Part VI Summary of the risk management plan

Summary of risk management plan for BCG Culture AJV (*Mycobacterium bovis* Bacillus Calmette-Guérin, Danish strain 1331, live attenuated)

This is a summary of the risk management plan (RMP) for BCG Culture AJV. The RMP details important risks of BCG Culture AJV and how more information will be obtained about BCG Culture AJV's risks and uncertainties (missing information).

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

I. The medicine and what it is used for

BCG Culture AJV is authorised for treatment of primary/recurrent flat urothelial cell carcinoma *in situ* of the bladder and adjuvant treatment after transurethral resection of primary or recurrent superficial urothelial cell carcinoma of the bladder in stage T_A or T_1, grade 1, 2 or 3 (see SmPC for the full indication). It contains 'live attenuated *Mycobacterium bovis* BCG (Bacillus Calmette-Guérin), Danish strain 1331' as the active substance and it is given by instillation in the urinary bladder.

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

Important risks of BCG Culture AJV, together with measures to minimise such risks and the proposed studies for learning more about BCG Culture AJV'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*.

II.A List of important risks and missing information

Important risks of BCG Culture AJV 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 BCG Culture AJV. 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	None

II.B Summary of important risks

There are no important risks for BCG Culture AJV.

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 BCG Culture AJV.

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

There are no studies required for BCG Culture AJV.