Summary of risk management plan for Methylphenidate Consilient Health 2 mg/ml oral solution(methylphenidate)

This is a summary of the risk management plan (RMP) for Methylphenidate Consilient Health 2 mg/ml oral solution(methylphenidate). The RMP details important risks of methylphenidate, how these risks can be minimised, and how more information will be obtained about methylphenidate's risks and uncertainties (missing information).

Methylphenidate's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how methylphenidate should be used.

Important new concerns or changes to the current ones will be included in updates of methylphenidate's RMP.

I. The medicine and what it is used for

Methylphenidate is authorised for attention-deficit hyperactivity disorder (ADHD) in children and adolescents from the age of 6 years and older when remedial measures alone are insufficient, and for narcolepsy in adults (see SmPC for the full indication). It contains methylphenidate hydrochloride as the active substance, and it is a solution given by oral route of administration.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of methylphenidate, together with measures to minimise such risks and the proposed studies for learning more about methylphenidate's risks, are outlined below.

Measures to minimise the risks identified for medicinal products can be:

- Specific information, such as warnings, precautions, and advice on correct use, in the package leaflet and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorised pack size — the amount of medicine in a pack is chosen so to ensure that the medicine is used correctly;
- The medicine's legal status — the way a medicine is supplied to the patient (e.g. with or without prescription) can help to minimise its risks.

Together, these measures constitute *routine risk minimisation* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed, including PSUR assessment so that immediate action can be taken as necessary. These measures constitute *routine pharmacovigilance activities*.

If important information that may affect the safe use of methylphenidate is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of methylphenidate are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken. Important risks can be regarded as identified or potential. Identified risks are concerns for which there is sufficient proof of a link with the use of methylphenidate. Potential risks are concerns for which an association with the use of this medicine is possible based on available data, but this association has not been established yet and needs further evaluation. Missing information refers to information on the safety of the medicinal product that is currently missing and needs to be collected (e.g. on the long-term use of the medicine);

List of important risks and missing information	
Important identified risks	• Serious Cardiovascular events • Psychosis/mania • Verbal and Motoric tics • Depression • Aggression • Drug abuse and drug dependence • Withdrawal syndrome • Decreased rate of growth* • Reduced weight gain* • Seizures • Cerebrovascular disorders • Neonatal toxicity**
Important potential risks	• Sexual maturation (delayed)* • Suicidality
Missing information	• Long-term effects

*only relevant for paediatric population
**only relevant for adult populations

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

II.C Post-authorisation development plan

II.C.1 Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of methylphenidate.

II.C.2 Other studies in post-authorisation development plan

There are no studies required for methylphenidate.