PART VI: Summary of the risk management plan

Summary of risk management plan for Neofordex (dexamethasone)

This is a summary of the risk management plan (RMP) for Neofordex. The RMP details important risks of Neofordex, how these risks can be minimised, and how more information will be obtained about Neofordex's risks.

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

This summary of the RMP for Neofordex should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

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

I. The medicine and what it is used for

Neofordex is authorised for the treatment of symptomatic multiple myeloma in combination with other medicinal products in adults (see SmPC for the full indication). It contains dexamethasone as the active substance and it is given orally.

Further information about the evaluation of Neofordex's benefits can be found in Neofordex's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage.

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

Important risks of Neofordex, together with measures to minimise such risks and the proposed studies for learning more about Neofordex'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.

II.A List of important risks and missing information

Important risks of Neofordex 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 Neofordex. 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	Medication error related to administration of 20 mg dose
Missing information	None

II.B Summary of important risks

Potential risk: Medication error related to administration of 20 mg dose	
Evidence for linking the risk to the medicine	This potential risk is based on the safety profile of the product as reflected in the product information for Neofordex as showed also in CTD section 2.7.4 - Summary of Clinical Safety.
Risk factors and risk groups	Besides the obvious risk group consisting of patients prescribed with a 20-mg dose of Neofordex, there are currently no established risk factors or risk groups.
Risk minimisation measures	<u>Routine risk minimisation measures</u> SmPC sections 4.2, 6.4, 6.6 PL section 3 Prescription only medicine
Additional pharmacovigilance activities	<u>Additional pharmacovigilance activities:</u> Removal of the score line for sub-division of the 40 mg tablet, and consequent deletion of the 20 mg posology. See section II.C of this summary for an overview of the post-authorisation development plan.

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 Neofordex.

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

Removal of the score line for sub-division of the 40 mg tablet, and consequent deletion of the 20 mg posology.

Purpose of the study:

An activity to mitigate the important potential risk "Medication error related to administration of 20 mg dose" and to eliminate the possibility to break tablets and to ensure their use as one dose.