European Medicines Agency
Pre-Authorisation Evaluation of Medicines for Human Use

London, 19 November 2009
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COMMITTEE FOR MEDICINAL PRODUCTS FOR HUMAN USE
SUMMARY OF POSITIVE OPINION*
for
TEMOMEDAC

International Nonproprietary Name (INN): **temozolomide**

On 19 November 2009 the Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion,** recommending to grant a marketing authorisation for the medicinal product Temomedac, 5, 20, 100, 140, 180 and 250 mg, hard capsules intended for treatment of glioblastoma and malignant glioma. The applicant for this medicinal product is Alfred E. Tiefenbacher GmbH & Co. KG.

The active substance of Temomedac is temozolomide, an antineoplastic and immunomodulating agent. Temozolomide (TMZ) is a triazene, which undergoes rapid chemical conversion at physiologic pH to the active monomethyl triazenoimidazole carboxamide (MTIC). The cytotoxicity of MTIC is thought to be due primarily to alkylation at the O6 position of guanine with additional alkylation also occurring at the N7 position. Cytotoxic lesions that develop subsequently are thought to involve aberrant repair of the methyl adduct.

Temomedac is a generic of Temodal, which has been authorised in the EU since 26 January 1999. Studies have demonstrated the satisfactory quality of Temomedac and its bioequivalence with Temodal. A question-and-answer document on generic medicines can be found here.

A pharmacovigilance plan for Temomedac, as for all medicinal products, will be implemented as part of the marketing authorisation.

The approved indications are as follows:
- For the treatment of adult patients with newly-diagnosed glioblastoma multiforme concomitantly with radiotherapy (RT) and subsequently as monotherapy treatment.
- For the treatment of children from the age of three years, adolescents and adult patients with malignant glioma, such as glioblastoma multiforme or anaplastic astrocytoma, showing recurrence or progression after standard therapy.

Detailed recommendations for the use of this product will be described in the Summary of Product Characteristics (SPC) which will be published in the European Public Assessment Report (EPAR) and will be available in all official European Union languages after the marketing authorisation has been granted by the European Commission.

The CHMP, on the basis of quality, safety and efficacy data submitted, considers that there is a favourable benefit to risk balance for Temomedac and therefore recommends the granting of the marketing authorisation.

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* Summaries of positive opinion are published without prejudice to the Commission Decision, which will normally be issued within 67 days from adoption of the Opinion.

** Applicants may request a re-examination of any CHMP opinion, provided they notify the EMEA in writing of their intention to request a re-examination within 15 days of receipt of the opinion.

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