PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of Risk Management Plan for Relfydess® (QM1114-DP)

This is a summary of the risk management plan (RMP) for Relfydess (QM1114-DP). The RMP details important risks of Relfydess, how these risks can be minimised, and how more information will be obtained about Relfydess's risks.

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

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

VI.1 The Medicine and What it is Used for

Relfydess is authorised for the temporary improvement in the appearance of:

- moderate to severe glabellar (frown) lines
- moderate to severe lateral canthal (crow) lines

alone, or in combination.

See the SmPC (Section 4.1) for the full indications. It contains botulinum toxin type A as the active substance, and it is given by intramuscular injection with the dose and location of injection dependent on which indication Relfydess is being used to treat.

VI.2 Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

There are no important risks for Relfydess.

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, Periodic Safety Update Report (PSUR) and signal detection 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 Relfydess is not yet available, it will be listed under 'missing information' below.

VI.2.A List of Important Risks and Missing Information

There are no important risks or missing information for Relfydess.

Important risks are risks that need further characterisation and/or special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely administered. Important risks can be regarded as identified or potential. Important identified risks are concerns for which there is sufficient proof of a link with the use of the product. Important 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).

Important identified and potential risks, together with missing information for Relfydess, are summarised below.

List of important risks and missing information	
Important identified risks	• None
Important potential risks	• None
Missing information	• None

VI.2.B Summary of Important Risks

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

VI.2.C Post-authorisation Development Plan

VI.2.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 Relfydess.

VI.2.C.2 Other Studies in Post-authorisation Development Plan

There are no other studies required for Relfydess.