Part VI: Summary of the risk management plan for "[Nationally completed name]"* 100 mg, 400 mg and 500 mg, Film-coated tablets

*** Bosutinib Sandoz 100 mg, 400 mg and 500 mg, Film-coated tablets**

This is a summary of the risk management plan (RMP) for Bosutinib Sandoz, 100 mg, 400 mg and 500 mg, film-coated tablets. The RMP details important risks of Bosutinib Sandoz, film-coated tablets, how these risks can be minimized, and how more information will be obtained about the risks and uncertainties (missing information).

The summary of product characteristics (SmPC) and package leaflet of Bosutinib Sandoz, film-coated tablets give essential information to healthcare professionals and patients on how it should be used.

Important new concerns or changes to the current ones will be included in updates of the Bosutinib Sandoz, film-coated tablet's RMP.

I. The medicine and what it is used for

Bosutinib Sandoz, film-coated tablets are authorized for the treatment of following indications in adult patients:

- Newly-diagnosed chronic phase (CP) Philadelphia chromosome-positive chronic myelogenous leukemia (Ph+ CML).
- CP, accelerated phase (AP), and blast phase (BP) Ph+ CML previously treated with one or more tyrosine kinase inhibitor(s) [TKI(s)] and for whom imatinib, nilotinib and dasatinib are not considered appropriate treatment options.

It contains bosutinib as an active substance and is taken orally as film-coated tablets (100 mg, 400 mg and 500 mg).

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

Important risks of Bosutinib Sandoz, film-coated tablets, if identified together with measures to minimize such risks and the proposed studies for learning more about Bosutinib Sandoz, film-coated tablet'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, 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 Bosutinib Sandoz, film-coated tablets is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of Bosutinib Sandoz, film-coated tablets are risks that need special risk management activities to further investigate or minimize the risk, so that the medicinal product can be safely taken. 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 Bosutinib Sandoz, film-coated tablets. 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).

Table 3 List of important risks and missing information

Important identified risks	None
Important potential risks	None
Missing information	Use in pediatric patients (age: ≤17 years)

II.B Summary of important risks

The safety information in the proposed Product Information is aligned to the reference medicinal product.

II.C Post-authorisation development plan

There are no studies, which are conditions of the marketing authorization or specific obligation for Bosutinib Sandoz, film-coated tablets.