PART VI: SUMMARY OF RISK MANAGEMENT PLAN FOR ZERBAXA (CEFTOLOZANE/TAZOBACTAM)

This is a summary of the risk management plan (RMP) for ZERBAXA. The RMP details important risks of ZERBAXA, and how these risks can be minimised.

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

This summary of the RMP for ZERBAXA should be read in the context of all this information including the assessment report of the evaluation and its plain-language summary, all which is part of the European Public Assessment Report (EPAR).

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

I. The Medicine and What it is Used for

ZERBAXA is authorised for the treatment of complicated bacterial infections (those that are difficult to treat) affecting the organs inside the abdomen (belly) or the kidneys and structures that carry urine (the urinary tract) or the lungs (see SmPC for the full indication). It contains ceftolozane and tazobactam as the active substances and it is given by intravenous infusion.

Further information about the evaluation of ZERBAXA's benefits can be found in ZERBAXA's EPAR, including in its plain-language summary, available on the EMA website, under the medicine's webpage:
https://www.ema.europa.eu/en/medicines/human/EPAR/zerbaxa

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

Important risks of ZERBAXA, together with measures to minimise such risks and the proposed studies for learning more about ZERBAXA'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 ZERBAXA 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 ZERBAXA. 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).

Since its approval in the EU in 2015, the safety profile for ZERBAXA has been well-characterised. There are no studies planned or warranted to further characterise any identified or potential risk that would alter the established risk-benefit profile for ZERBAXA. There are also no additional risk minimisation activities planned or warranted beyond communication of the safety profile in the SmPC and the package leaflet. As such, there are no important safety concerns (important identified or potential risks or missing information) for which prospective additional risk management is planned. Therefore, there are no important identified or potential risks or missing information associated with ZERBAXA to be addressed in the RMP.

In conclusion, continued spontaneous safety surveillance and the safety information available in the Product Information are considered sufficient to monitor the safety profile and to provide routine risk minimisation for ZERBAXA.

Table II.A.1: List of Important Risks and Missing Information

List of Important Risks and Missing Information	
Important identified risks	None
Important potential risks	None
Missing information	None

II.B Summary of Important Risks

The safety information for ZERBAXA is provided in the Product Information.

There are no identified risks, potential risks, or missing information in this RMP.

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 ZERBAXA.

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

There are no studies required for ZERBAXA.