PART VI: SUMMARY OF THE RISK MANAGEMENT PLAN

VI.1 Summary of risk management plan for diclofenac diethylamine gel

This is a summary of the risk management plan (RMP) for diclofenac diethylamine (DDEA) 1.16% and 2.32% gel). The RMP details important risks of DDEA gel, how these risks can be minimised, and how more information will be obtained about DDEA gel's risks and uncertainties (missing information).

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

VI.2 The medicine and what it is used for

Diclofenac diethylamine gel is authorised for the treatment of muscle and joint injuries (e.g. sprains, strains, bruises, backache, sports injuries), localised forms of soft tissue rheumatism (e.g. tendonitis) and mild arthritis of the knee or fingers (see SmPC for the full indication).

It is given by topical route of administration (i.e. applied on the skin).

VI.3 Risks associated with the medicine and activities to minimise or further characterise the risks

Important risks of DDEA gel, together with measures to minimise such risks and the proposed actions for learning more about DDEA gel'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.

In addition to these measures, information about adverse reactions 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 DDEA gel is not yet available, it is listed under ‘missing information’ below.

VI.3.1 List of important risks and missing information

Important risks of DDEA gel are those that need special risk management activities for further investigation or minimisation 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 DDEA gel. 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	
Important identified risks	None
Important potential risks	Systemic adverse reactions (gastrointestinal, cardiovascular, hepatic or renal disorders)
Missing information	Use in the pediatric population (<14 years of age)

VI.3.2 Summary of important risks

Important potential risk 'Systemic adverse reactions (gastrointestinal, cardiovascular, hepatic or renal disorders)'	
Evidence for linking the risk to the medicine	This risk is a class effect of NSAIDs when administered systemically. Due to the low systemic exposure to diclofenac following topical applications, the risk of systemic ADRs is unlikely when DDEA gel is administered per the recommended dosage and duration. However, the possibility of these ADRs may arise in case of administration to large areas of skin and for a prolonged period, i.e. in conditions that would increase the systemic exposure to diclofenac for a prolonged period.
Risk factors and risk groups	Patients with relevant underlying co-morbidities may be more susceptible to the risk of exceeding dose directions for a longer period of treatment than recommended in the EEA SmPC.
Risk minimisation measures	Routine risk minimization measures: SmPC section 4.4

Missing information 'Use in the pediatric population (<14 years of age)'

Risk minimisation measures	Routine risk minimisation measures: SmPC section 4.2, SmPC section 4.3

VI.4 Post-authorisation development plan

VI.4.1 Studies which are conditions of the marketing authorisation

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

VI.4.2 Other studies in post-authorisation development plan

There are no studies required for DDEA gel.