SCIENTIFIC DISCUSSION

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 Taxotere 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.

As a consequence, quality, safety and efficacy of the Docetaxel Winthrop medicinal product is identical to the up-to-date quality, safety and efficacy profile of Taxotere. Information on the scientific discussions can be found in the Taxotere CHMP assessment report and in the European Public Assessment Report (EPAR).

The approved indications are:

Breast cancer
Docetaxel Winthrop (docetaxel) in combination with doxorubicin and cyclophosphamide is indicated for the adjuvant treatment of patients with operable node- positive breast cancer.

Docetaxel Winthrop (docetaxel) in combination with doxorubicin is indicated for the treatment of patients with locally advanced or metastatic breast cancer who have not previously received cytotoxic therapy for this condition.

Docetaxel Winthrop (docetaxel) monotherapy is indicated for the treatment of patients with locally advanced or metastatic breast cancer after failure of cytotoxic therapy. Previous chemotherapy should have included an anthracycline or an alkylating agent.

Docetaxel Winthrop (docetaxel) in combination with trastuzumab is indicated for the treatment of patients with metastatic breast cancer whose tumours overexpress HER2 and who previously have not received chemotherapy for metastatic disease.

Docetaxel Winthrop (docetaxel) in combination with capecitabine is indicated for the treatment of patients with locally advanced or metastatic breast cancer after failure of cytotoxic chemotherapy. Previous therapy should have included an anthracycline.

Non-small cell lung cancer
Docetaxel Winthrop (docetaxel) is indicated for the treatment of patients with locally advanced or metastatic non-small cell lung cancer after failure of prior chemotherapy.

Docetaxel Winthrop (docetaxel) in combination with cisplatin is indicated for the treatment of patients with unresectable, locally advanced or metastatic non-small cell lung cancer, in patients who have not previously received chemotherapy for this condition.

Prostate cancer
Docetaxel Winthrop (docetaxel) in combination with prednisone or prednisolone is indicated for the treatment of patients with hormone refractory metastatic prostate cancer.

Gastric adenocarcinoma
Docetaxel Winthrop (docetaxel) in combination with cisplatin and 5-fluorouracil is indicated for the treatment of patients with metastatic gastric adenocarcinoma, including adenocarcinoma of the gastroesophageal junction, who have not received prior chemotherapy for metastatic disease.

Head and neck cancer
Docetaxel Winthrop (docetaxel) in combination with cisplatin and 5-fluorouracil is indicated for the induction treatment of patients with inoperable locally advanced squamous cell carcinoma of the head and neck.

2. Quality aspects

Since this application is an informed consent of the Taxotere application, the quality data in support of the Docetaxel Winthrop application are identical to the up-to-date quality data of the Taxotere dossier which have been assessed and approved (including all post-marketing procedures).

3. Non-clinical aspects

Since this application is an informed consent of the Taxotere application, the non-clinical data in support of the Docetaxel Winthrop application are identical to the up-to-date non-clinical data of the Taxotere dossier, which have been assessed and approved (including all post-marketing procedures).

4. Clinical aspects

Since this application is an informed consent of the Taxotere application, the clinical data in support of the Docetaxel Winthrop application are identical to the up-to-date clinical data of the Taxotere dossier, which have been assessed and approved (including all post-marketing procedures).

5. Pharmacovigilance

PSUR

As requested by the CHMP the PSUR cycle of Docetaxel Winthrop will correspond to the one attributed to the cross-referred product, Taxotere, until otherwise specified.

Detailed description of the Pharmacovigilance system

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

Risk Management Plan

The CHMP is of the opinion that no additional risk minimisation activities are required beyond those included in the product information and that routine pharmacovigilance was adequate to monitor the safety of the product.

6. Overall conclusions, risk/benefit assessment and recommendation

Since this application is an informed consent of the Taxotere application, the CHMP considered that the risk-benefit balance of Docetaxel Winthrop was favourable and therefore recommended the granting of the marketing authorisation for the following indications:

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