COLLEGE TER BEOORDELING VAN GENEESMIDDELEN

Public Assessment Report

Scientific discussion

Telmisartan Viatris 20 mg, 40 mg and 80 mg, tablets
(telmisartan)

NL/H/6668/001-003/DC

Date: 22 April 2026

This report reflects the scientific discussion for the approval of Telmisartan Viatris 20 mg, 40 mg and 80 mg, tablets. The procedure was finalised on 14 September 2011 in Germany (DE/H/2257/001-003/DC). After a transfer on 10 March 2026, the current RMS is the Netherlands. As a result, the product name, procedure number and layout have been updated in this report. For information on other changes after the finalisation 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
RH	Relative Humidity
RMP	Risk Management Plan
RMS	Reference Member State
SmPC	Summary of Product Characteristics
TSE	Transmissible Spongiform Encephalopathy

I. INTRODUCTION

Telmisartan is an angiotensin receptor blocker. It is indicated for

- Hypertension
  Treatment of essential hypertension in adults.
- Cardiovascular prevention
  Reduction of cardiovascular morbidity in patients with:
  - manifest atherothrombotic cardiovascular disease (history of coronary heart disease, stroke, or peripheral arterial disease) or
  - type 2 diabetes mellitus with documented target organ damage

This decentralised application concerns a generic version of Telmisartan 20 mg, 40 mg and 80 mg; under Telmisartan Viatris 20 mg, 40 mg and 80 mg, tablets. In this Assessment Report, the name Telmisartan is used.
The originator product is Micardis 20 mg, tablets, Boehringer Ingelheim International GmbH, Date of authorization 1998 – 12 – 16 (EU/1/98/090/099-12).

The clinical dossier is appropriate. It is a generic application.

The manufacturing sites have been certified and the manufacturing site has been inspected for GMP compliant manufacturing. The facility in India has been inspected and approved by the India authority. Also the facility in Dublin, Ireland which is responsible for the batch release has been inspected by the Irish Medicines Board. The alternate companies for the different market have been inspected and certificates are presented.

II. QUALITY ASPECTS

II.1 Drug Substance

Telmisartan is a non-peptide competitive antagonist of the oral II-receptor (AT1 subtype) for the treatment of hypertension. 4'-[[4-methyl-6-(1-methyl-1H-benzimidazol-2-yl)-2-propyl-1H-benzimidazol-1-yl] methyl]biphenyl-2-carboxylic acid is the chemical name.
It is a white or slightly yellowish, crystalline powder , practically insoluble in water, slightly soluble in methanol, sparingly soluble in methylene chloride. Telmisartan is marketed as a mono-substance product with the trade names Micardis or Pritor.

Quality control of drug substance
One supplier, Mylan laboratories limited, India is proposed for the drug substance. Matrix holds a Certificates of Suitability (R0-CEP 2008-256-Rev 00) to ensure that the quality of the active ingredient can be controlled by the current monograph.

II.2 Medicinal Product

Pharmaceutical development
The tablets are manufactured at Mylan Laboratories Limited, India.
All results meet the specified requirements.

Manufacturing process
Two production scale sizes are proposed. The batch sizes for the 20 mg, tablets are proposed with 140,000 as pilot batch size and 980,000 or 2,800,000 tablets as industrial batch size. The batch sizes for the 40 mg are proposed with 130,000 as pilot batch size and 460,000 or 1,400,000 tablets as industrial batch size and for the 80 mg product 130,000 as pilot batch size and 230,000 or 700,000 tablets as industrial batch size.

Stability of drug product
A shelf-life of 24 months with the condition "Store in the original package." is acceptable.

Conclusion to the day 160 response: There is only one outstanding issue from CMS Romania to the in use stability of the products.
The applicants states that the in use stability data are presented in the responses of the day 70/100 questions. However these data are missing and therefore the response is not acceptable.
In use stability data should be presented to verify the statement of the applicant.

III. NON-CLINICAL ASPECTS

III.1 Ecotoxicity/environmental risk assessment (ERA)

The applicant notes that an environmental risk assessment according to CPMP guideline CPMP/SWP/4447/00 (Note for Guidance on the Environmental Risk Assessment of Medicinal Products for Human Use) has not been provided.

This application is for a generic version of Micardis, a product that has been on the market in Europe since 1998. Telmisartan 20 mg, 40 mg and 80 mg tablets contain an identical amount of telmisartan and have been formulated with a range of commonly used excipients to be pharmaceutically equivalent to Micardis 20 mg, 40 mg and 80 mg tablets and as such are not considered to pose any greater environmental risk to that from the reference product. Furthermore, given that Telmisartan 20 mg, 40 mg and 80 mg tablets are aimed at replacing rather than increasing prescriptions of Micardis, no increased environmental burden is envisaged from the licensing of these products.

III.2 Discussion on the non-clinical aspects

Pharmacodynamic, pharmacokinetic and toxicological properties of Telmisartan are well known. As Telmisartan is a widely used, well-known active substance, no further studies are

required and the applicant provides none. Overview based on literature review is, thus, appropriate.

IV. OVERALL CONCLUSION, BENEFIT/RISK ASSESSMENT AND RECOMMENDATION

Based on the review of the data on quality, safety and efficacy, the RMS considers that the application for Telmisartan Viatris, in the treatment of

- Hypertension
  Treatment of essential hypertension in adults.

- Cardiovascular prevention
  Reduction of cardiovascular morbidity in patients with:
  - manifest atherothrombotic cardiovascular disease (history of coronary heart disease, stroke, or peripheral arterial disease) or
  - type 2 diabetes mellitus with documented target organ damage

is approvable.

The B/R ratio is positive.

A preliminary list of commitments:

Area[1]	**Description**
Quality	The applicant commits to perform hold time studies on lubricated blend and compressed tablets on first two commercial batches of all products covering a period of 30 days. The commitment will be added into the respective part of the overview
Quality	The applicant commits to inform the agencies, if any out of specification results are observed during the ongoing in-use stability studies.

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
DE/H/2257/001-3/IA/001/G	Change in the name and/or address of a manufacturer/ importer of the finished product (including batch release or quality control testing sites) - All other Submission of a new or updated Ph. Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance, For a starting material/reagent/ intermediate used in the manufacturing process of the active substance, For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	No	12-9-2012	Approved	N.A.
DE/H/2257/001-3/IA/002/G	Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site	No	30-11-2012	Approved	N.A.

	Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site				
DE/H/2257/001-3/IA/003	Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products - Other variation: To align the PSUR frequency and date of submission with the published EURD list.	Yes	15-5-2013	Approved	N.A.
DE/H/2257/001-3/IA/005	Change in the name and/or address of the marketing authorisation holder	Yes	14-10-2013	Approved	N.A.
DE/H/2257/001-3/IB/004	Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/ biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for	Yes	20-11-2013	Approved	N.A.

	which no new additional data are submitted by the MAH				
DE/H/2257/001-3/IA/006/G	Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a manufacturer responsible for importation and/or batch release - Not including batch control/testing Change in any part of the (primary) packaging material not in contact with the finished product formulation (such as colour of flip-off caps, colour code rings on ampoules, change	No No Yes Yes	16-1-2014	Approved	N.A.

	of needle shield (different plastic used)) - Change that affects the product information Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site	No No			
DE/H/2257/001-3/IB/008	Change in the shelf-life or storage conditions of the finished product - Extension of the shelf life of the finished product - As packaged for sale (supported by real time data)	Yes	18-5-2014	Approved	N.A.
DE/H/2257/001-3/IB/007	Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products	Yes	28-5-2014	Approved	N.A.

	- Other variation: Implementation of the outcome of a PRAC-recommendation ”Signal of calcium-channel blockers and breast cancer risk” and "Evaluation of a PSUSA procedure" (EMA/PRAC/729184/2013)				
DE/H/2257/001-3/IA/009/G	Change to importer, batch release arrangements and quality control testing of the finished product - Replacement or addition of a site where batch control/testing takes place Change in the batch size (including batch size ranges) of the finished product - Up to 10-fold compared to the originally approved batch size	No	18-9-2014	Approved	N.A.
DE/H/2257/001-3/IB/010	Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of (union referral procedure) - The medicinal product is covered by the defined scope of the procedure	Yes	19-6-2015	Approved	N.A.
DE/H/2257/001-3/IB/011	Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/	Yes	10-9-2015	Approved	N.A.

	biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data are submitted by the MAH				
DE/H/2257/001-3/IA/012/G	Introduction of, or changes to, a summary of pharmacovigilance system for medicinal products for human use - Introduction of a summary of pharmacovigilance system, changes in QPPV (including contact details) and/or changes in the Pharmacovigilance System Master File (PSMF) location	No	2-2-2016	Approved	N.A.
DE/H/2257/001-3/013/G	Change in test procedure for active substance or starting material/reagent/ intermediate used in the manufacturing process of the active substance - Minor changes to an approved test procedure Change in the name and/or address of a manufacturer/importer of the finished product (including batch release or quality control testing	No	4-4-2016	Approved	N.A.

	sites) - All other Submission of a new or updated Ph. Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance, For a starting material/reagent/ intermediate used in the manufacturing process of the active substance, For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer				
DE/H/2257/001 /IA/014/G	Change in the batch size (including batch size ranges) of the finished product - Downscaling down to 10-fold	No	18-4-2016	Approved	N.A.
DE/H/2257/001 -3/IA/015/G	Change in the name and/or address of the marketing authorisation holder	Yes	16-6-2016	Partially approved	N.A.
DE/H/2257/003 /IA/017	Change in pack size of the finished product - Change in the number of units (e.g. tablets, ampoules, etc.) in a pack - Change within the range of the currently approved pack sizes	Yes	19-12-2016	Approved	N.A.

DE/H/2257/001-3/WS/016	Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products. Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Secondary packaging site	No	27-5-2017	Approved	N.A.
DE/H/2257/001-3/IA/018/G	Submission of a new or updated Ph. Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance, For a starting material/reagent/ intermediate used in the manufacturing process of the active substance, For an excipient	No	18-7-2017	Approved	N.A.

	- European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - New certificate from a new manufacturer (replacement or addition)				
DE/H/2257/001-3/R/001	Renewal	No	22-12-2017	Approved	N.A.
DE/H/2257/001-3/IA/19/G	Change in the name and/or address of the marketing authorisation holder	Yes	6-2-2018	Approved	N.A.
DE/H/2257/001-3/P/001	Implementation of the safety features on the packaging	No	9-1-2019	Approved	N.A.
DE/H/2257/001-3/WS/020	Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Site where any manufacturing operation(s) take place, except batch-release, batch control, primary and secondary packaging, for non-sterile medicinal products. Replacement or addition of a manufacturing site for part or all of the manufacturing process of the finished product - Primary packaging site Replacement or addition of a manufacturing site for part or all of	No	28-7-2019	Approved	N.A.

	the manufacturing process of the finished product - Secondary packaging site				
DE/H/2257/001-3/IB/022	Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products - Other variation	Yes	21-12-2020	Approved	N.A.
DE/H/2257/001-3/IB/021/G	Submission of a new or updated Ph. Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance, For a starting material/reagent/ intermediate used in the manufacturing process of the active substance, For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer Change in the specification parameters and/or limits of an active substance, starting material / intermediate / reagent used in the manufacturing process of the active substance - Addition or replacement (excluding biological or immunological	No	28-4-2021	Approved	N.A.

	substance) of a specification parameter with its corresponding test method as a result of a safety or quality issue				
DE/H/2257/001-3/IB/023/G	Change in the name and/or address of the marketing authorisation holder Change in the (invented) name of the medicinal product - for Nationally Authorised products Change in the name and/or address of a manufacturer/ importer of the finished product (including batch release or quality control testing sites) - All other	Yes Yes No	2-3-2022	Approved	N.A.
DE/H/2257/001-3/IA/025	Submission of a new or updated Ph. Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance, For a starting material/reagent/ intermediate used in the manufacturing process of the active substance, For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph	No	14-9-2022	Approved	N.A.

	- Updated certificate from an already approved manufacturer				
DE/H/2257/001-3/IB/024	Change in the (invented) name of the medicinal product - for Nationally Authorised products	Yes	6-10-2022	Approved	N.A.
DE/H/2257/001-3/IB/026/G	Change in the name and/or address of the marketing authorisation holder Change in the (invented) name of the medicinal product - for Nationally Authorised products	Yes	26-5-2023	Approved	N.A.
DE/H/2257/001-3/IB/027	Change in the specification parameters and/or limits of the finished product - Deletion of a non-significant specification parameter (e.g. deletion of an obsolete parameter such as odour and taste or identification test for a colouring or flavouring material)	No	28-7-2023	Approved	N.A.
DE/H/2257/001-3/IA/029/G	Submission of a new or updated Ph. Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance, For a starting material/reagent/ intermediate used in the	No	27-8-2024	Approved	N.A.

	manufacturing process of the active substance, For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer Change in the name and/or address of a manufacturer/ importer of the finished product (including batch release or quality control testing sites) - All other				
DE/H/2257/001-3/IB/030	Change in test procedure for active substance or starting material/reagent/ intermediate used in the manufacturing process of the active substance - Other changes to a test procedure (including replacement or addition) for the active substance or a starting material/ intermediate	Yes	6-2-2025	Approved	N.A.
DE/H/2257/001-3/IA/031	Changes (Safety/Efficacy) to Human and Veterinary Medicinal Products - Other variation: Implementation of PRAC signal recommendation	Yes	20-2-2025	Approved	N.A.

DE/H/2257/001-3/IA/032/G	Submission of a new or updated Ph. Eur. certificate of suitability or deletion of Ph. Eur. certificate of suitability: For an active substance, For a starting material/reagent/ intermediate used in the manufacturing process of the active substance, For an excipient - European Pharmacopoeial Certificate of Suitability to the relevant Ph. Eur. Monograph - Updated certificate from an already approved manufacturer	No	14-8-2025	Approved	N.A.
DE/H/2257/001-3/WS/033	Change(s) in the Summary of Product Characteristics, Labelling or Package Leaflet of a generic/hybrid/ biosimilar medicinal products following assessment of the same change for the reference product - Implementation of change(s) for which no new additional data are submitted by the MAH	Yes	7-11-2025	Approved	N.A.