Part VI. SUMMARY OF THE RISK MANAGEMENT PLAN

Summary of risk management plan for Lapatinib Newbury

This is a summary of the risk management plan (RMP) for Lapatinib Newbury. The RMP details important risks of Lapatinib Newbury, how these risks can be minimized, and how more information will be obtained about Lapatinib Newbury's risks and uncertainties (missing information).

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

This summary of the RMP for Lapatinib Newbury 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 Lapatinib Newbury's RMP.

I. The medicine and what it is used for

Lapatinib Newbury is indicated for the treatment of adult patients with breast cancer, whose tumours overexpress human epidermal growth factor receptor 2.

- in combination with capecitabine for patients with advanced or metastatic disease with progression following prior therapy, which must have included anthracyclines and taxanes and therapy with trastuzumab in the metastatic setting.

- in combination with trastuzumab for patients with hormone receptor-negative metastatic disease that has progressed on prior trastuzumab therapy(ies) in combination with chemotherapy.

- in combination with an aromatase inhibitor for postmenopausal women with hormone receptor positive metastatic disease, not currently intended for chemotherapy.

Proposed strength for Lapatinib Newbury is 250 mg film-coated tablets.

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

Important risks of lapatinib, together with measures to minimize such risks and the proposed studies for learning more about lapatinib'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 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 public (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 Periodic Safety Update Report, 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 lapatinib is not yet available, it is listed under 'missing information' below.

II.A List of important risks and missing information

Important risks of lapatinib 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 lapatinib. 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	• Hepatobiliary events • Decreased left ventricular ejection fraction (LVEF) • Pneumonitis/ Interstitial lung disease (ILD) • Interactions with other drugs • QTc prolongation • Severe cutaneous reactions • Food effect
Important potential risks	• None
Missing information	• Elderly Pregnant or lactating females

II.B Summary of important risks

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

Important identified risk: Hepatobiliary events	
Risk minimisation measures	**Routine risk minimization measures:** SmPC sections: Section 4.2 (Posology and method of administration)
Important identified risk: Hepatobiliary events	
	Section 4.4 (Special warnings and precautions for use) Section 4.8 (Undesirable effects) Section 5.2 (Pharmacokinetic properties) Advice to patients provided in PL in section 2. Listed in PL section 4. Other routine risk minimisation measures beyond the Product Information: Legal status: Restricted medical prescription. **Additional risk minimisation measures:** None.

Important identified risk: Decreased left ventricular ejection fraction (LVEF)	
Risk minimisation measures	**Routine risk minimization measures:** SmPC sections: Section 4.2 (Posology and method of administration) Section 4.4 (Special warnings and precautions for use) Section 4.8 (Undesirable effects) Section 5.1 (Pharmacodynamic properties) Advice to patients provided in PL in section 2. Listed in PL section 4. Other routine risk minimisation measures beyond the Product Information: Legal status: Restricted medical prescription. **Additional risk minimisation measures:** None.

Important identified risk: Pneumonitis/ Interstitial lung disease

Risk minimisation measures	**Routine risk minimization measures:** SmPC sections: Section 4.2 (Posology and method of administration) Section 4.4 (Special warnings and precautions for use) Section 4.8 (Undesirable effects) Advice to patients provided in PL in section 2. Listed in PL section 4. Other routine risk minimisation measures beyond the Product Information: Legal status: Restricted medical prescription.
	Additional risk minimization measures: None.

Important identified risk: Interactions with other drugs	
Risk minimisation measures	**Routine risk minimization measures:** SmPC sections: Section 4.4 (Special warnings and precautions for use) Section 4.5 (Interaction with other medicinal products and other forms of interaction) Advice to patients provided in PL in section 2. Listed in PL section 4. Other routine risk minimisation measures beyond the Product Information: Legal status: Restricted medical prescription. **Additional risk minimization measures:** None.

Important identified risk: QTc prolongation

Risk minimisation measures	**Routine risk minimization measures:** SmPC sections: Section 4.4 (Special warnings and precautions for use) Section 4.8 (Undesirable effects) Section 5.1 (Pharmacodynamic properties) Listed in PL section 4. Other routine risk minimisation measures beyond the Product Information: Legal status: Restricted medical prescription. **Additional risk minimization measures:** None.

Important identified risk: Severe cutaneous reactions	
Risk minimisation measures	**Routine risk minimization measures:** SmPC sections: Section 4.4 (Special warnings and precautions for use) Section 4.8 (Undesirable effects) Advice to patients provided in PL in section 2. Listed in PL section 4. Other routine risk minimisation measures beyond the Product Information: Legal status: Restricted medical prescription.
	Additional risk minimization measures: None.

Important identified risk: Food effect

Risk minimisation measures	**Routine risk minimization measures:** SmPC sections: Section 4.2 (Posology and method of administration) Section 4.5 (Interaction with other medicinal products and other forms of interaction) Section 5.1 (Pharmacodynamic properties) Section 5.2 (Pharmacokinetic properties) Advice to patients provided in PL in section 2. Listed in PL section 4. Other routine risk minimisation measures beyond the Product Information: Legal status: Restricted medical prescription. **Additional risk minimization measures:** None.

Missing Information: Elderly	
Risk minimisation measures	**Routine risk minimization measures:** SmPC sections: Section 4.2 (Posology and method of administration) Advice to patients provided in PL in section 2. Listed in PL section 4. Other routine risk minimisation measures beyond the Product Information: Legal status: Restricted medical prescription. **Additional risk minimization measures:** None

Missing Information: Pregnant or lactating females	
Risk minimisation measures	**Routine risk minimization measures:** Section 4.6 (Fertility, pregnancy and lactation) of the SmPC. Advice to patients provided in PL in section 2. Listed in PL section 4. Other routine risk minimisation measures beyond the Product Information: Legal status: Restricted medical prescription. **Additional risk minimization measures:** None

II.C Post-authorisation development plan

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

Not Applicable

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

There are no studies required for Lapatinib Newbury.