PART VI SUMMARY OF THE RISK MANAGEMENT PLAN

SUMMARY OF RISK MANAGEMENT PLAN FOR ACTILYSE (ALTEPLASE)

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

Actilyse's SmPC and its PL give essential information to healthcare professionals and patients on how Actilyse should be used.

I. THE MEDICINE AND WHAT IT IS USED FOR

Actilyse is authorised for the indications Thrombolytic treatment in acute myocardial infarction, Thrombolytic treatment in acute massive pulmonary embolism with haemodynamic instability, and Thrombolytic treatment of acute ischaemic stroke in the EEA (see SmPC for the full indication). It contains alteplase as the active substance and it is given by injection.

II. RISKS ASSOCIATED WITH THE MEDICINE AND ACTIVITIES TO MINIMISE OR FURTHER CHARACTERISE THE RISKS

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

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

II.A List of important risks and missing information

Important risks of Actilyse 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 Actilyse. 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

PVI.Table 1 Summary of safety concerns

Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

There are no important identified, important potential risks or missing information.

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 Actilyse.

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

There are no studies required for Actilyse.

ABBREVIATIONS

EEA	European Economic Area
PL	Package leaflet
RMP	Risk management plan
SmPC	Summary of product characteristics