Part VI: Summary of the risk management plan

Summary of risk management plan for ELVANSE®/ TYVENSE®/ ELVANSE ADULTOS®/ ELVANSE VUXEN®/ ADUVANZ® (Lisdexamfetamine dimesylate)

This is a summary of the risk management plan (RMP) for ELVANSE®/ TYVENSE®/ ELVANSE ADULTOS®/ ELVANSE VUXEN®/ ADUVANZ®. The RMP details important risks of ELVANSE®/ TYVENSE®/ ELVANSE ADULTOS®/ ELVANSE VUXEN®/ ADUVANZ®, how these risks can be minimised, and how more information will be obtained about ELVANSE®/ TYVENSE®/ ELVANSE ADULTOS®/ ELVANSE VUXEN®/ ADUVANZ®'s risks and uncertainties (missing information).

ELVANSE®/ TYVENSE®/ ELVANSE ADULTOS®/ ELVANSE VUXEN®/ ADUVANZ® SmPC and its package leaflet give essential information to healthcare professionals and patients on how ELVANSE®/ TYVENSE®/ ELVANSE ADULTOS®/ ELVANSE VUXEN®/ ADUVANZ® should be used.

Important new concerns or changes to the current ones will be included in updates of ELVANSE®/ TYVENSE®/ ELVANSE ADULTOS®/ ELVANSE VUXEN®/ ADUVANZ®'s RMP.

I. The medicine and what it is used for

ELVANSE®/ TYVENSE®/ ELVANSE ADULTOS®/ ELVANSE VUXEN®/ ADUVANZ® are authorised as a comprehensive treatment programme for ADHD in children aged 6 years and over when response to previous methylphenidate treatment is considered clinically inadequate. It is also indicated as part of a comprehensive treatment programme for ADHD in adults with pre-existing symptoms of ADHD in childhood. ELVANSE VUXEN® is indicated as part of a comprehensive treatment programme for ADHD in adults with pre-existing symptoms of ADHD in childhood.- (see SmPCs for the full indication). It contains lisdexamfetamine dimesylate as the active substance and it is given orally.

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

Important risks of ELVANSE®/ TYVENSE®/ ELVANSE ADULTOS®/ ELVANSE VUXEN®/ ADUVANZ®'s, together with measures to minimise such risks and the proposed studies for learning more about ELVANSE®/ TYVENSE®/ ELVANSE ADULTOS®/ ELVANSE VUXEN®/ ADUVANZ®'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 continually and regularly analysed, including PSUR 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 ELVANSE®/ TYVENSE®/ ELVANSE ADULTOS®/ ELVANSE VUXEN®/ ADUVANZ® 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 ELVANSE®/ TYVENSE®/ ELVANSE ADULTOS®/ ELVANSE VUXEN®/ ADUVANZ®. 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	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

Not applicable

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 ELVANSE®/ TYVENSE®/ ELVANSE ADULTOS®/ ELVANSE VUXEN®/ ADUVANZ®.

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

There are no studies required for ELVANSE®/ TYVENSE®/ ELVANSE ADULTOS®/ ELVANSE VUXEN®/ ADUVANZ®.