COLLEGE TER BEOORDELING VAN GENEESMIDDELEN

Public Assessment Report

Scientific discussion

Pomalidomide Newbury 1 mg, 2 mg, 3 mg and 4 mg, hard capsules (pomalidomide)

NL/H/5934/001-4/DC

Date: 11 April 2025

This module reflects the scientific discussion for the approval of Pomalidomide Newbury 1 mg, 2 mg, 3 mg and 4 mg, hard capsules. The procedure was finalised on 11 December 2024. For information on changes after this date please refer to the 'steps taken after finalisation' at the end of this PAR.

List of abbreviations

ASMF	Active Substance Master File
CEP	Certificate of Suitability to the monographs of the European Pharmacopoeia
CHMP	Committee for Medicinal Products for Human Use
CMD(h)	Coordination group for Mutual recognition and Decentralised procedure for human medicinal products
CMS	Concerned Member State
EDMF	European Drug Master File
EDQM	European Directorate for the Quality of Medicines
EEA	European Economic Area
EMA	European Medicines Agency
ERA	Environmental Risk Assessment
ICH	International Conference of Harmonisation
MAH	Marketing Authorisation Holder
Ph.Eur.	European Pharmacopoeia
PL	Package Leaflet
PSURs	Periodic safety update reports
RH	Relative Humidity
RMP	Risk Management Plan
RMS	Reference Member State
SmPC	Summary of Product Characteristics
TSE	Transmissible Spongiform Encephalopathy

I. INTRODUCTION

Based on the review of the quality, safety and efficacy data, the Member States have granted a marketing authorisation for Pomalidomide Newbury 1 mg, 2 mg, 3 mg and 4 mg, hard capsules, from Newbury Pharmaceuticals AB.

The product is indicated:

- in combination with bortezomib and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least one prior treatment regimen including lenalidomide.
- in combination with dexamethasone, for the treatment of adult patients with relapsed and refractory multiple myeloma who have received at least two prior treatment regimens, including both lenalidomide and bortezomib, and have demonstrated disease progression on the last therapy.

A comprehensive description of the up-to-date indications and posology is given in the SmPC.

The marketing authorisation has been granted pursuant to Article 10(1) of Directive 2001/83/EC, which concerns a generic application.

In this decentralised procedure, essential similarity is proven between the new product and the innovator product Imnovid 1 mg, 2 mg, 3 mg and 4 mg hard capsules from Bristol Myers Squibb Pharma EEIG Ireland, which has been registered in the EEA via the centralised procedure EU/1/13/850/001-008 since 5 August 2013.

The concerned member states (CMS) involved in this procedure were Denmark, Norway and Sweden.

Similarity assessment

According to Article 8(1) of Regulation (EC) No 141/2000, no marketing authorisation can be granted for a product similar to an orphan medicinal product for a period of ten years, when this concerns a similar medicinal product with the same therapeutic indication. The MAH has provided a similarity assessment between Pomalidomide Newbury and the current orphan products authorised in the EU. These orphan products and their respective indications are:

- Indicated for the treatment of multiple myeloma:
    - Ninlaro (Ixazomib), Takeda Pharma A/S, EU/1/16/1094
    - Carvykti (Ciltacabtagene Autoleucel), Janssen-Cilag International NV, EU/1/22/1648
    - Abecma (Idecabtagene Vicleucel), Bristol-Myers Squibb Pharma EEIG, EU/1/21/1539
    - Kyprolis (Carfilzomib), Amgen Europe B.V., EU/1/15/1060
    - Farydak (Panobinostat), zr pharma& GmbH, EU/1/15/1023

- Indicated for the treatment of plasma cell myeloma:
    - Darzalex (Daratumumab), Janssen-Cilag International NV, EU/1/16/1101
    - Talvey (Talquetamab), Janssen-Cilag International NV.

The assessment included the comparison of the therapeutic indication, active substance, mechanism of action and principal (molecular) structure. After consideration of the MAH arguments, Pomalidomide Newbury is not considered similar to the orphan products with regard to the therapeutic indication (as defined in Article 3 of Commission Regulation (EC) No. 847/2000). Therefore, the existence of any market exclusivity for Ninlaro, Carvykti, Abecma, Kyprolis, Farydak, Darzalex and Talvey in the treatment of multiple myeloma or plasma cell myeloma does not prevent the granting of the marketing authorisation for Pomalidomide Newbury.

II. QUALITY ASPECTS

II.1 Introduction

Pomalidomide Newbury are hard capsules containing 1 mg, 2 mg, 3 mg or 4 mg pomalidomide as active substance. The hard capsules of the different strengths can be distinguished by their colour, shape and size and are as follows:

Pomalidomide Newbury 1 mg are hard capsules with yellow opaque cap and yellow opaque body, capsule shell size No. 4 (approximate 14 mm x 5 mm), imprinted in black ink with 'LP' on the cap and '664' on the body, filled with yellow granular powder. Each capsule contains 1 mg pomalidomide.

Pomalidomide Newbury 2 mg are hard capsules with orange opaque cap and orange opaque body, capsule shell size No. 3 (approximate 16 mm x 6 mm), imprinted in black ink with 'LP' on the cap and '665' on the body, filled with yellow granular powder. Each capsule contains 2 mg pomalidomide.

Pomalidomide Newbury 3 mg are hard capsules with powder blue opaque cap and powder blue opaque body, capsule shell size No. 2 (approximate 18 mm x 6 mm), imprinted in black ink with 'LP' on the cap and '690' on the body, filled with yellow granular powder. Each capsule contains 3 mg pomalidomide.

Pomalidomide Newbury 4 mg are hard capsules with blue opaque cap and blue opaque body, capsule shell size No. 2 (approximate 18 mm x 6 mm), imprinted in black ink with 'LP' on the cap and '667' on the body, filled with yellow granular powder. Each capsule contains 4 mg pomalidomide.

The excipients are:
Capsule contents - isomalt (E953), pregelatinized corn starch and sodium stearyl fumarate.

Capsule shell –) gelatin, titanium dioxide (E171), black printing ink, yellow iron oxide (E172) (only for 1 mg and 2 mg strength), red iron oxide (E172) (only for 2 mg strength), brilliant blue FCF (E133) (only for 3 mg and 4 mg strength) and Erythrosine (E127) (only for 4 mg strength).

Printing ink - shellac (E904), strong ammonia solution, potassium hydroxide and black iron oxide (E172).

The capsule fill of the four strengths is dose weight proportional.

The hard capsules are packed in in polyvinyl chloride/polychlorotrifluoroethylene (PVC/PCTFE) (Aclar) - aluminium blisters or unit dose blisters, or oriented polyamide/aluminium/polyvinyl chloride (OPA/Alu/PVC) – aluminium blisters or unit dose blisters.

II.2 Drug Substance

The active substance is pomalidomide, an established active substance which is not described in the European Pharmacopoeia (Ph.Eur.). The active substance is a pale yellow to yellow, non-hygroscopic crystalline powder, very slightly soluble in water. The drug substance shows polymorphism, no optical rotation is observed. Pomalidomide has one stereochemical centre and is obtained as a racemic mixture. For this product the polymorphic A form is consistently produced by the manufacturer and is sufficiently controlled. The drug substance is micronized.

The Active Substance Master File (ASMF) procedure is used for the active substance. The main objective of the ASMF procedure, commonly known as the European Drug Master File (EDMF) procedure, is to allow valuable confidential intellectual property or 'know-how' of the manufacturer of the active substance (ASM) to be protected, while at the same time allowing the applicant or marketing authorisation holder (MAH) to take full responsibility for the medicinal product, the quality and quality control of the active substance. Competent Authorities/EMA thus have access to the complete information that is necessary to evaluate the suitability of the use of the active substance in the medicinal product.

Manufacturing process

The manufacturing process consists of several steps for synthesis and a final purification step. No class 1 organic solvents are used in the process. The active substance, starting materials solvents and reagents used in the synthesis have been adequately characterised and adequate specifications are adopted to control their quality.

Quality control of drug substance

The active substance specification is considered adequate to control the quality and meets the requirements of the ASMF and in-house specifications with an additional test for particle size distribution. The drug substance specification of the drug product manufacturer has been justified and are acceptable. Batch analytical data demonstrating compliance with this specification have been provided for two full scale batches and a fraction of two full scale batches.

Stability of drug substance

Stability data on the active substance have been provided for four production scaled batches in accordance with applicable European guidelines. Based on the data submitted, a retest period could be granted of 5 years, when stored under the stated conditions.

II.3 Medicinal Product

Pharmaceutical development

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines. The choice of the excipients is justified, and their functions explained. The main development studies were for the choice of un-micronized or micronized drug substance, optimisation of the formulation and development of the dissolution method. A bioequivalence (BE) study has been performed with the 4 mg product strength. The test batch used in the BE study was manufactured according to the finalised formulation and manufacturing process and at a representative scale. A biowaiver of strengths has been requested for the lower strengths 1 mg, 2 mg and 3 mg, see details in section IV.2.

Manufacturing process

The manufacturing process includes multiple blending steps, encapsulation and packaging. Due to the low amount of active substance per capsule (<2%), the finished product is considered a specialised pharmaceutical dose form and the manufacturing process is considered non-standard. The manufacturing process has been validated according to the relevant European/ICH guidelines. Process validation data on the product have been presented for four full scale batches per strength.

Control of excipients

The excipients of the capsule fill comply with the current version of the Ph.Eur. monograph. In-house specifications have been presented for the capsules. These specifications are acceptable.

Quality control of the drug product

The finished product specifications are adequate to control the relevant parameters for the dosage form. The specification includes tests for appearance, identification, water content, assay, uniformity of dosage units, related substances, dissolution and microbial quality. The release and shelf-life tests and limits are identical. Limits in the specification have been justified and are considered appropriate for adequate quality control of the product. An adequate nitrosamines risk evaluation report has been provided. No risk for presence of nitrosamines in the drug product was identified. No risks were identified in the risk assessment for elemental impurities.

Satisfactory validation data for the analytical methods have been provided.

Batch analytical data from four full scale batches per strength from the proposed production site(s) have been provided, demonstrating compliance with the specification.

Stability of drug product

Stability data on the product have been provided for four batches of the 1 mg strength and four batches of the 4 mg strength, stored at 25°C/ 60% RH (36 months) and 40°C/75% RH (6 months) in accordance with applicable European guidelines. A bracketing approach has been applied which is considered acceptable. No changes were observed at long term or accelerated conditions when packed in the commercial packaging. Furthermore, photostability studies were performed in accordance with ICH recommendations and showed that the product is stable when exposed to light. On basis of the data submitted, a shelf life was granted of 4 years. No specific storage conditions needed to be included in the SmPC or on the label.

Specific measures concerning the prevention of the transmission of animal spongiform encephalopathies

Scientific data and/or certificates of suitability issued by the EDQM for the excipient gelatine have been provided and compliance with the Note for Guidance on Minimising the Risk of Transmitting Animal Spongiform Encephalopathy Agents via medicinal products has been satisfactorily demonstrated.

II.4 Discussion on chemical, pharmaceutical and biological aspects

Based on the submitted dossier, the member states consider that Pomalidomide Newbury has a proven chemical-pharmaceutical quality. Sufficient controls have been laid down for the active substance and finished product.

No post-approval commitments were made.

III. NON-CLINICAL ASPECTS

III.1 Ecotoxicity/environmental risk assessment (ERA)

Since Pomalidomide Newbury is intended for generic substitution, this will not lead to an increased exposure to the environment. An environmental risk assessment was therefore not deemed necessary.

III.2 Discussion on the non-clinical aspects

This product is a generic formulation of Imnovid which is available on the European market. Reference was made to the preclinical data obtained with the innovator product. A non-clinical overview on the pharmacology, pharmacokinetics and toxicology has been provided, which was based on up-to-date and adequate scientific literature. The overview justifies why there is no need to generate additional non-clinical pharmacology, pharmacokinetics and toxicology data. Therefore, the member states agreed that no further non-clinical studies are required.

IV. CLINICAL ASPECTS

IV.1 Introduction

Pomalidomide is a well-known active substance with established efficacy and tolerability. A clinical overview has been provided, which is based on scientific literature. The member states agreed that no further clinical studies are required, besides the two bioequivalence studies discussed below.

IV.2 Pharmacokinetics

The MAH conducted a pivotal bioequivalence study (Study 1) in which the pharmacokinetic profile of the test product Pomalidomide Newbury 4 mg, hard capsules, (Newbury Pharmaceuticals AB, Sweden) was compared with the pharmacokinetic profile of the reference product Imnovid 4 mg hard capsules (from MAH Bristol Myers Squibb Pharma EEIG, Ireland; manufactured by Celgene Distribution B.V., the Netherlands). A biowaiver was requested for the lower strengths 1 mg, 2 mg and 3 mg.

The choice of the reference product in the bioequivalence study has been justified by comparison of dissolution study results and composition. An additional BE study (Study 2) was submitted to support the dissolution limits.

Biowaiver

Pomalidomide has been classified as an BCS Class IV compound (low solubility/low permeability). For pomalidomide there is a linear pharmacokinetic behaviour over the therapeutic dose range. The following general requirements were met for the waiver for additional strength, according to the EMA Bioequivalence guideline:

a. all strengths are manufactured by the same process
b. The drug input is linear over the therapeutic dose range
c. The qualitative composition of the different strengths is the same
d. The composition of the different strengths is quantitatively proportional
e. The dissolution profiles of the additional strengths are similar under identical conditions to the profile of the batch used in the bioequivalence study.

The general biowaiver criteria listed in the EMA Guideline on the Investigation of Bioequivalence are met. At pH 1.2, dissolution of all strengths exceeded 85% in 15 minutes and no further mathematical evaluation was needed. Dissolution of the bio batch at pH 4.5 and of the 2 mg strength at pH 6.8 was slightly below 85% after 15 minutes requiring mathematical evaluation by bootstrap. At pH 4.5, dissolution of the 1 mg strength and of the bio batch needed to be compared at the same dose as a concentration effect was seen. The biowaiver of strengths is acceptable from a chemical-pharmaceutical point of view.

The test bio batch used for the additional study was a submission batch with up to 5% lower release compared to the initial test bio batch used by the pivotal study. Therefore, to support the biowaiver, additional dissolution data was submitted comparing the new test bio batch (4 mg) with the biowaiver strengths (1 mg, 2 mg and 3 mg strengths). All dissolution profiles at

pH 1.2 0.1 N HCl, pH 4.5 acetate buffer and pH 6.8 phosphate buffer were comparable as indicated by a lower boundary of the 90% confidence interval for $f_{2, exp}$ ≥50. The used bootstrap procedure was in agreement with the approach indicated in the guideline. The comparison of multiple capsules to eliminate a concentration effect is acceptable. Overall, the followed procedure is acceptable.

Bioequivalence studies

Study 1, pivotal study

Design

A single-dose, open label, randomised, balanced, two-period, two-treatment, two-sequence, crossover bioequivalence study was carried out under fasted conditions in 28 healthy male subjects, aged 23-41 years. Each subject received a single dose (4 mg) of one of the two pomalidomide formulations. The tablet was orally administered with 240 mL water after a 10-hour fasting period. There were two dosing periods separated by a washout period of 7 days.

Blood samples were collected pre-dose (within 2 hours prior dosing) and at 0.33, 0.67, 1, 1.25, 1.5, 1.75, 2, 2.25, 2.5, 2.75, 3, 3.5, 4, 5, 6, 7, 8, 10, 12, 16, 24, 36 and 48 hours after administration of the products.

Results

All 28 subjects completed both periods of the study and were eligible for pharmacokinetic analysis.

Table 1. Pharmacokinetic parameters (non-transformed values; arithmetic mean ± SD, t_{max} (median, range)) of pomalidomide, 4 mg under fasted conditions, pivotal study.

Treatment N=28	**AUC_{0-t} (ng.h/mL)**	**$AUC_{0-\infty}$ (ng.h/mL)**	**C_{max} (ng/mL)**	**t_{max} (h)**
Test	744 ± 161	756 ± 165	94 ± 23	2.00 (0.67 – 5.00)
Reference	713 ± 163	724 ± 168	83 ± 15	1.50 (0.67 – 4.00)
***Ratio (90% CI)**	1.05 (1.01-1.08)	---	1.12 (1.04 -1.20)	---

$AUC_{0-\infty}$	Area under the plasma concentration-time curve from time zero to infinity
AUC_{0-t}	Area under the plasma concentration-time curve from time zero to the last measurable plasma concentration / to t = 48 hours
C_{max}	Maximum plasma concentration
t_{max}	Time after administration when maximum plasma concentration occurs
CI	Confidence interval

**ln-transformed values*

Study 2, additional bioequivalence study

Design

A single-dose, open label, randomised, balanced, two-period, two-treatment, two-sequence, crossover bioequivalence study was carried out under fasted conditions in 24 healthy male subjects, aged 18-45 years. Each subject received a single dose (4 mg) of one of the two pomalidomide formulations. The tablet was orally administered with 240 mL water after a 10-hour fasting period. There were two dosing periods separated by a washout period of 7 days.

Blood samples were collected pre-dose (within 1 hour prior dosing) and at 0.33, 0.67, 1, 1.25, 1.5, 1.75, 2, 2.25, 2.5, 2.75, 3, 3.5, 4, 5, 6, 7, 8, 10, 12, 16, 24, 36 and 48 hours after administration of the products.

Results

All 24 subjects completed both periods of the study and were eligible for pharmacokinetic analysis.

Table 2. Pharmacokinetic parameters (non-transformed values; arithmetic mean ± SD, t_{max} (median, range)) of pomalidomide, 4 mg under fasted conditions, additional study.

Treatment N=24	**AUC_{0-t} (ng.h/mL)**	**$AUC_{0-\infty}$ (ng.h/mL)**	**C_{max} (ng/mL)**	**t_{max} (h)**
Test	727 ± 147	740 ± 153	73 ± 17	2.00 (0.67 – 5.00)
Reference	692 ± 168	706± 175	72 ± 18	2.37 (0.67 – 5.00)
***Ratio (90% CI)**	1.06 (1.01-1.10)	---	1.01 (0.92-1.10)	---

$AUC_{0-\infty}$	Area under the plasma concentration-time curve from time zero to infinity
AUC_{0-t}	Area under the plasma concentration-time curve from time zero to the last measurable plasma concentration / to t = 48 hours
C_{max}	Maximum plasma concentration
t_{max}	Time after administration when maximum plasma concentration occurs
CI	Confidence interval

**ln-transformed values*

The design of the studies is acceptable. Pomalidomide may be taken without reference to food intake. From the literature it is known that food does not interact with the absorption of pomalidomide. Therefore, a food interaction study is not deemed necessary. The bioequivalence study under fasting conditions is in accordance with CPMP/EWP/QWP/1401/98 Note for Guidance on the investigation of bioavailability and bioequivalence.

Analytical/statistical methods

The analytical method has been adequately validated and is considered acceptable for analysis of the plasma samples. The methods used in this study for the pharmacokinetic calculations and statistical evaluation are considered acceptable.

Conclusion on bioequivalence studies:

- Study 1: The 90% confidence intervals calculated for AUC_{0-t}, $AUC_{0-\infty}$ and C_{max} are within the bioequivalence acceptance range of 0.80 – 1.25. Based on the submitted bioequivalence study 1, Pomalidomide Newbury 4 mg is considered bioequivalent with Imnovid 4 mg.

- Study 2: Based on the pharmacokinetic parameters of pomalidomide, Pomalidomide Newbury 4 mg is considered bioequivalent with Imnovid 4 mg with respect to the extent and rate of absorption under fasting conditions. The 90% confidence intervals calculated for AUC_{0-t} and C_{max} are within the bioequivalence acceptance range of 0.80 – 1.25.

The results of the bioequivalence studies with the 4 mg formulation can be extrapolated to lower strengths 1 mg, 2 mg and 3 mg, according to conditions in Guideline on the Investigation of Bioequivalence CPMP/EWP/QWP/1401/98 Rev. 1/Corr*, section 4.1.6.

The MEB has been assured that the bioequivalence study has been conducted in accordance with acceptable standards of Good Clinical Practice (GCP, see Directive 2005/28/EC) and Good Laboratory Practice (GLP, see Directives 2004/9/EC and 2004/10/EC).

IV.3 Risk Management Plan

The MAH has submitted a risk management plan, in accordance with the requirements of Directive 2001/83/EC as amended, describing the pharmacovigilance activities and interventions designed to identify, characterise, prevent or minimise risks relating to Pomalidomide Newbury hard capsules, 1 mg, 2 mg, 3 mg and 4 mg. At the time of approval, the most recent version of the RMP was version 0.3 dated 12 September 2024.

Table 3. Summary table of safety concerns as approved in RMP

Important identified risks	- Cardiac failure - Non-melanoma skin cancer - Severe infection due to neutropenia and pancytopenia - Teratogenicity - Thrombocytopenia and bleeding
Important potential risks	- Cardiac arrhythmia - Other second primary malignancies
Missing information	None

At the time of approval of this product, it was considered that additional risk minimisation measures (including educational material for healthcare professionals and patients) were necessary for the safe and effective use of the product. The educational material should be submitted by the MAH to the competent authorities of the Member States and its content and implementation should be agreed with the competent authorities prior to launch.

The educational Healthcare Professional's Kit must contain the following key elements:

- Educational Healthcare Professional brochure
- Educational brochures for patients
- Patient card
- Risk awareness forms
- Information where to find the latest Summary of Product Characteristics (SmPC)

The risk minimisation measures, the safety information in the proposed product information is aligned to the reference medicinal product. Besides routine risk minimisation measures, the applicant provides information on additional risk minimisation measures for the safety concerns 'teratogenicity', 'Thrombocytopenia and bleeding' and 'Cardiac failure', which consist of a PPP, HCP Educational Materials and Patient Educational Materials. Regarding additional pharmacovigilance activities, the applicant has included the monitoring of the implementation of the pregnancy prevention programme (PPP) as additional pharmacovigilance activity to investigate risks of teratogenicity, which is in line with the reference product RMP version 17.0. Safety updates will be submitted with future PSURs (as required per EURD list). Overall, the proposed safety specification, additional pharmacovigilance activities and the key elements are in line with the RMP of the reference product Imnovid (version 17.0) and are acceptable.

The Marketing Authorization Applicant (MAA) shall implement a pregnancy prevention program (PPP) in each Member State. Details of the PPP should be agreed with the National Competent Authorities in each Member State and put in place prior to the launch of the medicinal product.

The MAA should agree the final text of the contents of the Educational Healthcare Professional's Kit with the National Competent Authority in each Member State prior to launch of the medicinal product and ensure that the materials contain the key elements as described below.

The MAA should agree on the implementation of the controlled access programme in each Member State.

IV.4 Discussion on the clinical aspects

For this authorisation, reference is made to the clinical studies and experience with the innovator product Imnovid. No new clinical studies were conducted. The MAH demonstrated through a bioequivalence study that the pharmacokinetic profile of the product is similar to the pharmacokinetic profile of this reference product. Risk management is adequately addressed. This generic medicinal product can be used instead of the reference product.

V. USER CONSULTATION

The package leaflet (PL) has been evaluated via a user consultation study in accordance with the requirements of Articles 59(3) and 61(1) of Directive 2001/83/EC.

A user consultation with target patient groups on the package leaflet (PL) has been performed on the basis of a bridging report making reference to Imnovid 1 mg, 2 mg, 3 mg and 4 mg hard capsules, EU/1/13/850/001-008, EMEA/H/C/002682 for content and to Ticagrelor 60/90 mg film-coated tablets, EE/H/0338/001-002/DC for design and layout. The bridging report submitted by the MAH has been found acceptable; bridging is justified for both content and layout of the leaflet.

VI. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

Pomalidomide Newbury 1 mg, 2 mg, 3 mg and 4 mg, hard capsules, have a proven chemical-pharmaceutical quality and are generic forms of Imnovid 1 mg, 2 mg, 3 mg and 4 mg hard capsules. Imnovid is a well-known medicinal product with an established favourable efficacy and safety profile.

Bioequivalence has been shown to be in compliance with the requirements of European guidance documents.

This procedure was discussed in a Break-Out Session (BOS) and in a Board meeting. The following concerns were discussed:

At day 120 of the procedure, a quality major objection (MO) was raised regarding the dissolution limits. At day 160, the MAH has submitted an additional bioequivalence study (BE study 2) to support the dissolution limits. In the new bioequivalence study, the test bio batch used was a submission batch with up to 5% lower release compared to the initial test bio batch from BE study 1. Based on the BE study 2, the MAH proposed the new dissolution limits which are found acceptable. The dissolution similarity of the new BE batch with the former BE batch as well as with the reference product Imnovid has been adequately established. The RMS did not deem it necessary to repeat the dissolution similarity with all strengths, as the strength biowaiver was already supported with the former BE batch. However, there were still some concerns about the BE study 2 and the biowaiver. Therefore, a BOS was held with the MAH on 27 November 2024 to discuss a pharmacokinetic MO (raised by the RMS on day 180) relating to missing long-term stability data of the plasma samples from the BE study 2, and to discuss a potential serious risk to public health (PSRPH) (raised by a CMS on D195) relating to the biowaiver of strengths. The MO was also discussed in the Board meeting 1066 held on 21 November 2024. As requested, additional data was submitted by the MAH supporting the long-term stability of the samples and the biowaiver of strength. The concerns of the RMS and CMSs were all resolved before the end of the procedure (see section IV.2.). Furthermore, an automated referral was started on 11 December 2024 due to the RMS position switched from

negative to positive after day 205. However, agreement from all CMSs was received before this date. Therefore, the referral has been withdrawn and the day 210 date is kept as date of approval as well as for calculating the common renewal date.

There was no discussion in the CMD(h). Agreement between member states was reached during a written procedure. The member states, on the basis of the data submitted, considered that essential similarity has been demonstrated for Pomalidomide Newbury with the reference product, and have therefore granted a marketing authorisation. The decentralised procedure was finalised with a positive outcome on 11 December 2024.

STEPS TAKEN AFTER THE FINALISATION OF THE INITIAL PROCEDURE - SUMMARY

Procedure number	Scope	Product Information affected	Date of end of procedure	Approval/ non approval	Summary/ Justification for refuse
N.A.	N.A.	N.A.	N.A.	N.A.	N.A.