PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of the risk management plan for Fludebro

This is a summary of the risk management plan (RMP) for Fludebro. Fludebro's summary of product characteristics (SmPC) and its package leaflet give essential information to healthcare professionals and patients on how Fludebro should be used.

I. The medicine and what it is used for

Fludebro is authorised for diagnostic use only. Fludeoxyglucose(18F) is indicated for use with positron emission tomography (PET) (see SmPC for the full indication). It contains Fludeoxyglucose (18F) as the active substance and it is given intravenously.

II. Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of Fludebro, together with measures to minimize such risks and the proposed studies for learning more about Fludebro'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;
- 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.
- The fact that the medicine is used in hospitals only under well controlled conditions.

Together, these measures constitute routine risk minimisation measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analysed 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 Fludebro 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 Fludebro. 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);

1m ortant identified risks	None
1m ortant otential risks	None
1m ortant missin information	None

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the core SmPC.

II.C Post-authorisation development plan

II.C. I Studies which are conditions of the marketing authorisation

There are no studies which are conditions of the marketing authorisation or specific obligation of Fludebro.

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

There are no studies required for Fludebro