



European Medicines Agency
Evaluation of Medicines for Human Use

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**COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
(CHMP)**

**OPINION FOLLOWING AN ARTICLE 30 REFERRAL FOR
Gemzar**

International Non-Proprietary Name (INN): gemcitabine

BACKGROUND INFORMATION

Gemzar, 200 mg, 1000 mg, powder for solution for infusion, is a pyrimidine antagonist and is given in the management of solid tumours. It is indicated in bladder cancer, advanced non-small cell lung cancer, advanced pancreatic cancer, breast cancer and ovarian cancer.

On 8 June 2007, the European Commission presented to the EMEA a referral under Article 30 of Directive 2001/83/EC, as amended, in order to harmonise the nationally authorised Summaries of Product Characteristics (SPC), Labelling and Package Leaflet including quality aspects of the medicinal product Gemzar.

The basis for referral was that there were divergences in the Summaries of Product Characteristics (SPC) including quality aspects of Gemzar approved across EU Member States, mainly with respect to the approved indications, the posology, the contra-indications and the warnings.

This medicinal product belongs to the list of products for SPC harmonisation.

The procedure started on 21 June 2007. The Marketing Authorisation Holder provided supplementary information on 20 December 2007.

During its June 2008 meeting, the CHMP, in the light of the overall submitted data and the scientific discussion within the Committee, was of the opinion that the proposal for the harmonisation of the SPC, Labelling and Package leaflet including the quality aspects was acceptable and that they should be amended.

The CHMP gave a positive opinion on 26 June 2008 recommending the harmonisation of the SPC, Labelling and Package Leaflet including quality aspects for Gemzar.

The list of product names concerned is given in Annex I. The scientific conclusions are provided in Annex II together with the amended SPC, Labelling and Package Leaflet in Annex III.

A Decision was issued by the European Commission on 23 September 2008.