PART VI. SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for FSME IMMUN/FSME-IMMUN Junior; TICOVAC/ TICOVAC Junior (Tick-Borne Encephalitis Virus vaccine)

This is a summary of the RMP for **FSME IMMUN/FSME-IMMUN Junior; TICOVAC/ TICOVAC Junior** (tick-borne encephalitis virus vaccine; herein after referred to as TBE vaccine). The RMP details important risks of TBE vaccine, how these risks can be minimised, and how more information will be obtained about invented name's risks and uncertainties (missing information).

TBE vaccine's summary of product characteristics (SmPCs) and their Package Leaflets (PLs) give essential information to healthcare professionals and patients on how TBE vaccine should be used.

I. The Medicine and What It Is Used For

TBE vaccine is authorised for the active (prophylactic) immunisation of persons against TBE (see SmPCs for the full indication). It contains tick-borne encephalitis virus as the active substance and it is given by intramuscular route of administration. The vaccine may be administered subcutaneously in adult subjects with a bleeding disorder or subjects receiving prophylactic anticoagulation. Limited data in healthy adults suggest comparable immune response for subcutaneous booster vaccinations when compared to intramuscular booster vaccinations. However, subcutaneous administration might lead to an increased risk for local adverse reactions. No data are available for the elderly. Furthermore, no data are available for primary immunization via the subcutaneous route.

II. Risks Associated with the Medicine and Activities to Minimise or Further Characterise the Risks

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

If important information that may affect the safe use of TBE vaccine is not yet available, it is listed under 'missing information' below.

II.A. List of Important Risks and Missing Information

There are no important identified/potential risks or missing information for TBE vaccines.

II.B. Summary of Important Risks

Not applicable.

II.C. Post-Authorisation Development Plan

II.C.1. Studies which are Conditions of the Marketing Authorisation

There are no studies that are conditions of the marketing authorisation or specific obligation of TBE vaccine.

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

There are no studies required for TBE vaccine.