PART VI: SUMMARY OF RISK MANAGEMENT PLAN

Summary of risk management plan for Sonazoid (perfluorobutane)

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

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

I. The medicine and what it is used for

Sonazoid is authorised for diagnostic ultrasonic imaging of focal hepatic lesions (see SmPC for the full indication). It contains perfluorobutane microbubbles as the active substance and it is given by i.v. injection by physicians or other qualified health personnel.

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

Important risks of Sonazoid, together with measures to minimise such risks and the proposed studies for learning more about Sonazoid'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, such as warnings, precautions, and advice on correct use;
- 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.

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

For Sonazoid there are currently no important risks or missing information identified that should be included in the list of safety concerns. All the risks and missing information identified for Sonazoid are known risks require no further characterisation and no additional pharmacovigilance activities or additional risk minimisation measures.

Important risks of Sonazoid 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 Sonazoid. 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 *(from Part 2 Module SVIII)*	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of important risks

Not applicable for Sonazoid as there are no important identified or important potential risks identified in the table of safety concerns. Therefore, no *additional risk minimisation measures* or *additional pharmacovigilance activities* are proposed.

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 Sonazoid.

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

There are no studies required for Sonazoid.