PUBLIC ASSESSMENT REPORT
of the Medicines Evaluation Board
in the Netherlands

Irbesartan Hydrochlorothiazide Torrent 150 mg/12.5 mg, 300 mg/12.5 mg and 300 mg/25 mg, film-coated tablets
Torrent Pharma GmbH, Germany

irbesartan / hydrochlorothiazide

This assessment report is published by the MEB pursuant Article 21 (3) and (4) of Directive 2001/83/EC. The report comments on the registration dossier that was submitted to the MEB and its fellow –organisations in all concerned EU member states.
It reflects the scientific conclusion reached by the MEB and all concerned member states at the end of the evaluation process and provides a summary of the grounds for approval of a marketing authorisation.
This report is intended for all those involved with the safe and proper use of the medicinal product, i.e. healthcare professionals, patients and their family and carers. Some knowledge of medicines and diseases is expected of the latter category as the language in this report may be difficult for laymen to understand.

This assessment report shall be updated by a following addendum whenever new information becomes available.

General information on the Public Assessment Reports can be found on the website of the MEB.

To the best of the MEB’s knowledge, this report does not contain any information that should not have been made available to the public. The MAH has checked this report for the absence of any confidential information.

EU-procedure number: NL/H/2067/001-003/DC
Registration number in the Netherlands: RVG 107931-32, 107935

20 December 2011

Pharmacotherapeutic group: angiotensin II antagonists, plain
ATC code: C09CA04
Route of administration: oral
Therapeutic indication: essential hypertension in adult patients whose blood pressure is not adequately controlled on irbesartan or hydrochlorothiazide alone

Prescription status: prescription only
Date of first authorisation in NL: 3 November 2011
Concerned Member States: Decentralised recognition procedure with DE, LT, RO, UK
Application type/legal basis: Directive 2001/83/EC, Article 10(1)

For product information for healthcare professionals and users, including information on pack sizes and presentations, see Summary of Product Characteristics (SPC), package leaflet and labelling.
I  INTRODUCTION

Based on the review of the quality, safety and efficacy data, the member states have granted a marketing authorisation for Irbesartan Hydrochlorothiazide Torrent 150 mg/12.5 mg, 300 mg/12.5 mg and 300 mg/25 mg, film-coated tablets from Torrent Pharma GmbH. The date of authorisation was on 3 November 2011 in the Netherlands.

The product is indicated for treatment of essential hypertension. This fixed dose combination is indicated in adult patients whose blood pressure is not adequately controlled on irbesartan or hydrochlorothiazide alone.

A comprehensive description of the indications and posology is given in the SPC.

Irbesartan/hydrochlorothiazide is a combination of an angiotensin II receptor antagonist, irbesartan, and a thiazide diuretic, hydrochlorothiazide. The combination of these ingredients has an additive antihypertensive effect, reducing blood pressure to a greater degree than either component alone.

Irbesartan is a potent, orally active, selective angiotensin-II receptor (AT1 subtype) antagonist. It is expected to block all actions of angiotensin-II mediated by the AT1 receptor, regardless of the source or route of synthesis of angiotensin-II. The selective antagonism of the angiotensin-II (AT1) receptors results in increases in plasma renin levels and angiotensin-II levels, and a decrease in plasma aldosterone concentration. Serum potassium levels are not significantly affected by irbesartan alone at the recommended doses in patients without risk of electrolyte imbalance. Irbesartan does not inhibit ACE (kinase-II), an enzyme which generates angiotensin-II and also degrades bradykinin into inactive metabolites. Irbesartan does not require metabolic activation for its activity.

Hydrochlorothiazide is a thiazide diuretic. The mechanism of antihypertensive effect of thiazide diuretics is not fully known. Thiazides affect the renal tubular mechanisms of electrolyte reabsorption, directly increasing excretion of sodium and chloride in approximately equivalent amounts. The diuretic action of hydrochlorothiazide reduces plasma volume, increases plasma renin activity, increases aldosterone secretion, with consequent increases in urinary potassium and bicarbonate loss, and decreases in serum potassium. Presumably through blockade of the renin-angiotensin-aldosterone system, co-administration of irbesartan tends to reverse the potassium loss associated with these diuretics.

This decentralised procedure concerns a generic application claiming essential similarity with the innovator product CoAprovel 150/12.5 mg, 300/12.5 mg and 300/25 mg, film-coated tablets (EU License EU/1/98/086/016-022) which have been registered through the centralised procedure by Sanofi Pharma Bristol-Myers Squibb SNC since 15 October 1998. Further information can be found in the EPAR of CoAprovel (http://www.ema.europa.eu/htms/human/epar/).

The marketing authorisation is granted based on article 10(1) of Directive 2001/83/EC.

This type of application refers to information that is contained in the pharmacological-toxicological and clinical part of the dossier of the authorisation of the reference product. A reference product is a medicinal product authorised and marketed on the basis of a full dossier, i.e. including chemical, biological, pharmaceutical, pharmacological-toxicological and clinical data. This information is not fully available in the public domain. Authorisations for generic products are therefore linked to the ‘original’ authorised medicinal product, which is legally allowed once the data protection time of the dossier of the reference product has expired. For this kind of application, it has to be demonstrated that the pharmacokinetic profile of the product is similar to the pharmacokinetic profile of the reference product. To this end the MAH has submitted one bioequivalence study in which the pharmacokinetic profile of the product is compared with the pharmacokinetic profile of the reference product CoAprovel 300/25 mg tablets, registered in the EEA. A bioequivalence study is the widely accepted means of demonstrating that difference of use of different excipients and different methods of manufacture have no influence on efficacy and safety. This generic product can be used instead of its reference product.
No new pre-clinical and clinical studies were conducted, which is acceptable for this abridged application.

No scientific advice has been given to the MAH with respect to these products, and no paediatric development programme has been submitted, as this is not required for generic medicinal products.

II SCIENTIFIC OVERVIEW AND DISCUSSION

II.1 Quality aspects

Compliance with Good Manufacturing Practice
The MEB has been assured that acceptable standards of GMP (see Directive 2003/94/EC) are in place for these product types at all sites responsible for the manufacturing of the active substance as well as for the manufacturing and assembly of this product prior to granting its national authorisation.

Active substance

Irbesartan

Irbesartan, an established active substance described in the European Pharmacopoeia (Ph.Eur.*), is a white or almost white crystalline powder, which is practically insoluble in water, sparingly soluble in methanol, and slightly soluble in ethanol, acetone and in methylene chloride. Irbesartan structure contains neither chiral nor asymmetric Carbon atom in its structure and hence does not exhibit isomerism.

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 4 steps and has been well described. A process flow diagram, route of synthesis and brief description of the manufacturing process have been included. The starting material and solvents have been sufficiently specified.

Quality control of drug substance
The drug substance specification is in line with the Ph.Eur. with additional in-house tests and limits for particle size. The specification is acceptable in view of the route of synthesis and the various European guidelines. Batch analytical data demonstrating compliance with the drug substance specification have been provided for two production-scale batches.

Stability of drug substance
Stability data on the active substance have been provided for three full-scale and three pilot-scale batches stored at 30°C/65% RH (3 batches for 6 months and 3 batches for 24 months) and 40°C/75% RH(6 months). No changes or trends were observed. The granted retest period is 30 months with the storage condition "Preserve in tight containers and store at a temperature below 30°C”.

Hydrochlorothiazide

Hydrochlorothiazide (HCTZ) is an established active substance described in the Ph. Eur. This active substance is a white or almost white crystalline powder, which is very slightly soluble in water, soluble in
acetone and slightly soluble in ethanol (96%). It dissolves in dilute solutions of alkali hydroxides. Hydrochlorothiazide does not have any chiral center; hence does not exhibit optical isomerism.

* Ph.Eur. is an official handbook (pharmacopoeia) in which methods of analysis with specifications for substances are laid down by the authorities of the EU.

**Medicinal Product**

**Composition**

Irbesartan Hydrochlorothiazide Torrent 150 mg/12.5 mg is pinkish orange coloured oval shaped, biconvex film-coated tablets, debossed with "L183" on one side and plain on other side.

Irbesartan Hydrochlorothiazide Torrent 300 mg/12.5 mg is a pale pink with orange shade coloured, oval shaped, biconvex film-coated tablets, debossed with "L184" on one side and plain on other side.

Irbesartan Hydrochlorothiazide Torrent 300 mg/25 mg is a pinkish brown, oval shaped, biconvex film-coated tablets, debossed with "L185" on one side and plain on other side.

The film-coated tablets are packed in PVC/PVDC/Aluminium blisters.

The excipients are:

**Core** – lactose monohydrate, croscarmellose sodium, povidone K-30, iron oxide red (E172), iron oxide yellow (E172), magnesium stearate.

**Film-coating** – iron oxide red (E172), iron oxide yellow (E172), hypromellose 5 cP, lactose monohydrate, macrogol 4000, titanium dioxide (E171).

The 150/12.5 mg tablets are dose proportional to the 300/25 mg strength. The composition of the 300/25 and 300/12.5 mg tablets is similar with the exemption of the amount of hydrochlorothiazide. The amount of hydrochlorothiazide is less than 5% of the total weight.

**Pharmaceutical development**

The development of the product has been described, the choice of excipients and packaging is justified and their functions explained.

A bioequivalence study was performed with the 300/25 mg tablet strength against the reference product CoAprovel film-coated tablets 300/25 mg manufactured by Sanofi-Aventis (UK product). The obtained results indicate that the test batch is bioequivalent to the reference product. From a chemical-pharmaceutical point of view the biowaiver for the 150/12.5 and 300/12.5 mg strengths is accepted. Comparative dissolution profiles of the 300/25 mg test product versus 300/12.5 mg and 150/12.5 mg test product in pH 4.5 and pH 6.8 media have been provided demonstrating comparable dissolution. The pharmaceutical development has been described in sufficient detail.

**Manufacturing process**

The manufacturing process consists of wet granulation, mixing, tableting and coating. The product is manufactured using conventional manufacturing techniques. Process validation has been performed on three production-scale batches of each strength. It has been demonstrated that the manufacturing process can adequately produce a product that is in line with the specifications. The results from the process validation have been included in the dossier.

**Control of excipients**

The excipients comply with the Ph.Eur. with some additional tests. These specifications are acceptable.

**Quality control of drug product**

The product specification includes tests for description, identification of irbesartan and titanium oxide, average mass, uniformity of mass, disintegration time, loss on drying, dissolution, uniformity of dosage units, assay, related substances and microbiological quality. A difference was made between release and shelf-life limits for loss on drying. The analytical methods have been adequately described and validated. Batch analytical data from the proposed production site have been provided on three full-scale batches per strength, demonstrating compliance with the release specification.
Stability of drug product
Stability data on the product has been provided for three full-scale batches per strength stored at 25°C/60% RH (24 months) and 40°C/75% RH (6 months). The conditions used in the stability studies are according to the ICH stability guideline. The batches were stored in the proposed PVC/PVdC-Al blister packaging. At accelerated conditions an increase in water content, impurity B and total impurities was observed. At long term conditions no trends were observed. The product was shown to be photostable. Based on the included stability data the proposed shelf life of 36 months was granted, when stored in a PVC/PVdC-Al blister without special storage condition.

Specific measures concerning the prevention of the transmission of animal spongiform encephalopathies
The lactose monohydrate is of milk sourced from healthy animals in the same conditions as milk collected for human consumption and the lactose is prepared without the use of other ruminant materials than calf rennet. Magnesium stearate is of vegetable origin.

II.2 Non-clinical aspects
These products are generic formulations of CoAprovel, which is available on the European market. No new preclinical data have been submitted, and therefore the application has not undergone preclinical assessment. This is acceptable for this type of application.

Environmental risk assessment
The product is intended as a substitute for other identical products on the market. The approval of this product will not result in an increase in the total quantity of irbesartan or hydrochlorothiazide released into the environment. It does not contain any component, which results in an additional hazard to the environment during storage, distribution, use and disposal.

II.3 Clinical aspects
Irbesartan and hydrochlorothiazide are well-known active substances with established efficacy and tolerability.

For this generic application, the MAH has submitted a bioequivalence study in which the pharmacokinetic profile of the test product Irbesartan Hydrochlorothiazide Torrent 300 mg/25 mg (Torrent Pharma GmbH, Germany) is compared with the pharmacokinetic profile of the reference product CoAprovel 300/25 mg (Sanofi Pharma BMS Ltd, France).

The choice of the reference product
CoAprovel 300/25 mg tablets are registered via the centralised procedure and hence are presumed to be identical in all member states of the EEA.

The formula and preparation of the bioequivalence batch is identical to the formula proposed for marketing.

Design
A single-dose, randomised, two-period, two-treatment, two-sequence, crossover bioequivalence study was carried out under fasted conditions in 44 healthy male subjects, aged 18-37 years. Each subject received a single dose (300 mg/25 mg) of one of the two formulations. The tablet was orally administered with 240 ml water after a fasting period of 10 hours. Breakfast was provided 4 hours upon drug administration. There were 2 dosing periods, separated by a washout period of 7 days.

Blood samples were collected pre-dose and at 0.5, 0.75, 1, 1.25, 1.5, 1.75, 2, 2.25, 2.5, 2.75, 3, 3.25, 3.5, 4, 5, 6, 8, 10, 12, 24, 36, 48 after administration of the products.

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

**Results**

Three subjects dropped out of the study. Two subjects did not show up for the second period and one subject was tested positive on alcohol breath just before the second period. Pharmacokinetic and statistical analysis was performed on data from 41 subjects.

**Table 1.** Pharmacokinetic parameters (non-transformed values; arithmetic mean ± SD, \( t_{\text{max}} \) (median, range)) of irbesartan under fasted conditions.

<table>
<thead>
<tr>
<th>Treatment</th>
<th>( \text{AUC}_{0-t} ) µg.h/ml</th>
<th>( \text{AUC}_{0-\infty} ) µg.h/ml</th>
<th>( C_{\text{max}} ) µg/ml</th>
<th>( t_{\text{max}} ) h</th>
<th>( t_{1/2} ) h</th>
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<tbody>
<tr>
<td><strong>Test</strong></td>
<td>17.91 ± 5.82 18.4 ± 5.98 3.70 ± 1.09</td>
<td>1.25 (0.50 – 4.0)</td>
<td>8.89 ± 3.14</td>
<td></td>
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<tr>
<td><strong>Reference</strong></td>
<td>19.8 ± 6.14 20.3 ± 6.15 3.42 ± 0.92</td>
<td>2.25 (0.75 – 4.5)</td>
<td>7.67 ± 1.82</td>
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<tr>
<td>*Ratio (90% CI)</td>
<td>0.91 (0.85 – 0.97) 0.91 (0.85 – 0.97) 1.08 (1.00 – 1.16)</td>
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<tr>
<td>CV (%)</td>
<td>17.6 17.9 19.3 -- --</td>
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</table>

\( \text{AUC}_{0-t} \): area under the plasma concentration-time curve from time zero to t hours

\( \text{AUC}_{0-\infty} \): area under the plasma concentration-time curve from time zero to infinity

\( C_{\text{max}} \): maximum plasma concentration

\( t_{\text{max}} \): time for maximum concentration

\( t_{1/2} \): half-life

\*ln-transformed values

**Table 2.** Pharmacokinetic parameters (non-transformed values; arithmetic mean ± SD, \( t_{\text{max}} \) (median, range)) of hydrochlorothiazide under fasted conditions.

<table>
<thead>
<tr>
<th>Treatment</th>
<th>( \text{AUC}_{0-t} ) µg.h/ml</th>
<th>( \text{AUC}_{0-\infty} ) µg.h/ml</th>
<th>( C_{\text{max}} ) µg/ml</th>
<th>( t_{\text{max}} ) h</th>
<th>( t_{1/2} ) h</th>
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<tr>
<td><strong>Test</strong></td>
<td>1304 ± 393 1351 ± 394 181 ± 52</td>
<td>1.75 1.00 – 4.00</td>
<td>8.52 ± 1.04</td>
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<tr>
<td><strong>Reference</strong></td>
<td>1322 ± 407 1374 ± 411 181 ± 64</td>
<td>1.75 1.00 – 4.50</td>
<td>8.69 ± 1.58</td>
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<tr>
<td>*Ratio (90% CI)</td>
<td>1.00 0.94 – 1.06 0.99 (0.94 – 1.05) 1.02 0.95 – 1.10</td>
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<tr>
<td>CV (%)</td>
<td>15.7 15.9 20.7 -- --</td>
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\( \text{AUC}_{0-t} \): area under the plasma concentration-time curve from time zero to t hours

\( \text{AUC}_{0-\infty} \): area under the plasma concentration-time curve from time zero to infinity

\( C_{\text{max}} \): maximum plasma concentration

\( t_{\text{max}} \): time for maximum concentration

\( t_{1/2} \): half-life

\*ln-transformed values

The 90% confidence intervals calculated for \( \text{AUC}_{0-t} \), \( \text{AUC}_{0-\infty} \) and \( C_{\text{max}} \) are in agreement with those calculated by the MAH and are within the bioequivalence acceptance range of 0.80–1.25. Based on the pharmacokinetic parameters of irbesartan and hydrochlorothiazide under fasted conditions, it can be concluded that Irbesartan Hydrochlorothiazide Torrent 300 mg/25 mg and CoAprovel 300 mg/25 mg film-
coated tablets are bioequivalent with respect to rate and extent of absorption, and fulfil the bioequivalence requirements outlined in the relevant CHMP Note for Guidance.

Irbesartan Hydrochlorothiazide may be taken without reference to food intake. From the literature it is known that food does not interact with the absorption. 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.

**Extrapolation to other strengths**

In accordance with the CPMP guidance, the results of the bioequivalence study can be extrapolated to the 75 mg and 150 mg strength, as the following conditions are fulfilled:
- the pharmaceutical products are manufactured by the same manufacturer and process
- the pharmacokinetics has been shown to be linear over the therapeutic range
- the qualitative composition of the different strengths is the same
- the ratio between amounts of active substance and excipients is the same
- the dissolution profile is similar under identical conditions for the additional strengths and the strength of the biobatch.

All these conditions hold for Irbesartan/ Hydrochlorothiazide manufactured by the MAH, therefore it would be considered that the 150/12.5 mg will also be bioequivalent to its 300/25 mg counterpart. With respect to the 300/12.5 mg formulation, this formulation only differs from the 300/25 mg with respect to the amount hydrochlorothiazide. As this is less than 5% of the total weight extrapolation from the 300/25 to the 300/12.5 is considered acceptable.

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).

**Risk management plan**

The MAH submitted a statement on the absence of a Risk Management Plan, and indicated that the current application concerns a generic product, for which the active ingredients have been in use for many years, and have a well-established safety profile. Routine Pharmacovigilance activities in accordance with EU regulations will be undertaken whilst the product are authorized. As the safety profile of the drug is well-established, a Risk Minimisation Plan is not considered necessary.

The reasoning of the MAH is accepted. At present, no risk management plan is needed.

**Product information**

**SPC**

The content of the SPC approved during the decentralised procedure is in accordance with that accepted for the reference product CoAprovel.

**Readability test**

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 test consisted of a pilot test with 2 participants, followed by two rounds with 10 participants each. The test was performed in English. Questions were designed to determine whether users can identify key information that is necessary for appropriate use. There were sufficient questions about the critical sections and the areas traceability, comprehensibility and applicability were sufficiently covered. The test included 19 questions related to the content of the PL. Three questions were related to the structure/appearance of the PL. A satisfactory outcome was achieved when 90% of the participants were able to find information and when 90% was able to show that they could understand the information and act upon it appropriately.

In round 1, 98.95% of the time the correct section was located to answer the question. Each question was correctly answered 98.95% of the time. In the second round 98.42% of the participants were able to locate
the section and 98.95% were able to answer the questions. Therefore no further changes were considered to be required. The user test is considered acceptable.
III OVERALL CONCLUSION AND BENEFIT-RISK ASSESSMENT

Irbesartan Hydrochlorothiazide Torrent 150 mg/12.5 mg, 300 mg/12.5 mg and 300 mg/25 mg, film-coated tablets have a proven chemical-pharmaceutical quality and are generic forms of CoAprovel 150 mg/12.5 mg, 300 mg/12.5 mg and 300 mg/25 mg tablets. CoAprovel 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.

The MAH has provided written confirmation that systems and services are in place to ensure compliance with their pharmacovigilance obligations.

The SPC, package leaflet and labelling are in the agreed templates and are in agreement with other irbesartan containing products.

The Board followed the advice of the assessors.

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 Irbesartan Hydrochlorothiazide Torrent 150 mg/12.5 mg, 300 mg/12.5 mg and 300 mg/25 mg with the reference product, and have therefore granted a marketing authorisation. The decentralised procedure was finished on 13 October 2011. Irbesartan Hydrochlorothiazide Torrent 150 mg/12.5 mg, 300 mg/12.5 mg and 300 mg/25 mg, film-coated tablets were authorised in the Netherlands on 3 November 2011.

The date for the first renewal will be: 13 October 2016.

The following post-approval commitment has been made during the procedure:

Quality - medicinal product
- The MAH committed to submit an updated GMP-certificate which states the new name of the manufacturing site of the finished product, issued by the inspection services of the competent authorities as soon as available.
List of abbreviations

ASMF  Active Substance Master File
ATC   Anatomical Therapeutic Chemical classification
AUC   Area Under the Curve
BP    British Pharmacopoeia
CEP   Certificate of Suitability to the monographs of the European Pharmacopoeia
CHMP  Committee for Medicinal Products for Human Use
CI    Confidence Interval
Cmax  Maximum plasma concentration
CMD(h) Coordination group for Mutual recognition and Decentralised procedure for human medicinal products
CV    Coefficient of Variation
EDMF  European Drug Master File
EDQM  European Directorate for the Quality of Medicines
EU    European Union
GCP   Good Clinical Practice
GLP   Good Laboratory Practice
GMP   Good Manufacturing Practice
ICH   International Conference of Harmonisation
MAH   Marketing Authorisation Holder
MEB   Medicines Evaluation Board in the Netherlands
OTC   Over The Counter (to be supplied without prescription)
PAR   Public Assessment Report
Ph.Eur. European Pharmacopoeia
PIL   Package Leaflet
PSUR  Periodic Safety Update Report
SD    Standard Deviation
SPC   Summary of Product Characteristics
t½    Half-life
tmax  Time for maximum concentration
TSE   Transmissible Spongiform Encephalopathy
USP   Pharmacopoeia in the United States
### STEPS TAKEN AFTER THE FINALISATION OF THE INITIAL PROCEDURE - SUMMARY

<table>
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<tr>
<th>Scope</th>
<th>Procedure number</th>
<th>Type of modification</th>
<th>Date of start of the procedure</th>
<th>Date of end of the procedure</th>
<th>Approval/non approval</th>
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