HUNGARIAN NATIONAL CENTER FOR PUBLIC HEALTH AND PHARMACY

Public Assessment Report

Scientific discussion

Dagetia 5mg and 10 mg film-coated tablets

(dapagliflozin propanediol monohydrate)

HU/H/0920/001-002/DC

Applicant:
PharmaPath S.A.

Date: 20.03.2026.

This module reflects the scientific discussion for the approval of Dagetia 5mg and 10 mg film-coated tablets. The procedure was finalised at Day 210, 12.08.2024**. For information on changes after this date please refer to the module 'Update'.**

I. INTRODUCTION

In accordance to the Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use, an application has been submitted to the reference and competent authorities of the Member State concerned.
This Decentralised Procedure application Reference member state, RMS: Hungary, concerned member states, CMSs:

HU/H/0916/001-002/DC (Dapagliflozin PharmaPath 5 mg and 10mg filmtabletta) CMS: MT
HU/H/0917/001-002/DC (Daperin 5mg and 10 mg filmtabletta) CMS: ES, PT
HU/H/0918/001-002/DC (Pazeral 5mg and 10 mg filmtabletta) CMS: ES, PL
HU/H/0919/001-002/DC (Dapibia 5mg and 10 mg filmtabletta) CMS: AT, CZ, PL
HU/H/0920/001-002/DC (Dagetia 5mg and 10 mg filmtabletta) CMS: BG, CZ, PL, RO, SK
HU/H/0921/001-002/DC (Zadegar 5mg and 10 mg filmtabletta) CMS: FR
HU/H/0922/001-002/DC (Dagidron 5mg and 10 mg filmtabletta) CMS: EL
HU/H/0923/001-002/DC (Pilagan 5mg and 10 mg filmtabletta) CMS: MT
HU/H/0924/001-002/DC (Dapazin 5mg and 10 mg filmtabletta) CMS: NL

concerned the generic version of *Forxiga 10 mg film-coated* tablets by AstraZeneca AB, registered since 12-11-2012.

The application has been filed pursuant to Article 10(1) of Directive 2001/83/EC and therefore contained no new clinical or preclinical data, other than supporting literature where necessary.
The reference product is *Forxiga 10 mg film-coated tablets* approved for more than 10 years within the European Economic Area.

Based on the review of the quality, safety and efficacy data, the Member States have granted marketing authorisations for Dapagliflozin 5 mg and 10mg filmtabletta.

A comprehensive description of the indications and posology is given in the Summary of Product Characteristics.

II. QUALITY ASPECTS

II.1 Introduction

The chemical-pharmaceutical assessment report concerns the application for Marketing Authorisation via the Decentralised Procedure (DCP) for products Dapagliflozin 5 mg and 10 mg film-coated tablets according to Article 10(1) of consolidated Directive 2001/83/EC (i.e. a generic application). The product has been developed by PharmaPath S.A.

In order to prove essential similarity, bioequivalence studies have been performed using the centrally authorised original products Forxiga 10 mg film-coated tablets (AstraZeneca AB), a biowaiver is requested for the 5 mg strength.

The finished dosage forms are film-coated tablets for oral administration, manufactured, packaged, tested and released by PharmaPath S.A., Greece.
GMP compliance of the product manufacture has been adequately proven.

The film-coated tablets contain 5 mg and 10 mg of the active substance dapagliflozin (as propanediol monohydrate).
The film-coated tablets are packed in Al/Al non-perforated blisters, Al/Al non-perforated calendar

blisters or Al/Al perforated unit dose blisters in a carton box.

II.2 Drug Substance (dapagliflozin propanediol monohydrate)

General information

INN name:	Dapagliflozin
Chemical name:	D-Glucitol, 1,5-anhydro-1-C-[4-chloro-3-[(4-ethoxyphenyl) methyl]phenyl]-, (1S)-, compounded with (2S)-1,2-propanediol, hydrate (1:1:1)

The active substance dapagliflozin is an established active substance, for which no Ph. Eur. monograph is in place, but a draft monograph for Dapagliflozin propylene glycol monohydrate has been published in Pharmeuropa 35.4 for comments, the Applicant's and API manufacturer's attention is drawn to this fact.
Dapagliflozin propanediol monohydrate is soluble in dimethyl sulphoxide and dimethyl formamide, sparingly soluble in ethanol (96%), practically insoluble in water and cyclohexane.

For dapagliflozin propanediol monohydrate, an Active Substance Master File in CTD-format has been provided by Metrochem API Private Ltd., India.

Manufacturing process
The active substance dapagliflozin propanediol monohydrate is manufactured by Metrochem API Private Ltd., India. See assessment of the ASMFs in separate assessment reports. All issues concerning the Restricted Part of the ASMF have been solved, which could affect the drug product manufacturer's API specification.

Quality control of drug substance
The drug substance parameters specified by the finished product manufacturer are identical to those specified by the active substance manufacturer, without any additional parameters. The specification is in general in accordance with the Ph. Eur. general monograph on Substances for pharmaceutical use and the ICH Q3A, Q3C and Q6A guidelines.
The specifications reflect all relevant quality attributes of the active substance and were found to be in general adequate to control the quality of the drug substance.

The analytical methods that are used by the drug product manufacturer for the analysis of the drug substance, are the same as described in the current ASMF.

Batch analysis data provided by the active substance manufacturer indicates the good performance of testing methods and demonstrate the batch-to-batch consistency of the production, this has been supplemented by acceptable results of batches measured by the drug product manufacturer.

Information presented on the reference standards is adequate.

The information provided on the packaging materials is available in the ASMF.

Stability of drug substance
Stability tests performed by the active substance manufacturer have been adopted by the drug product manufacturer.

GMP compliance of the active substance manufacture has been adequately demonstrated at this point.

II.3 Medicinal product

Description and composition
The drug products are film-coated tablets containing the equivalent of 5 mg and 10 mg of dapagliflozin in the form of propanediol monohydrate. The excipients used in the tablet cores are lactose monohydrate,

microcrystalline cellulose, crospovidone, povidone K-30, colloidal anhydrous silica, and magnesium stearate, while the film coating consist of polyvinyl alcohol part hydrolised, titanium dioxide, macrogol, and talc as well as yellow iron oxide. The tablet core compositions are dose-proportional. The dosage form is considered as standard.

- 5 mg: Yellow round bi-convex film-coated tablets, with '5' debossed on one side and plain on the other side.
- 10 mg: Yellow bi-convex oval film-coated tablets, with '10' debossed on one side and plain on the other side.

The products are packed in Aluminium-OPA/Al/PVC blisters. The excipients and packaging are usual for this type of dosage form.

The description and composition of the finished products are satisfactorily given.

Pharmaceutical development

The development of the product has been presented in detail.
General properties of the drug substance have been satisfactorily described. Standard excipients were selected, their functions are indicated. The excipients are in adequate concentration for the proposed dosage form.

The aim of the development work was to formulate film-coated tablets for oral administration, equivalent to the reference product Forxiga film-coated tablets (AstraZeneca AB).

The impurity profiles have been compared: test product batches show similar levels for assay and impurities as the European innovator Forxiga.

Bioequivalence studies (BEQ) have been performed comparing the test product Dapagliflozin 10 mg film-coated tablets (batch no. DPG10P2) of production scale size 100 000 pcs to Forxiga 10 mg film-coated tablets (batch no. TAUE).
Comparative dissolution data of the developed Dapagliflozin film-coated tablets and the reference product used in the BEQ studies in different dissolution media have been presented. Over 85% of the drug is dissolved within 15 minutes in all media.

Biowaiver has been requested for the lower strength. The presented data support the biowaiver request.

The description of the manufacturing process development is satisfactory.

Manufacturing process

The drug product is manufactured by PharmaPath, Greece.

The process steps include a blending step of the API with part of the excipients, wet granulation followed by addition of further excipients, lubrication, compression and coating, finally the film-coated tablets are packaged. These constitute a standard manufacturing process.
Presentation of the manufacturing process and in-process controls is satisfactory.

Based on the presented process validation report, the manufacturing process is robust and reproducible, giving a product in compliance with the specifications.

Excipients

All excipients comply with the respective Ph. Eur. monographs, except for iron oxides, which comply with EU 231/2012. The drug product manufacturer has in-house specifications for the coating material.
The TSE/BSE status of the relevant excipients is acceptably confirmed.
All specifications are acceptable.

Quality control of drug product
The product specification includes tests for appearance and dimensions, identification of the active substance, uniformity of dosage units (content uniformity), dissolution, assay, related substances, and microbiological purity. The attention of the Applicant is drawn to the fact that a draft monograph for Dapagliflozin propylene glycol tablets has been published in Pharmeuropa 35.4 for comments.
The limits are acceptable at present, the limit for unknown impurities will be re-evaluated as more stability data become available.

The analytical methods have been adequately described and adequate method validation data have been provided.

Batch analytical data are satisfactory.

The discussion of impurities is adequate. The nitrosamine risk assessment is acceptable.

The section on reference materials is adequate.

The container closure system comprising Aluminium-OPA/Al/PVC blisters is satisfactorily described. The primary packaging for in-process and bulk holding storage is also adequately described.

Stability of drug product
The conditions used in the stability studies are according to the ICH stability guideline, applying an acceptable matrixing design.

- Finished product:
The following results have been presented:
Long-term (25°C/60% RH) data have been presented in the document up to 12 months
Accelerated conditions (40°C/75% RH) data have been presented in the document up to 6 months.

The proposed shelf-life of 24 months with no special storage conditions is acceptable.

- Bulk product:
The holding time studies are satisfactory.

Samples were packed in the packaging material described in section P.7. Monitored parameters and specified limits correspond to those listed in the shelf-life specifications (P.5.1.)

All results conform to the proposed specifications to the presented time-points.

Photostability studies have been performed, the product is not sensitive to light.

The post approval stability commitment for the finished product is acceptable.

SPC, PIL, label
The pharmaceutical data in the SPC, PIL and label are acceptable.

Commitments

1. The Applicant commits to repeat the study for Bulk holding time on the first commercial batches. Final blends of the first commercial scale validation batches will be stored for 30 days (or more) and finished product batches manufactured from these stored blends will be put on the stability programme to verify the proposed holding time for the final blend.

2. The applicant commits that as more stability results become available, the unknown impurities will be re-evaluated, if necessary.

III. NON-CLINICAL ASPECTS

III.1 Introduction

The applications were submitted as generic medicinal products in accordance with Article 10(1) of Directive 2001/83/EC.

No new non-clinical studies were submitted with the applications. This approach is considered acceptable for generic applications, since the active substance dapagliflozin is well known and its pharmacological, pharmacokinetic and toxicological properties have been extensively characterised.

The Applicant provided a non-clinical overview based on a review of the published literature describing the pharmacology, pharmacokinetics and toxicology of dapagliflozin. The overview summarises available information from non-clinical studies and publicly available regulatory documents.

III.2 Pharmacology

Dapagliflozin is a selective inhibitor of sodium-glucose co-transporter-2 (SGLT2), which is predominantly expressed in the proximal renal tubules. Inhibition of SGLT2 reduces renal glucose reabsorption and increases urinary glucose excretion, leading to a reduction in plasma glucose concentrations. The pharmacological mechanism of action is well established.

III.3 Pharmacokinetics

The pharmacokinetic profile of dapagliflozin has been characterised in animal models and shows adequate oral absorption, distribution and metabolism. Elimination occurs mainly via metabolic pathways with subsequent excretion in urine and faeces.

III.4 Toxicology

The non-clinical safety profile of dapagliflozin has been evaluated in a comprehensive non-clinical development programme including studies on repeat-dose toxicity, genotoxicity, carcinogenicity, reproductive and developmental toxicity and safety pharmacology.

No genotoxic potential has been identified in standard *in vitro* and *in vivo* studies. Carcinogenicity studies did not reveal a treatment-related increase in tumour incidence that would be considered relevant for humans.

Reproductive and developmental toxicity studies did not demonstrate significant adverse effects on fertility or embryofetal development at clinically relevant exposures. However, as with other SGLT2 inhibitors, findings in juvenile animals indicated potential effects on the developing kidney, which is reflected in the warnings and precautions included in the product information.

III.5 Ecotoxicology/environmental risk assessment (ERA)

Since Dapagliflozin film coated tablets is intended for generic substitution, this will not lead to an increased exposure to the environment. An environmental risk assessment is therefore not deemed necessary.

III.6 Discussion on the non-clinical aspects

Overall, the non-clinical safety profile of dapagliflozin is well characterised and does not raise concerns for the proposed indications and dosing regimen.

Taking into account the well-established non-clinical profile of dapagliflozin and the generic nature of the application, the absence of new non-clinical studies is considered acceptable.

The RMS considers that the non-clinical aspects of the applications are **acceptable**.

IV. CLINICAL ASPECTS

IV.1 Introduction

The applications concern dapagliflozin 5 mg and 10 mg film-coated tablets submitted as generic medicinal products in accordance with Article 10(1) of Directive 2001/83/EC.

Dapagliflozin is a selective sodium-glucose co-transporter-2 (SGLT2) inhibitor used in the treatment of type 2 diabetes mellitus, chronic heart failure and chronic kidney disease. The active substance reduces renal glucose reabsorption and increases urinary glucose excretion, thereby lowering blood glucose levels via a mechanism that is independent of insulin.

The reference medicinal product is authorised in the European Union more than 10 years and has an established efficacy and safety profile.

The Applicant submitted a clinical overview based on published literature and provided a bioequivalence study comparing the 10mg strength test product with the reference medicinal product (*Forxiga 10 mg film-coated* tablets by AstraZeneca AB, registered since 12-11-2012).

IV.2 Pharmacokinetics

The pharmacokinetic properties of dapagliflozin are well established.

Dapagliflozin is rapidly absorbed following oral administration, with peak plasma concentrations generally reached within approximately 2 hours. The absolute oral bioavailability is high. The compound is extensively bound to plasma proteins and undergoes metabolism primarily via glucuronidation.

Elimination occurs mainly via renal and hepatic pathways, with the majority of the administered dose recovered as metabolites. The pharmacokinetics of dapagliflozin are generally dose-proportional over the therapeutic dose range.

IV.3 Pharmacodynamics

Dapagliflozin selectively inhibits SGLT2 in the proximal renal tubules, reducing glucose reabsorption and promoting urinary glucose excretion. This mechanism results in decreased plasma glucose concentrations in patients with type 2 diabetes mellitus.

In addition to its glucose-lowering effects, dapagliflozin has been shown to provide beneficial effects on cardiovascular and renal outcomes in appropriate patient populations.

IV.4 Clinical efficacy

The clinical efficacy of dapagliflozin has been demonstrated in numerous clinical trials involving patients with type 2 diabetes mellitus, heart failure and chronic kidney disease.

Treatment with dapagliflozin has been shown to improve glycaemic control, as measured by reductions in glycated haemoglobin (HbA1c), and to contribute to weight reduction and modest decreases in blood pressure.

In addition, large outcome trials have demonstrated cardiovascular and renal benefits in relevant patient populations.

Given that the application concerns a generic medicinal product, demonstration of bioequivalence with the reference medicinal product is considered sufficient to bridge efficacy data.

IV.5 Clinical safety

The safety profile of dapagliflozin is well established.

The most commonly reported adverse reactions include genital infections and urinary tract infections. Hypoglycaemia may occur when dapagliflozin is used in combination with insulin or insulin secretagogues.

Rare but serious adverse reactions may include diabetic ketoacidosis and volume depletion.

Overall, the safety profile of dapagliflozin is well characterised through extensive clinical use.

IV.6 Clinical studies

GCP aspects

A statement on the application of appropriate GCP standards in the submitted study has been provided. The study commenced only after a written approval was obtained from the Conscience Independent Ethics Committee. The study was conducted in accordance with the protocol, relevant SOPs of Cliantha Research, pertinent requirements of 'EMA', ICH 'Guidance on Good Clinical Practice', the ICMR Ethical guidelines, Declaration of Helsinki and all applicable Indian regulatory requirements. All associates assisting in the conduct of study were informed regarding their obligations.

Study C1B02732: 10 mg single-dose, fasting

To support the application, the applicant has submitted as report one (1) open label, randomized, two-period, two-treatment, two-sequence, crossover, balanced, single dose oral bioequivalence study in healthy, adult, human subjects under fasting conditions.
This is considered adequate for an immediate release single unit formulation, where the SmPC recommends intake under fasting or fed conditions, as it is in case of Dapagliflozin, since fasting conditions represent the most sensitive condition to detect a potential difference between formulations, until no special requirements are demanded.

Study Design

Title of the study:
Single dose oral bioequivalence study of Dapagliflozin Film Coated Tablets 10 mg and Forxiga film-coated tablets 10 mg in healthy adult human subjects under fasting conditions.

Short description of the study

An open label, randomized, two-period, two treatment, two-sequence, crossover, balanced, single dose oral bioequivalence study.

The study population showed the following features

Healthy adult, human volunteers, non- smokers, non-tobacco and non-alcoholic users (i.e. had no past history of smoking, tobacco and alcohol consumption for at least one year prior

to study), 18 to 45 years old (both inclusive), had body weight more than 50 kg with a Body Mass Index (BMI) 18.5 to 30.0 kg/m2 both inclusive, who were judged as healthy on the basis of a pre-study physical examination (clinical examination) and clinical laboratory tests.
Based on the sample size estimates, a sample size of 43 subjects were to be sufficient to establish bioequivalence with adequate power. Considering dropouts and withdrawals, 52 subjects were enrolled.

Drug intake procedures

After an overnight fasting of at least 08 hours, a single 10 mg oral dose of investigational product was administered to the subjects as per the randomization schedule in a sitting posture with about 240 mL of 20% glucose water at ambient temperature in each period under the supervision of trained study personnel. Investigational products (Test or Reference) were swallowed whole and were not chewed, crushed or divided. Immediately after dose administration oral cavity and hands were checked to confirm medication and fluid consumption. 60 mL of 20% glucose solution in water was provided to the subjects approximately at every 01 hour up to 04 hours post dose in each period. No signs or symptoms of hypoglycemia occurred during the study.
The interval between doses was 07 days.

Sampling schedule

In each period, total 22 venous blood samples (05 mL each) were collected in vacutainers containing K3EDTA at pre-dose (0.0 hour) and at 0.25, 0.5, 0.75, 1.0, 1.25, 1.50, 1.75, 2.0, 2.333, 2.667, 3.0, 3.50, 4.0, 5.0, 6.0, 8.0, 10.0, 12.0, 16.0, 24.0 and 48.0 hours post dose. The samples were collected in prelabelled vacutainers (protocol number, subject number, period number, sampling time point, sample number as per Master sheet of Cliantha Research).
The pre-dose (0.0 hour) blood samples were collected within 120 minutes prior to dosing in each period. All post-dose samples from 0.25 to 24.0 hours were collected within +2 minutes of the scheduled time and the ambulatory blood sample 48.0 was collected within +60 minutes of the scheduled time in each period.

Bioanalysis

Dapagliflozin was measured with validated LC/MS/MS method.
Analytical Report, Method Validation, relevant SOPs and QA statement were attached. The analytical method was acceptable.

Pharmacokinetic Variables

- Primary pharmacokinetic parameters: Cmax and AUC0-t
- Secondary pharmacokinetic parameters: AUCinf, Tmax, Kel, AUC_%Extrap_obs and tHalf

Statistics applied for the assessment of pharmacokinetic parameters

Statistical analysis was performed on population defined in section 9.7.1 (A) using SAS® statistical software (Version: 9.4; SAS Institute Inc, USA).
Bioequivalence criteria: The 90% confidence interval of the relative mean (geometric least square mean) of the test to reference product for Ln-transformed pharmacokinetic parameters Cmax and AUC0-t was to be within 80.00% to 125.00% for Dapagliflozin to establish bioequivalence.

Test & Reference Geometric mean, Ratio, 90% Confidence Intervals, Acceptance Criteria and Outcome of BE result based on Ln-transformed data for Dapagliflozin

Pharmacokinetic parameter	Geometric mean				Ratio (%)
	N	Test	N	Reference	
Cmax (ng/mL)	49	123.208	49	127.842	96.38
AUCt (ng /mL)*(hr)	49	537.133	49	546.981	98.20
Pharmacokinetic parameter	**90% Confidence Intervals**		**Acceptance Criteria**		**Outcome of BE result**
Cmax (ng/mL)	(92.22%;100.72%)		80.00% - 125.00%		Bioequivalent
AUCt (ng/mL)*(hr)	(96.58%; 99.84%)		80.00% - 125.00%		

Safety results
A total of two (02) adverse events were reported by two (02) subjects during the entire study.
AEs were mild in severity. There was one (01) AE (White Blood Cell Count Increased) which was considered unlikely related to the test product T. There was one (01) AE (White Blood Cell Count Increased) which was considered unlikely related to the reference product R.
No severe, serious or life-threatening adverse events were reported during the course of the study.

IV.7 Biowaiver

The applicant requested a biowaiver for the 5 mg strength.
Conditions requested by "Guideline On The Investigation Of Bioequivalence" CPMP/EWP/QWP/1401/98 Rev. 1/ Corr ** were fulfilled. Consequently, a biowaiver for the 5mg strength formulation was granted.

IV.8 Conclusion

Based on the results provided, it could be concluded, that the Test product Dapagliflozin 10 mg Film-Coated Tablets is bioequivalent with the Reference product Forxiga® Dapagliflozin 10 mg film-coated tablets, under fasting conditions. Biowaiver for the 5 mg strength was granted.

IV.9 Pharmacovigilance

Product's name: Dagetia 5mg and 10 mg film-coated tablets
Active substance: Dapagliflozin propanediol monohydrate
MAH: Medochemie Ltd., Cyprus
Reference number: HU/H/0920/001-002/DC

IV.9.1 Summary of the Pharmacovigilance System

On Day 2014 the Applicant (PharmaPath) submitted a signed Summary of the Applicant's/MAH Pharmacovigilance System (version number: 1.0, dated on 10.12.2024).
In meanwhile MAH transfer was performed to Medochemie Ltd., Cyprus, in HU, CZ, SK, RO and BG and a Summary of Pharmacovigilance System Master File (PSMF) of this Company was acknowledged in the HU/H/0920/001-002/IA/002 procedure on 18.02.2026.

Provided that the Pharmacovigilance System Master File fully complies with the new legal requirements as set out in the Commission Implementing Regulation 520/2012 and as detailed in the relevant GVP module, the Summary is considered acceptable.

IV.9.2 Risk Management Plan (closing sequence, version number: 1.0, dated on 10.12.2024)

- **Summary of safety concerns**

Summary of safety concerns	
Important identified risks	• Diabetic Ketoacidosis including events with atypical presentation
Important potential risks	• Bladder cancer • Breast cancer • Prostate cancer • Lower limb amputation
Missing information	• Use in patients with NYHA class IV • Long-term safety in the paediatric population (aged 10 years and above)

The summary list of safety concerns is acceptable, as it complies with the reference product's updated RMP (Forxiga film-coated tablets, Version number: 29.0, data lock point: 17-01-2023).

- **Pharmacovigilance Plan**

Routine pharmacovigilance activities are considered sufficient to manage all of the safety concerns connected to Dagetia 5mg and 10 mg film-coated tablets.No additional activities are proposed.
However, follow-up questionnaires are in place in the originator's RMP as routine pharmacovigilance activities beyond ADRs reporting and signal detections for the following risks:

- Bladder cancer, breast cancer and prostate cancer
- Lower limb amputations
- Diabetic ketoacidosis

Applicant introduced these questionnaires in Part III.1 of the submitted RMPs and attached them into Annex 4.

- **Risk Minimisation Measures**

Routine risk minimisation measures (i.e. wording in SmPC, PL and classification as a prescription only medicine) are considered sufficient to manage all of the safety concerns connected to Dagetia 5mg and 10 mg film-coated tablets. No additional activities are proposed. For any further information on risk minimisation, please refer to the product information.

IV.9.3 Periodic Safety Update Reports

The requirements for submission of periodic safety update reports for this medicinal product are set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and any subsequent updates published on the European medicines web-portal.

IV.10 Discussion on the clinical aspects

Abridged applications avoid the need for repetitive tests on animals and humans. For these application the bioequivalence (as described in section IV.2) is pivotal.

V. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

V.1 Summary

The submitted documentation is administratively adequate and scientifically sound. The quality of the product is satisfactory. There were no non-clinical or clinical concerns raised.

The therapeutic benefit/risk assessment is, therefore, **positive**.

V.2 Classification

The Product is subject of medicinal prescription only.

V.3 Package Leaflet and user consultation

The package leaflet 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. The language used for the purpose of user testing the patient information leaflet was English.

Modul 6
Steps taken after the initial procedure with an influence on the Public Assessment Report

Procedure number	Type of modification [1]	Date of start of the procedure	Date of end of procedure	Approval/non approval
HU/H/0920/1-2/IB/001	C.I.z). Other variation	2025.12.19	2026.01.18	Approved
HU/H/0920/1-2/IA/002	C.I.8.a). Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location	2026.01.19	2026.02.18	Positive