Part VI: Summary of the risk management plan

Summary of risk management plan for <Invented name> 1 mg/mL, eye drops, solution (dexamethasone).

This is a summary of the risk management plan (RMP) for <Invented name> 1 mg/mL, eye drops, solution. The RMP details important risks of <Invented name> 1 mg/mL, eye drops, solution, how these risks can be minimized, and how more information will be obtained about <Invented name> 1 mg/mL, eye drops, solution, risks and uncertainties (missing information).

<Invented name>'s 1 mg/mL, eye drops, solution, summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how <Invented name> 1 mg/mL, eye drops, solution, should be used.

I. The medicine and what it is used for

<Invented name> 1 mg/mL, eye drops, solution, is indicated for:

- For treatment of non-infectious inflammatory conditions affecting the anterior segment of the eye.

<Invented name> 1 mg/mL, eye drops, solution, contains dexamethasone and it is given by drops into the eyes.

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

Important risks of <Invented name> 1 mg/mL, eye drops, solution, together with measures to minimise such risks and the proposed studies for learning more about <Invented name>'s 1 mg/mL, eye drops, solution, 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 analyzed 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 <Invented name> 1 mg/mL, eye drops, solution, is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of <Invented name> 1 mg/mL, eye drops, solution, 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. 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

**the safety concerns for a substance/reference product are published on the CMDh website*

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

There are no studies which are conditions of the marketing authorization or specific obligation of <Invented name> 1 mg/mL, eye drops, solution.

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

There are no studies which are conditions of the market authorization or specific obligation <Invented name> 1 mg/mL, eye drops, solution.

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

There are no studies required for <Invented name> 1 mg/mL, eye drops, solution.