PART VI SUMMARY OF THE RISK MANAGEMENT PLAN

SUMMARY OF RISK MANAGEMENT PLAN FOR ACTILYSE CATHFLO (ALTEPLASE)

This is a summary of the RMP for Actilyse Cathflo. The RMP details how more information will be obtained about Actilyse Cathflo.

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

I. THE MEDICINE AND WHAT IT IS USED FOR

Actilyse Cathflo is authorised for the indication thrombolytic treatment of occluded central venous access devices including those used for haemodialysis in the EEA (see SmPC for the full indication). It contains alteplase as the active substance and it is given by intra-luminal instillation.

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

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 Cathflo is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

List of important risks and missing information

Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

None.

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 Cathflo.

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

There are no studies required for Actilyse Cathflo.

ABBREVIATIONS

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