**Public Assessment Report**

**National Procedure**

**<NAME(S) OF PRODUCT(S) FROM SmPC(S)>**

**<active substance(s)/common name(s)>**

**<PRODUCT LICENCE NUMBER(S);**

**<MAH Name>LAY SUMMARY**

**<PLEASE NOTE THAT THIS LAY SUMMARY IS INTENDED TO BE INFORMATIVE TO THE PATIENT AND SHOULD CONTAIN NON-PROMOTIONAL INFORMATION TO HELP PATIENTS UNDERSTAND MORE ABOUT THEIR MEDICINES.>**

**< name of product(s) from SmPC(s), including pharmaceutical form and strength(s)> i.e. <X>**

**<active substance(s)/common name(s)>**

This is a summary of the Public Assessment Report (PAR) for <X>. It explains how this product/these products was/were assessed and its/their authorisation recommended, as well as its/their conditions of use. It is not intended to provide practical advice on how to use this product/these products.

<*If necessary, include shortened name and the following text*:

This product/These products will be referred to as <XX> in this lay summary for ease of *below.)*

For practical information about using <X>, patients should read the Patient Information Leaflet (PIL) or contact their doctor or pharmacist.

**What is/are <X> and what is it/are they used for?**

This application/These applications is/are full-dossier applications. This means that the results of pharmaceutical, non-clinical and clinical tests have been submitted to show that this medicine is suitable for treating the specified indications.

<X is used in the treatment of/X can be used by patients who…>

*<Include the relevant information on indications, e.g. copy the relevant information from PIL section “What X is and what is it used for”. Note that the PIL is directed to the patient, rewrite accordingly if necessary.>*

**How does/do <X> work?**

<*Copy the relevant information from Section 1 of the PIL “What X is and what is it used for”.>*

**How is/are <X> used?** **<AVOID USING GRAPHICS, TEXT ONLY>**

The pharmaceutical form of this medicine is <pharmaceutical form> and the route of administration is <route of administration>.

*<This section should include: pharmaceutical form(s); main dosing recommendations; route/method of administration; duration of treatment if specified; need for any specific monitoring of certain parameters or for diagnostic tests; prescription status.>*

For further information on how <X> is used, refer to the PIL and Summary/Summaries of Product Characteristics (SmPC(s)) available on the Medicines and Healthcare products Regulatory Agency (MHRA) website.

**Either:**

<This medicine/These medicines can only be obtained with a prescription.>

**Or:**

<This medicine/These medicines can be obtained without a prescription.>

**Either (if being administered by the patient themselves):**

<The patient should always take the medicine exactly as their doctor/pharmacist has told them. The patient should check with their doctor or pharmacist if they are not sure.>

**Or (if being administered by a healthcare practitioner):**

<The patient should ask the administering healthcare practitioner if they have any questions concerning the medicine.>

**What benefits of <X> have been shown in studies?**

**Either**

<Indication 1>

<X> has been studied in patients with… Patients who took <X> had a XX improvement of symptoms compared to placebo/active comparator.

<Indication 2>

<X> has been studied in patients with… Patients who took <X> had a XX improvement of symptoms compared to placebo/active comparator.

***<A brief description from Section 5.1 of the SmPC written in lay language to explain the studies submitted for grant of the marketing authorisation.>***

**Or**

<No additional studies were needed as <X> is a line extension of the existing product(s) <Y>. The data submitted previously for <Y> is sufficient to demonstrate that <X> shows a benefit in the indications listed.>

**Or**

<X> is a line extension of the existing product(s) <Y>. The data submitted previously for <Y> and the new stud(ies) <detail new studies eg bioequivalence or PK studies> are sufficient to demonstrate that <X> shows a benefit in the indications listed.>

*<For some PARs, more than one statement may be necessary, if the line extension also contains data to add a new indication.>*

**What are the possible side effects of <X>?**

For the full list of all side effects reported with this medicine/these medicines, see Section 4 of the PIL or the SmPC(s) available on the MHRA website.

If a patient gets any side effects, they should talk to their doctor, pharmacist or nurse. This includes any possible side effects not listed in the product information or the PIL that comes with the medicine. Patients can also report suspected side effects themselves, or a report can be made on their behalf by someone else who cares for them, directly via the Yellow Card scheme at <https://yellowcard.mhra.gov.uk>or search for ‘MHRA Yellow Card’ online. By reporting side effects, patients can help provide more information on the safety of this medicine.

**<Where applicable>**

Because<X>is a line extension of the existing product(s) <Y>, its benefits and possible side effects are taken as being the same as <Y>.

**Why was/were <X> approved?**

**Either**

It was concluded that <X> has/have been shown to be effective in the treatment of…. Furthermore, the side effects observed with use of this product/these products are considered to be typical for this type of treatment. Therefore, the MHRA decided that the benefits are greater than the risks and recommended that this medicine/these medicines can be approved for use.

**OR**

It was concluded that, as <X> is a line extension of <Y>, the indications and side effects observed with <Y> are applicable to <X>. Therefore, the MHRA decided that, as for <Y>, the benefits are greater than the risks and recommended that <X> can be approved for use.

*<For some PARs, both statements are necessary, if the line extension also contains data to add a new indication.>*

*<If applicable include the following statements>*

**Either**

< <X> has been authorised under “exceptional circumstances”. This means that because of the rarity of this disease it has been impossible to get complete information on this medicine. Any new information on < X> will be reviewed every year and this report will be updated as necessary.>

**Or**

<X> has been authorised with the condition to perform further studies and/or to provide additional measures to minimise the risk. See section below “What measures are being taken to ensure the safe and effective use of <X>?”

**Or**

<X> has been authorised with a Conditional Marketing Authorisation (CMA). CMAs are intended for medicinal products that address an unmet medical need, such as a lack of alternative therapy for a serious and life-threatening disease. CMAs may be granted where comprehensive clinical data is not yet complete, but it is judged that such data will become available soon.

*<If applicable include the following statement>*

<X> has been authorised as a GB Orphan medicine. Orphan medicines are intended for use against rare conditions that are life-threatening or chronically debilitating. To qualify as an orphan medicine, certain criteria, for example concerning the rarity of the disease and the lack of currently available treatments, must be fulfilled.

**What measures are being taken to ensure the safe and effective use of <X>?**

**<PLEASE COMPILE FROM RELEVANT SECTIONS OF THE RISK MANAGEMENT PLAN>**

As for all newly-authorised medicines, a Risk Management Plan (RMP) has been developed for <x> The RMP details the important risks of <x>, how these risks can be minimised, any uncertainties about <x> (missing information), and how more information will be obtained about the important risks and uncertainties.

The following safety concerns have been recognised for <x>:

Important identified risks:

Important potential risks:

Missing information:

<or>

<if applicable: There are no safety concerns associated with use of <x>.>

<if applicable: describe additional risk management measures, such as obligations to provide educational materials, establish patient registries, or carry out further studies e.g. in specific populations or for long-term safety/efficacy data.>

The information included in the SmPC and the PIL is compiled based on the available quality, non-clinical and clinical data, and includes appropriate precautions to be followed by healthcare professionals and patients.  Side effects of <x> are continuously monitored and reviewed including all reports of suspected side-effects from patients, their carers, and healthcare professionals.

An RMP and a summary of the pharmacovigilance system have been provided with this/these application(s) and are satisfactory.

**Other information about <X>**

A marketing authorisation application / Marketing authorisation applications for <X> was/were granted in the United Kingdom (UK) on <date of issue of the marketing authorisation(s)>.

The full PAR for <X> follows this summary.

This summary was last updated in February 2024.

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I INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the Medicines and Healthcare products Regulatory Agency (MHRA) considered that the application(s) for <Name(s) of the product(s) from the SmPC> (<Product licence number(s)>) could be approved.

The product(s) is/are approved for the following indication(s) :*<Include the relevant information on indications, copied from the SmPC(s)>*

<Name(s) of the active substance(s)> is/are….

*<Include a summary of the mechanism of action of each active substance, taken from the Overview of the assessment report (MRP/DCP) or from the national assessment report/Module 2 summaries or Section 5.1 of the SmPC>*

**Either**

This/These application(s) was/were approved under Regulation 50 of The Human Medicines Regulation 2012, as amended (previously Article 8(3) of Directive 2001/83/EC, as amended), a full-dossier application(s). All non-clinical data submitted were from studies conducted in accordance with Good Laboratory Practice (GLP). All clinical data submitted were from studies conducted in accordance with Good Clinical Practice (GCP).

**OR**

This/These application(s) was/were approved under Regulation 50 of The Human Medicines Regulation 2012, as amended (previously Article 8(3) of Directive 2001/83/EC, as amended), a full-dossier application(s). However, as this/these application(s) are for a line extension(s) of the existing product(s) <STATE EXISTING PRODUCTS AND PL NUMBER>, the non-clinical and clinical data are identical to those submitted previously.

*<If any new data have been submitted but this is still a line extension include information on the studies conducted.>*

**<For ILAP procedures the following text should be added>**

This/these medicines were developed utilising the Innovative Licensing and Access Pathway (ILAP). The ILAP aims to accelerate the time to market for innovative medicines, thereby facilitating patient access to them.

As part of the pathway, these medicines were granted an Innovation Passport on XXX <insert date>, which provided access to enhanced regulatory and other stakeholder input and support for the safe, timely and efficient development of the product(s).

**<For Rolling Review, the following text should be added>**

This/these application(s) was/were evaluated as part of the rolling review licensing route. The rolling review process is intended to streamline the development of novel medicines. As part of the process the applicant submitted increments of the dossier for pre-assessment by the MHRA, rather than submitting a consolidated full dossier at the end of the product development process.

**<For Project Orbis applications, the following text should be added>**

This/these application(s) was/were evaluated as part of Project Orbis, which is a programme coordinated by the US Food and Drug Administration (FDA) involving the regulatory authorities of Australia (TGA), Canada (Health Canada), Singapore (HSA), Brazil (ANVISA), Switzerland (Swissmedic) and the MHRA (UK), to review and approve promising cancer treatments. Project Orbis provides a framework for concurrent submission and review of oncology products among international partners. Each regulator made independent decisions regarding approval of the application(s).

**<For Access applications, the following text should be added>**

This/these application(s) was/were evaluated as part of the Access Consortium, which consists of the regulatory authorities of Australia (TGA) Canada (Health Canada), Singapore (HSA), Switzerland (Swissmedic) and the MHRA (UK). Work-sharing for this application was conducted between <list the regulators involved>. Each regulator made independent decisions regarding approval of the application(s).

**<For products granted a conditional marketing authorisation, the following text should be added>**

This/these products or <X> has/have been authorised as (a) Conditional Marketing Authorisations (CMA(s)). CMAs are granted in the interest of public health and are intended for medicinal products that fulfil an unmet medical need and the benefit of immediate availability outweighs the risk posed from less comprehensive data than normally required. Unmet medical needs include, for example, treatment or diagnosis of serious and life-threatening diseases where no satisfactory treatment methods are available. CMAs may be granted where comprehensive clinical data is not yet complete, but it is judged that such data will become available soon. Adequate evidence of safety and efficacy to enable the MHRA to conclude that the benefits are greater than the risks is required, and has been provided for ,X>. The CMA(s) for <X>, including the provision of any new information, will be reviewed every year and this report will be updated as necessary.

**<For Orphan applications, the following text should be added>**

<This/these application(s) was/were evaluated for fulfilment of orphan designation criteria and was/were examined by the Commission on Human Medicines (CHM) on <state dates(s) of CHM discussion. It was concluded that fulfilment of the criteria for approval as an orphan medicinal product <was/was not> satisfactorily demonstrated. Please see Annex 1 for a summary of the orphan <approval/refusal>.>

**<For Paediatric applications, the following text should be added>**

**<Either for an agreed PIP:>**

In line with the legal requirements for children's medicines, the application included a licensing authority decision on the agreement of a paediatric investigation plan (PIP) *{insert PIP number}*

At the time of the submission of the application the PIP was *{completed}/{not yet completed as some measures were deferred}*

**<If full/final compliance check>** The licensing authority issued an opinion on compliance of the PIP *{insert PIP number}*

**<OR for a full product specific waiver>**

In line with the legal requirements for children's medicines, the application included a licensing authority decision on the agreement of a full product specific waiver *{insert waiver number}*

**<OR class waiver>**

In line with the legal requirements for children's medicines, the application included a licensing authority decision on the granting of a class waiver *{insert class waiver number}*

The MHRA has been assured that acceptable standards of Good Manufacturing Practice (GMP) are in place for this/these product(s) at all sites responsible for the manufacture, assembly and batch release of this/these product(s).

A Risk Management Plan (RMP) and a summary of the pharmacovigilance system have been provided with this/these application(s) and are satisfactory.

**<For applications referred to CHM>**Advice was sought from the Commission of Human Medicines (CHM) on <state dates(s) of CHM discussions> because….

*<A brief description of the main non-clinical/clinical reason(s) (but not specific quality issues as these can be commercially confidential) that the application(s) was/were referred to CHM should be given and how the issue(s) was resolved.>.*

A marketing authorisation application/Marketing authorisations applications for <X> was/were received on x date, and marketing authorisation(s) was/were granted in the United Kingdom (UK) on <date of issue of the Marketing Authorisation(s)>.

II QUALITY ASPECTS

**II.1 Introduction**

This/These product(s) consist(s) of…

*<Include the relevant information from Section 2 of the SmPC(s) that describes each product>*

In addition to <state active substance(s)>, this/these product(s) also contain the excipients <list excipients, as per Section 6.1 of the SmPC(s), including Oxford commas>.

The finished product(s) is/are packaged in <list packaging, as per Section 6.5 of the SmPC(s)>. Satisfactory specifications and Certificates of Analysis have been provided for all packaging components. All primary packaging complies with the current regulations concerning materials in contact with food.

**II.2 ACTIVE SUBSTANCE(S)**

**rINN: <state active substance rINN>**

Chemical Name: <state chemical name, as per the Quality assessment report or Module 3.2.S>

Molecular Formula: <state molecular formula, as per the Quality assessment report or Module 3.2.S>

Chemical Structure: <provide chemical structure, as per the Quality assessment report or Module 3.2.S>

Molecular Weight: <state molecular weight, as per the Quality assessment report or Module 3.2.S>

Appearance: <state appearance, as per the Quality assessment report or Module 3.2.S>

Solubility: <state solubility, as per the Quality assessment report or Module 3.2.S>

**Either**

<Name of active substance> is the subject of a European Pharmacopoeia monograph.

All aspects of the manufacture and control of the active substance are covered by a European Directorate for the Quality of Medicines and Healthcare (EDQM) Certificate of Suitability.

*<Please note that if the packaging and retest period have not been covered by the EDQM certificate, these will have been assessed by the Quality assessor and so the following should be added>*

Suitable specifications have been provided for all packaging used. The primary packaging complies with the current regulations concerning materials in contact with food.

Appropriate stability data have been generated supporting a suitable retest period when stored in the proposed packaging.

**Or**

<The information related to the active substance was provided in an ASMF.  The Active substance is the subject of a Ph.Eur. monograph.>

Synthesis of the active substance from the designated starting materials has been adequately described and appropriate in-process controls and intermediate specifications are applied. Satisfactory specifications are in place for all starting materials and reagents, and these are supported by relevant Certificates of Analysis.

Appropriate proof-of-structure data have been supplied for the active substance. All potential known impurities have been identified and characterised.

An appropriate specification is provided for the active substance. Analytical methods have been appropriately validated and are satisfactory for ensuring compliance with the relevant specifications. Batch analysis data are provided and comply with the proposed specification. Satisfactory Certificates of Analysis have been provided for all working standards.

Suitable specifications have been provided for all packaging used. The primary packaging has been shown to comply with current regulations concerning materials in contact with food.

Appropriate stability data have been generated supporting a suitable retest period when stored in the proposed packaging.

*<Repeat the above for each active substance in the medicinal product(s)>*

**II.3 DRUG PRODUCT(S)**

**Pharmaceutical development**

A satisfactory account of the pharmaceutical development has been provided.

All excipients comply with either their respective European/national monographs, or a suitable in-house specification. Satisfactory Certificates of Analysis have been provided for all excipients.

**Either**

No excipients of animal or human origin are used in the finished product(s).

**Or**

With the exception of <state excipient>, no excipients of animal or human origin are used in the final products. *<State whether any EDQM certificates have been provided for the excipients of animal origin>*

<If appropriate: The supplier of lactose monohydrate has confirmed that it is sourced from healthy animals under the same conditions as milk for human consumption.>

<If appropriate: Confirmation has been given that the magnesium stearate used in the tablets is of vegetable origin.>

This product(s) does/do not contain or consist of genetically modified organisms (GMO).

**Manufacture of the product(s)**

A description and flow-chart of the manufacturing method has been provided.

Satisfactory batch formulation data have been provided for the manufacture of the product(s), along with an appropriate account of the manufacturing process. The manufacturing process has been validated and has shown satisfactory results.

**Finished Product Specification(s)**

The finished product specifications at release and shelf-life are satisfactory. The test methods have been described and adequately validated. Batch data have been provided that comply with the release specifications. Certificates of Analysis have been provided for any working standards used.

**Stability**

Finished product stability studies have been conducted in accordance with current guidelines, using batches of the finished product stored in the packaging proposed for marketing. Based on the results, a shelf-life of <INSERT SHELF LIFE FROM SMPC>, with the storage conditions <INSERT STORAGE CONDITIONS FROM THE SMPC>, is acceptable.

**<ADDITIONAL SHELF-LIFE/STORAGE CONDITIONS, SUCH AS FROM IN-USE STABILITY STUDIES OR AFTER RECONSTITUTION CAN BE ADDED HERE.>**

**<If applicable>** Suitable post approval stability commitments have been provided to continue stability testing on batches of finished product.

**II.4 Discussion on chemical, pharmaceutical and biological aspects**

The grant of (a) marketing authorisation(s) is recommended.

III NON-CLINICAL ASPECTS

**III.1 Introduction**

**Either**

The following non-clinical studies were submitted with this/these applications:

***<A list of studies should be provided>***

**Or**

As this/these application(s) are for a line extension(s) of the existing product(s) <STATE EXISTING PRODUCTS AND PL NUMBER>, the non-clinical data are identical to those submitted previously.

*<If any new data have been submitted but this is still a line extension, include information on the studies conducted.>*

All studies were conducted in accordance with current Good Laboratory Practice (GLP).

**III.2 Pharmacology**

**Either**

***<A summary of the main conclusions from the pharmacology studies should be provided here>***

**Or (for line extensions)**

No new pharmacology data were provided and none were required for this/these application(s).

**III.3 Pharmacokinetics**

**Either**

***<A summary of the main conclusions from the pharmacokinetic studies should be provided here>***

**Or (for line extensions)**

No new pharmacokinetic data were provided and none were required for this/these application(s).

**III.4 Toxicology**

**Either**

***<A summary of the main conclusions from the toxicology studies should be provided here>***

**Or (for line extensions)**

No new toxicology data were provided and none were required for this/these application(s).

**III.5 Ecotoxicity/Environmental Risk Assessment**

**Either**

A full Environmental Risk Assessment (ERA) was submitted with this/these application(s)

*<The main results and the conclusion of the ERA assessment should be presented here>*

The effects of the finished product(s) on the environment have been fully characterised, in‑line with current guidance. No further action regarding the environmental fate of this/these products is required.

**Or (for line extensions)**

Suitable justification has been provided for non-submission of an Environmental Risk Assessment. As this is a line extension of an already authorised product(s), it is not expected that environmental exposure will increase following approval of the Marketing Authorisation(s) for the proposed product(s).

**III.6 Discussion on the non-clinical aspects**

***<Any meaningful discussion of the non-clinical studies can be presented here>***

The grant of a marketing authorisations is recommended.

IV CLINICAL ASPECTS

**IV.1 Introduction**

**Either**

The following clinical studies were submitted with this/these applications:

***<A list of studies should be provided>***

**Or**

As this/these application(s) are for a line extension(s) of the existing product(s) <STATE EXISTING PRODUCTS AND PL NUMBER>, the clinical data are identical to those submitted previously.

*<If any new data have been submitted but this is still a line extension, include information on the studies conducted.>*

All studies were conducted in line with current Good Clinical Practice (GCP).

**IV. 2 Pharmacokinetics**

**Either**

In support of the application(s), the following was/were submitted:

<PHARMACOKINETIC STUDY 1>

***<A suitable description of the study should be provided here, for example the main objective(s) of the study, details of the study population (main inclusion/exclusion criteria), the methodology (duration of study, dosing, timepoints, etc), the main pharmacokinetic parameter(s)/endpoint(s) measured, any analysis of these parameter(s)/endpoint(s), the main results of the study and conclusion. This should be available in the clinical assessment report.>***

<PHARMACOKINETIC STUDY 2>

<In instances where more than one pharmacokinetic study was performed, each should be described as per above>.

**Or (for line extensions)**

No new pharmacokinetic data have been submitted for this/these application(s) and none were required.

***< If this is a line extension, but additional data have been provided, this can be adapted>.***

**IV.3 Pharmacodynamics**

**Either**

In support of the application(s), the following was/were submitted:

<PHARMACODYNAMIC STUDY 1>

***<A suitable description of the study should be provided here, for example the main objective(s) of the study, details of the study population (main inclusion/exclusion criteria), the methodology (duration of study, dosing, timepoints, etc), the main pharmacodynamic parameter(s)/endpoint(s) measured, any analysis of these parameter(s)/endpoint(s), the main results of the study and conclusion. This should be available in the clinical assessment report.>***

<PHARMACODYNAMIC STUDY 2>

<In instances where more than one pharmacodynamic study was performed, each should be described as per above>.

**Or (for line extensions)**

No new pharmacodynamic data have been submitted for this/these application(s) and none were required.

***< If this is a line extension, but additional data have been provided, this can be adapted>.***

**IV.4 Clinical efficacy**

**Either**

In support of the application(s), the following was/were submitted:

<EFFICACY STUDY 1>

***<A suitable description of the study should be provided here, for example the main objective(s) of the study, details of the study population (main inclusion/exclusion criteria), the methodology (duration of study, dosing, timepoints, etc), the main efficacy parameter(s)/endpoint(s) measured, any analysis of these parameter(s)/endpoint(s), the main results of the study and conclusion. This should be available in the clinical assessment report.>***

<EFFICACY STUDY 2>

<In instances where more than one efficacy study was performed, each should be described as per above>.

**Or (for line extensions)**

No new efficacy data have been submitted for this/these application(s) and none were required.

***< If this is a line extension, but additional data have been provided, this can be adapted>.***

**IV.5 Clinical safety**

**Either**

***<A description and assessment of the adverse events observed during the clinical studies should be provided. This should include a global assessment of the adverse event occurrence (including severity), serious adverse event occurrence, treatment-related adverse events, any comparison with other treatments, and an overall conclusion of the safety of the product. This should be available in the clinical assessment report>.***

**Or (for line extensions)**

No new safety data were submitted with this/these application(s) and none were required. The safety profile for this/these product(s) is considered to be the same as <STATE NAMES OF LEAD PRODUCTS FOR THESE LINE EXTENSION PRODUCTS>.

***< If this is a line extension, but additional data have been provided, this can be adapted>.***

**IV.6 Risk Management Plan (RMP)**

**Either**

The applicant has submitted an RMP, in accordance with the requirements of Regulation 182 of The Human Medicines Regulation 2012, as amended. The applicant proposes only routine pharmacovigilance and routine risk minimisation measures for all safety concerns. This is acceptable.

**Or**

The applicant has submitted an RMP, in accordance with the requirements of Regulation 182 of The Human Medicines Regulation 2012, as amended. In addition to routine pharmacovigilance and risk minimisation measures, the following additional < if applicable: pharmacovigilance> <and> < if applicable: risk minimisation> measures have been proposed:

<Insert table of risk minimisation and additional pharmacovigilance measures from part VI ‘II.B Summary of important risks‘ of the final RMP in the case folder>.

This is acceptable.

**IV.7 Discussion on the clinical aspects**

**Either**

<A review of the conclusions from the studies submitted should be presented here. This should be taken from the clinical assessment report>

**Or (for line extensions)**

The grant of a marketing authorisation(s) is recommended for this/these application(s).

V USER CONSULTATION

A full colour mock-up of the Patient Information Leaflet (PIL) was provided with the application in accordance with legal requirements, including user consultation.

<Or>

A text draft of the Patient Information Leaflet (PIL) was presented. A commitment to provide a mock-up and evidence of user consultation of the PIL to the MHRA prior to marketing was accepted.

VI OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

**Either**

The quality of the product(s) is acceptable. The non-clinical and clinical data submitted have shown the positive benefit/risk of this/these products in the treatment of… <ADD TREATMENT INDICATIONS>.

**Or (for line extensions)**

The quality of the product(s) is acceptable, and no non-clinical or clinical safety concerns have been identified. Clinical experience with <name of active> is considered to have demonstrated the therapeutic value of the compound. The benefit/risk is, therefore, considered to be positive.

*<Select statements below if required and amend as necessary>*

**<For products authorised under exceptional circumstances>**

As comprehensive data on the product are not available, <X> has been authorised under “exceptional circumstances”. The Marketing Authorisation Holder shall complete, within the stated timeframe, the following measures:

|  |  |
| --- | --- |
| **Description** | **Due date** |
|  |  |

**<For products authorised with conditions>**

<X> has been authorised with the condition to perform further studies and/or to provide additional measures to minimise the risk. The Marketing Authorisation Holder shall complete, within the stated timeframe, the following measures:

|  |  |
| --- | --- |
| **Description** | **Due date** |
|  |  |

**<For products granted a conditional marketing authorisation.>**

<X> has been authorised with a Conditional Marketing Authorisation (CMA). The Marketing Authorisation Holder shall complete, within the stated timeframe, the following measures:

|  |  |
| --- | --- |
| **Description** | **Due date** |
|  |  |

The Summary of Product Characteristics (SmPC), Patient Information Leaflet (PIL) and labelling are satisfactory, and in line with current guidelines.

In accordance with legal requirements, the current approved UK versions of the SmPCs and PILs for these products are available on the MHRA website.

TABLE OF CONTENT OF THE PAR UPDATE

Steps taken after the initial procedure with an influence on the Public Assessment Report (non-safety variations of clinical significance).

Please note that only non-safety variations of clinical significance are recorded below and in the annexes to this PAR. The assessment of safety variations where significant changes are made are recorded on the MHRA website or European Medicines Agency (EMA) website. Minor changes to the marketing authorisation are recorded in the current SmPC and/or PIL available on the MHRA website.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **Application type** | **Scope** | **Product information affected** | **Date of grant** | **Outcome** | **Assessment report attached**  **Y/N** |
|  |  |  |  |  |  |
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