS	
SELECTIVE SEROTONIN RE-UPTAKE INHIBITORS (SSRI)	
FLUOXETINE	
<i>Authorised indication</i>	Moderate to severe depression if depression is unresponsive to psychotherapy after 4-6 sessions and only in combination with psychotherapy. Bulimia Obsessive-compulsive disorder
<i>Authorised age group</i>	> 8 years
<i>Authorised dose</i>	Oral: 10 mg/day starting dose, increased after 1-2 weeks to 20 mg/day if needed
<i>Authorised formulation</i>	Capsules 20 mg Liquid 20 mg/5 ml

	Dispersible tablets 20 mg
<i>Needs</i>	Data on safety and efficacy in children for indications other than depression (compulsive behaviour, anxiety, bulimia and posttraumatic stress) in children > 8 years Long-term safety data: growth, sexual maturation, cognitive, emotional, and behavioural development
FLUVOXAMINE MALEATE	
<i>Authorised indication</i>	Obsessive-compulsive disorder (OCD), depression
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	-
<i>Needs</i>	Data on PK, safety and efficacy in children > 8 years in obsessive-compulsive disorder Oral age appropriate formulation Long-term safety data: growth, sexual maturation, cognitive, emotional, and behavioural development in OCD
SERTRALINE	
<i>Authorised indication</i>	Obsessive-compulsive disorder Depression
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	-
<i>Needs</i>	Data on PK, safety and efficacy in > 8 years in obsessive-compulsive disorder Oral age appropriate formulation (without alcohol) Long-term safety data: growth, sexual maturation, cognitive, emotional, and behavioural development in OCD
TRICYCLIC	
CLOMIPRAMINE	
<i>Authorised indication</i>	Obsessive-compulsive disorder , Depressive illness, adjunctive treatment of cataplexia associated with narcolepsy
<i>Authorised age group</i>	Child > 5 years (<i>Germany, Finland, Portugal</i>)
<i>Authorised dose</i>	75 mg daily, increase daily dose within 10 days to 75 mg twice daily (5-7 years), 75 mg twice to five times daily (8-14 years old) 5-7 years 20 mg/day, 8-14 years 20-50 mg/day, >14 years 50 mg and more /day in FI (maximum: 150 mg/day)
<i>Authorised formulation</i>	Solution for injection, Sustained release tablets, dragees, Tablets 10 mg, 25 mg, depot tablet 75 mg
<i>Needs</i>	Data on PK, safety and efficacy in children > 8 years in obsessive-compulsive disorder Long-term safety data: growth, sexual maturation, cognitive, emotional, and behavioural development in OCD
Other antidepressants	
MIRTAZAPINE	
<i>Authorised indication</i>	Depression
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-

<i>Authorised formulation</i>	-
<i>Needs</i>	Data on PK, safety (potential suicidal risk) and efficacy in children > 12 years
BUPROPION	
<i>Authorised indication</i>	Depression, smoking cessation
<i>Authorised age group</i>	Adults
<i>Authorised dose</i>	-
<i>Authorised formulation</i>	-
<i>Needs</i>	Data on PK, safety (potential suicidal risk) and efficacy in children > 12 years
CNS STIMULANTS AND OTHER DRUGS FOR ADHD	
ATOMOXETINE	
<i>Authorised indication</i>	ADHD
<i>Authorised age group</i>	> 6 years
<i>Authorised dose</i>	< 70 kg: usual maintenance dose 1.2 mg/kg > 70 kg: usual maintenance dose 80 mg daily
<i>Authorised formulation</i>	Capsules 10 mg, 18 mg, 40 mg, 60 mg
<i>Needs</i>	Long-term safety data Availability in all Member States
METHYLPHENIDATE HYDROCHLORIDE	
<i>Authorised indication</i>	ADHD
<i>Authorised age group</i>	Child > 6 years
<i>Authorised dose</i>	Child 4-6 years: 2.5 mg twice daily (max. 1.4 mg/kg daily) Child > 6 years: 5-10 mg 1-2 times daily (max. 60 mg daily in divided doses)
<i>Authorised formulation</i>	Tablets 5 mg, 10 mg Modified release tablets: 18 mg, 36 mg, and capsules: 10 mg, 20 mg, 30 mg
<i>Needs</i>	Long-term safety data

If not stated separately, the need for availability in all Member States of the Community applies to all medicinal products in this list.

NO NEEDS: Medicinal products considered by the PEG to be devoid of interest to be developed in paediatric psychiatric indications or below the authorised age group:

DIPHENHYDRAMINE

DIAZEPAM

CLONAZEPAM

BUSPIRONE

PERPHENAZIDE

PIMOZIDE

SULPIRIDE

TRIFLUOPERAZINE

AMITRIPTYLINE HYDROCHLORIDE

IMIPRAMINE HYDROCHLORIDE

NORTRIPTYLINE

CITALOPRAM

DULOXETINE

DESVENLAFAXINE

REBOXETINE
