Summary of risk management plan for Axhidrox 2.2 mg/ pump actuation cream (glycopyrronium bromide)

This is a summary of the risk management plan (RMP) for Axhidrox 2.2 mg/ pump actuation cream. The RMP details important risks of Axhidrox, how these risks can be minimized, and how more information will be obtained about Axhidrox's risks and uncertainties (missing information).

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

Important new concerns or changes to the current ones will be included in updates of Axhidrox's RMP.

I. The medicine and what it is used for

Axhidrox is authorized for the topical treatment of severe primary axillary hyperhidrosis in adults (see SmPC for the full indication). It contains glycopyrronium bromide as the active substance and it is given by the topical route of administration.

II. Risks associated with the medicine and activities to minimize or further characterize the risks

Important risks of Axhidrox, together with measures to minimize such risks and the proposed studies for learning more about Axhidrox's risks, are outlined below.

Measures to minimize 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 authorized 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 minimize its risks.

Together, these measures constitute *routine risk minimization* measures.

In addition to these measures, information about adverse reactions is collected continuously and regularly analyzed, 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 Axhidrox is not yet available, it is listed under ‘missing information’ below.

II.A List of important risks and missing information

Important risks of Axhidrox are risks that need special risk management activities to further investigate or minimize 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 Axhidrox. 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	None
Missing information	Use in pregnancy and lactation

II.B Summary of important risks

Missing information: use in pregnancy and lactation	
Risk minimization measures	Routine risk communication: SmPC, Sections 4.6, 5.3 PL, Section 2 Routine risk minimization activities recommending specific clinical measures to address the risk: None Other routine risk minimization measures beyond the Product Information: Legal status: medical prescription Additional risk minimization measures: none

II.C Post-authorization development plan

II.C.1 Studies which are conditions of the marketing authorization

Not applicable.

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

Not applicable.