

## PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

### Summary of Risk Management Plan for CONCERTA (Methylphenidate Hydrochloride)

This is a summary of the Risk Management Plan (RMP) for CONCERTA. The risks associated with CONCERTA are well characterized and managed with routine risk minimization measures. There are no important risks or missing information associated with this product.

CONCERTA's Summary of Product Characteristics (SmPC) and its Package Leaflet give essential information to healthcare professionals and patients on how CONCERTA should be used.

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

#### I. The Medicine and What It Is Used For

CONCERTA is authorized for attention deficit hyperactivity disorder (ADHD) (see SmPC for the full indication). It contains methylphenidate hydrochloride as the active substance and it is given orally by prolonged-release tablets.

#### II. Risks Associated With the Medicine and Activities to Minimize or Further Characterize the Risks

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

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

- Specific information, such as warnings, precautions, and advice on correct use, in the PL and SmPC addressed to patients and healthcare professionals;
- Important advice on the medicine's packaging;
- The authorized 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 (eg, with or without prescription) can help to minimize its risks.

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

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

#### II.A. List of Important Risks and Missing Information

Important risks of CONCERTA are risks that need special risk management activities to further investigate or minimize 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 CONCERTA. 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 (eg, on the long-term use of the medicine).

There are no important identified risks, important potential risks, or missing information for CONCERTA.

## **II.B. Summary of Important Risks**

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

## **II.C. Postauthorization Development Plan**

### **II.C.1. Studies Which are Conditions of the Marketing Authorization**

No studies are conditions of the marketing authorization or specific obligations of CONCERTA.

### **II.C.2. Other Studies in Postauthorization Development Plan**

No studies are required for CONCERTA.