Summary of Risk Management Plan for Semglee® (insulin glargine)

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

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

This summary of the RMP for Semglee® should be read in the context of all the 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 Semglee®'s RMP.

I. The Medicine and What it is Used For

Semglee® is authorised for treatment of diabetes mellitus in adults, adolescents and children aged 2 years and above. It contains insulin glargine as the active substance and it is given by subcutaneous injection.

Further information about the evaluation of Semglee®'s benefits can be found in Semglee®'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 Semglee®, together with measures to minimise such risks are outlined below, if applicable.

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 public (e.g. with or without prescription) can help to minimises its risks.

Together, these measures constitute routine risk minimisation measures.

In addition to these measures, information about adverse events 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 Semglee® are risks that need special risk management activities to further investigate or minimise the risk, so that the medicinal product can be safely taken by patients. 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 Semglee®. 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/use in special patient populations etc.);

There are no important risks or missing information considered as relevant for Semglee®'s RMP.

II.B Summary of Important Risks

There are no important identified or potential risks and no missing information for insulin glargine that qualifies for inclusion in this RMP version.

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 Semglee®.

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

There are no studies required for Semglee®.