IPAR

Public Assessment Report for a
Medicinal Product for Human Use

Scientific Discussion

Atomoxetine Azure 40 mg hard capsules
Atomoxetine hydrochloride
PA22871/034/004

The Public Assessment Report reflects the scientific conclusion reached by the Health Products Regulatory Authority (HPRA) at the end of the evaluation process and provides a summary of the grounds for approval of a marketing authorisation for a specific medicinal product for human use. It is made available by the HPRA for information to the public, after deletion of commercially sensitive information. The legal basis for its creation and availability is contained in Article 21 of Directive 2001/83/EC, as amended. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the HPRA leading to the approval of the medicinal product for marketing in Ireland.

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I. INTRODUCTION

Based on the review of the data on quality, safety and efficacy, the HPRA has granted a marketing authorisation for Atomoxetine Azure 10 mg, 18 mg, 25 mg, 40 mg. 60 mg, 80 mg and 100 mg hard capsules, from Azure Pharmaceuticals Ltd 8th May 2026 for treatment of Attention-Deficit/Hyperactivity Disorder (ADHD) in children of 6 years and older, in adolescents and in adults as part of a comprehensive treatment programme.

This application was submitted in accordance with Article 10(1) of Directive 2001/83/EC and is referred to as a 'generic' application. With Ireland as the Reference Member State (RMS) in this decentralised procedure, Azure Pharmaceuticals Ltd. applied for a marketing authorisation for Atomoxetine 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg and 100 mg hard capsules in Slovenia. The reference product was Strattera 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg and 100 mg hard capsules, MAH: Lilly Deutschland GmbH.

The Summary of Product Characteristics (SmPC) for this medicinal product is available on the HPRA's website at www.hpra.ie

Name of the product	Atomoxetine Azure 40 mg hard capsules
Name(s) of the active substance(s) (INN)	Atomoxetine hydrochloride
Pharmacotherapeutic classification (ATC Code)	N06BA09
Pharmaceutical form and strength(s)	40 mg hard capsules
Marketing Authorisation Number(s) in Ireland (PA)	PA22871/034/004
Marketing Authorisation Holder	Azure Pharmaceuticals Ltd. 12 Hamilton Drive The Rock Road Blackrock Dundalk Co. Louth A91 T997 Ireland
MRP/DCP No.	IE/H/1352/001-007
Reference Member State	IE
Concerned Member State(s)	SI

II. QUALITY ASPECTS

II.1. Introduction

This application is for Atomoxetine 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg and 100 mg hard capsules.

II.2 Drug substance

The active substance is Atomoxetine hydrochloride, an established active substance described in the European Pharmacopoeia, and is manufactured in accordance with the principles of Good Manufacturing Practice (GMP).

The active substance specification is considered adequate to control the quality and meets current pharmacopoeial requirements. Batch analytical data demonstrating compliance with this specification has been provided.

II.3 Medicinal product

P.1 Composition

The excipients in the medicinal product are listed in section 6.1 of the SmPC.
A visual description of the product is included in section 3 of the SmPC.

P.2 Pharmaceutical Development

The product is an established pharmaceutical form and its development is adequately described in accordance with the relevant European guidelines.

P.3 Manufacture of the Product

The product is manufactured in accordance with the principles of good manufacturing practice (GMP) at suitably qualified manufacturing sites.

The manufacturing process has been validated according to relevant European guidelines and the process is considered to be sufficiently validated.

P.4 Control of Other Substances (Excipients)

All ingredients comply with Ph. Eur. or are adequately controlled by the manufacturer's specifications.

P.5 Control of Finished Product

The Finished Product Specification is based on the pharmacopoeial monograph for capsules, and the tests and control limits are considered appropriate for this type of product.

The analytical methods used are described in sufficient detail and are supported by validation data.

Batch analytical data for a number of batches from the proposed production site have been provided, and demonstrate the ability of the manufacturer to produce batches of finished product of consistent quality.

P.7 Packaging material

The approved packaging for this product is described in section 6.5 of the SmPC.

Evidence has been provided that the packaging complies with EU legislation for use with foodstuffs requirements.

P.8 Stability of the Finished Product

Stability data on the finished product in the proposed packaging have been provided in accordance with EU guidelines and support the shelf-life and storage conditions listed in sections 6.3 and 6.4 of the SmPC.

II.4 Discussion on Chemical, Pharmaceutical and Biological Aspects

The important quality characteristics of the product are well-defined and controlled. Satisfactory chemical and pharmaceutical documentation has been provided, assuring consistent quality of Atomoxetine 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg and 100 mg hard capsules.

III. NON-CLINICAL ASPECTS

III.1 Introduction

This active substance is a generic formulation of Strattera 10, 18, 25, 40, 60, 80 and 100 mg hard capsules on the European market. No new nonclinical data have been submitted. This is acceptable for this type of application.

III.2 Pharmacology

N/A

III.3 Pharmacokinetics

N/A

III.4 Toxicology

N/A

III.5 Ecotoxicity/environmental risk assessment

As Atomoxetine 10 mg hard capsules are generic products, they will not lead to an increased exposure to the environment. Additional studies on environmental risk are not deemed necessary.

III.6 Discussion on the non-clinical aspects

Pharmacodynamic, pharmacokinetic and toxicological properties of atomoxetine are well known. As atomoxetine is a widely used, well-known active substance, the applicant has not provided additional nonclinical studies, and further studies are not required. The nonclinical overview on the nonclinical pharmacology, pharmacokinetics and toxicology provided is adequate. Nonclinical sections of the SmPC are in with the originator.

IV. CLINICAL ASPECTS

IV.1 Introduction

Atomoxetine is a well-known active substance with established efficacy and tolerability.

The content of the SmPC approved during the decentralised procedure is in accordance with that accepted for the reference product Strattera hard capsules marketed by Lilly Deutschland GmbH.

No bioequivalence study has been submitted to support the application. A BCS-based biowaiver in accordance with ICH M9 has been proposed by the applicant and considered acceptable, based on the following: drug substance is highly soluble/highly permeable (BCS Class I); no excipients included in the formulation which impact on absorption; comparative *in vitro* dissolution between the test and reference product show comparability in dissolution profiles.

IV.2 Pharmacokinetics

No new pharmacokinetic data were submitted. A BCS-based biowaiver in accordance with ICH M9 has been proposed and considered acceptable.

IV.3 Pharmacodynamics

No new pharmacodynamic data were submitted and none are required for an application of this type.

IV.4 Clinical Efficacy

No new efficacy data were submitted and none are required for an application of this type.

IV.5 Clinical Safety

No new safety data were submitted with this application.

Risk Management Plan

A Risk Management Plan, version 0.3, dated 22 January 2026 has been submitted, 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 Atomoxetine Azure 10mg/18mg/25mg/40mg/60mg/80mg/100mg Hard Capsules. It is concluded that routine pharmacovigilance and risk minimisation measures are sufficient.

Summary table of safety concerns as approved in RMP:

Summary of safety concerns	
Important identified risks	None
Important potential risks	None
Missing information	None

The active substance is currently listed in the published EURD list
With regard to PSUR submission, the MAH should take the following into account:

- PSURs shall be submitted in accordance with the requirements set out in the list of Union reference dates (EURD list) provided for under Article 107c(7) of Directive 2001/83/EC and published on the European medicines web-portal. Marketing authorisation holders shall continuously check the European medicines web-portal for the DLP and frequency of submission of the next PSUR.
- For medicinal products authorized under the legal basis of Article 10(1) or Article 10a of Directive 2001/83/EC, no routine PSURs need to be submitted, unless otherwise specified in the EURD list.
- In case the active substance will be removed in the future from the EURD list because the MAs have been withdrawn in all but one MS, the MAH shall contact that MS and propose DLP and frequency for further PSUR submissions together with a justification.

V. OVERALL CONCLUSIONS

Atomoxetine Azure 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg and 100 mg hard capsules are generic forms of Strattera 10 mg, 18 mg, 25 mg, 40 mg, 60 mg, 80 mg and 100 mg hard capsules. Strattera is a well-known medicinal product with a proven chemical-pharmaceutical quality and an established favourable efficacy and safety profile. A BCS-based biowaiver has been granted in accordance with ICH M9.

VI. REVISION DATE

07.05.2031