European Medicines Agency
Evaluation of Medicines for Human Use

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CHMP ASSESSMENT REPORT
FOR
DULOXETINE BOEHRINGER INGELHEIM
International Nonproprietary Name:
Duloxetine
Procedure No. EMEA/H/C/001007

Assessment Report as adopted by the CHMP with
all information of a commercially confidential nature deleted

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TABLE OF CONTENS

1. BACKGROUND INFORMATION ON THE PROCEDURE

1.1 Submission of the dossier

The applicant Boehringer Ingelheim International GmbH submitted on 14 March 2008 an application for Marketing Authorisation to the European Medicines Agency (EMEA) for DULOXETINE BOEHRINGER INGELHEIM, through the centralised procedure according to Regulation (EC) No 726/2004.

The legal basis for this application refers to Article 10(c) of Directive 2001/83/EC, as amended – relating to informed consent from the marketing authorisation holder, Eli Lilly Nederland B.V., for the authorised medicinal product Ariclaim (EU/1/04/283/001-012).

Scientific Advice:

The applicant did not seek scientific advice at the CHMP.

Licensing status:

The reference medicinal product, Ariclaim, has been given a Community Marketing Authorisation on on 11 August 2004.

The Rapporteur appointed by the CHMP and the evaluation teams was:

Rapporteur: Gonzalo Calvo Rojas

1.2 Steps taken for the assessment of the product

- The application was received by the EMEA on 14 March 2008.
- The procedure started on 30 March 2008.
- The Rapporteur's first Assessment Report was circulated to all CHMP members on 07/05/2008.
- During the meeting on 27 - 30 May 2008, the CHMP agreed on the consolidated List of Questions to be sent to the applicant. The final consolidated List of Questions was sent to the applicant on 03 June 2008.
- The applicant submitted the responses to the CHMP consolidated List of Questions on 06 June 2008.
- The Rapporteur circulated the Assessment Report on the applicant's responses to the List of Questions to all CHMP members on 17 July 2008.
- During the meeting on 21-24 July 2008, the CHMP, in the light of the overall data submitted and the scientific discussion within the Committee, issued a positive opinion for granting a Marketing Authorisation to DULOXETINE BOEHRINGER INGELHEIM Hard gastro-resistant capsules (20 mg, 30 mg, 40 mg and 60 mg strength) on 24 July 2008. The applicant provided the letter of undertaking on the follow-up measures to be fulfilled post-authorisation on 22 July 2008.

2. SCIENTIFIC DISCUSSION

2.1 Introduction

This application has been submitted as an informed consent application in accordance with Article 10c of Directive 2001/83/EC as amended.
Therefore, consent from the MAH of the Ariclaim application, which had been submitted as a full application under Art 8(3) of Directive 2001/83/EC as amended, has been given allowing access to Module 2 to Module 5 of the initial dossier of this authorised product and any subsequent post-marketing procedures submitted, assessed and approved. The application for DULOXETINE BOEHRINGER INGELHEIM consists only of Module 1 information.

As a consequence, quality, safety and efficacy of DULOXETINE BOEHRINGER INGELHEIM 20 mg, 30 mg, 40 mg, 60 mg hard gastro-resistant capsules are identical to the up-to-date quality, safety and efficacy profile of Ariclaim 20 mg, 30 mg, 40 mg, 60 mg hard gastro-resistant capsules. Information on the scientific discussions can be found in the Ariclaim CHMP assessment report and in the European Public Assessment Report (EPAR).

The approved indication is: DULOXETINE BOEHRINGER INGELHEIM is indicated for women for the treatment of moderate to severe Stress Urinary Incontinence (SUI), and the treatment of diabetic peripheral neuropathic pain (DPNP) in adults.

2.2 Quality aspects

Since this application is an informed consent of the Ariclaim application, the quality data in support of the DULOXETINE BOEHRINGER INGELHEIM 20 mg, 30 mg, 40 mg, 60 mg hard gastro-resistant capsules application are identical to the up-to-date quality data of the Ariclaim dossier which have been assessed and approved (including all post-marketing procedures).

2.3 Non-clinical aspects

Since this application is an informed consent of the Ariclaim application, the non-clinical data in support of the DULOXETINE BOEHRINGER INGELHEIM 20 mg, 30 mg, 40 mg, 60 mg hard gastro-resistant capsules application are identical to the up-to-date non-clinical data of the Ariclaim dossier which have been assessed and approved (including all post-marketing procedures).

2.4 Clinical aspects

Since this application is an informed consent of the Ariclaim application, the clinical data in support of the DULOXETINE BOEHRINGER INGELHEIM 20 mg, 30 mg, 40 mg, 60 mg hard gastro-resistant capsules application are identical to the up-to-date clinical data of the Ariclaim dossier which have been assessed and approved (including all post-marketing procedures).

- User Consultation

Consultation with target patient groups has been requested by CHMP for the DULOXETINE BOEHRINGER INGELHEIM 20 mg, 30 mg, 40 mg, 60 mg hard gastro-resistant capsules and is part of a follow up measure.

Considering that consultation with target patient groups is currently being carried out on the package leaflet for Cymbalta (Duloxetine, EU/1/04/296/001-009) and that the package leaflets of Cymbalta and DULOXETINE BOEHRINGER INGELHEIM are highly similar, the CHMP agreed that changes that

will be implemented in the Cymbalta package leaflet as a result of the on-going consultation with target patient groups should also be implemented in the package leaflet of DULOXETINE BOEHRINGER INGELHEIM. Also a bridging report clearly justifying the appropriateness of extrapolation of data should be submitted as part of this FUM.

2.5 Pharmacovigilance

Detailed description of the Pharmacovigilance system

The CHMP considered that the Pharmacovigilance system as described by the applicant fulfils the legislative requirements.

The pharmacovigilance system for DULOXETINE BOEHRINGER INGELHEIM, Edition 4.0 dated 30.07.2007 is associated with the pharmacovigilance system from Eli Lilly and Company, version 2.2. The MAH explained the interactions between Eli Lilly and Company and Boehringer Ingelheim International with regards to the Pharmacovigilance systems and provided the Pharmacovigilance System in place at Boehringer Ingelheim International.

Risk Management Plan

The MAA submitted a risk management plan, which included a risk minimisation plan
The Table Summary of the risk management plan is attached in Appendix 1 of this document.

The CHMP, having considered the data submitted in the application, is of the opinion that no additional risk minimisation activities are required beyond those included in the product information.

2.6 Overall conclusions, risk/benefit assessment and recommendation

Since this application is an informed consent of the Ariclaim application, the CHMP considered that the risk-benefit balance of DULOXETINE BOEHRINGER INGELHEIM 20 mg, 30 mg, 40 mg, 60 mg hard gastro-resistant capsules was favourable and therefore recommended the granting of the marketing authorisation for the following indication:

DULOXETINE BOEHRINGER INGELHEIM is indicated for women for the treatment of moderate to severe Stress Urinary Incontinence (SUI), and the treatment of diabetic peripheral neuropathic pain (DPNP) in adults.