Part VI: Summary of the Risk Management Plan

Summary of Risk Management Plan for Humulin (Insulin Human)

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

Humulin's SmPC and its package leaflet give essential information to healthcare professionals and patients on how Humulin should be used.

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

I - The Medicine and What It Is Used for

Humulin is authorised for the treatment of patients with DM who require insulin for the maintenance of glucose homeostasis. It contains insulin human as the active substance, and it is given by subcutaneous route of administration.

II - Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

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

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*.

If important information that may affect the safe use of Humulin is not yet available, it is listed under 'missing information' below.

II.A List of Important Risks and Missing Information

Important risks of Humulin are risks that need 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. Identified risks are concerns for which there is sufficient proof of a link with the use of Humulin. 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 (for example, on the long-term use of the medicine).

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

II.B Summary of Important Risks

Not applicable

II.C Post-Authorisation Development Plan

II.C.1 Studies that are Conditions of the Marketing Authorisation

There are no studies that are conditions of the marketing authorisation or specific obligation of Humulin.

II.C.2 Other Studies in Post-Authorisation Development Plan

Not applicable