14 April 2011
EMA/CHMP/304146/2011
Committee for medicinal products for human use (CHMP)

Summary of opinion[1] (post authorisation)

Pradaxa

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On 14 April 2011 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion recommending a variation to the terms of the marketing authorisation for the medicinal product Pradaxa. The marketing authorisation holder for this medicinal product is Boehringer Ingelheim International GmbH. They may request a re-examination of the CHMP opinion, provided that they notify the European Medicines Agency in writing of their intention within 15 days of receipt of the opinion.

The CHMP adopted *a new indication* as follows:

"**Prevention of stroke and systemic embolism in adult patients with nonvalvular atrial fibrillation with one or more of the following risk factors:**

Previous stroke, transient ischemic attack, or systemic embolism (SEE)

- **Left ventricular ejection fraction < 40 %**
- **Symptomatic heart failure, ≥ New York Heart Association (NYHA) Class 2**
- **Age ≥ 75 years**
- **Age ≥ 65 years associated with one of the following: diabetes mellitus, coronary artery disease, or hypertension**"

The CHMP adopted a change to a *contraindication* as follows:
"Concomitant treatment with systemic ketoconazole, **cyclosporine, itraconazole and tacrolimus (see section 4.5)**".

Detailed conditions for the use of this product will be described in the updated summary of product characteristics (SmPC), which will be published in the revised European public assessment report (EPAR), and will be available in all official European Union languages after the variation to the marketing authorisation has been granted by the European Commission.

[1] Summaries of positive opinion are published without prejudice to the commission decision, which will normally be issued within 44 days (Type II variations) and 67 days (Annex II applications) from adoption of the opinion.

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For information, the full indications for Pradaxa will be as follows[2]:

For 75 mg strength

Primary prevention of venous thromboembolic events in adult patients who have undergone elective total hip replacement surgery or total knee replacement surgery.

For 110 and 150 mg strengths

Primary prevention of venous thromboembolic events in adult patients who have undergone elective total hip replacement surgery or total knee replacement surgery.

Prevention of stroke and systemic embolism in adult patients with nonvalvular atrial fibrillation with one or more of the following risk factors:

- **Previous stroke, transient ischemic attack, or systemic embolism (SEE)**
- **Left ventricular ejection fraction < 40 %**
- **Symptomatic heart failure, ≥ New York Heart Association (NYHA) Class 2**
- **Age ≥ 75 years**
- **Age ≥ 65 years associated with one of the following: diabetes mellitus, coronary artery disease, or hypertension**

For information, the full contraindication(s) for Pradaxa will be as follows[3]:

- Hypersensitivity to the active substance or to any of the excipients
- Patients with severe renal impairment (CrCL < 30 ml/min)
- Active clinically significant bleeding
- Organic lesion at risk of bleeding
- Spontaneous or pharmacological impairment of haemostasis
- Hepatic impairment or liver disease expected to have any impact on survival
- Concomitant treatment with systemic ketoconazole, **cyclosporine, itraconazole and tacrolimus (see section 4.5)**

[2] The text in bold represents the new or the amended indication.

[3] The text in bold represents the new or the amended contraindication.