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Questions and answers on Docetaxel Teva Generics (docetaxel, 20 mg and 80 mg powder and solvent for solution for infusion)

Outcome of a procedure under Article 29 of Directive 2001/83/EC as amended

The European Medicines Agency has completed an arbitration procedure following a disagreement among Member States of the European Union (EU) regarding the authorisation of the medicine Docetaxel Teva Generics. The Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that the benefits of Docetaxel Teva Generics outweigh its risks, and that the marketing authorisation can be granted in the Netherlands as well as in Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Poland, Romania, Slovakia, Slovenia, Spain, Sweden, United Kingdom and Norway.

What is Docetaxel Teva Generics?

Docetaxel Teva Generics is a medicine that contains the active substance docetaxel. It is available as a powder and solvent to be made up into a solution for infusion (drip into a vein). Docetaxel Teva Generics is intended to treat the following types of cancer: breast cancer, non-small-cell lung cancer, prostate cancer, gastric adenocarcinoma (a type of stomach cancer), and head and neck cancer.

Docetaxel Teva Generics is a generic medicine based on a 'reference medicine', Taxotere, which has an EU-wide marketing authorisation since 1995.

The active substance in Docetaxel Teva Generics, docetaxel, belongs to the group of anticancer medicines known as the taxanes. Docetaxel blocks the ability of cancer cells to destroy the internal 'skeleton' that allows them to divide and multiply. With the skeleton still in place, the cells cannot divide and they eventually die. Docetaxel also affects non-cancer cells such as blood cells, which can cause side effects.

Why was Docetaxel Teva Generics reviewed?

Teva Generics BV submitted an application for Docetaxel Teva Generics to the Netherlands for a decentralised procedure. This is a procedure where one Member State (the 'reference Member State',

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An agency of the European Union

in this instance the Netherlands) assesses a medicine with a view to granting a marketing authorisation that will be valid in this country as well as in other Member States (the 'concerned Member States', in this instance all other EU Member States (except Portugal) and Norway).

However, the Member States were not able to reach an agreement and the Netherlands referred the matter to the CHMP on 29 July 2010 for arbitration.

The grounds for the referral were that a 'bioequivalence' study in humans, to show that Docetaxel Teva Generics produces comparable levels of the active substance in the body as Taxotere, had not been performed. Some Member States considered this needed since the form of Docetaxel Teva Generics (a powder and a solvent to be made into a solution) is different to the form of the reference medicine (a concentrated solution) and the two medicines contain different excipients (inactive ingredients).

What are the conclusions of the CHMP?

Based on an evaluation of the currently available data and the scientific discussion within the Committee, the CHMP concluded that additional data was not needed because Docetaxel Teva Generics is expected to produce comparable levels of the active substance in the body as the reference medicine. The CHMP therefore concluded that the benefits of Docetaxel Teva Generics outweigh its risks and recommended that the marketing authorisation be granted in the Netherlands and the concerned Member States.

The European Commission issued a decision on 7 July 2011.