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Questions and answers on Paracetamol/ibuprofen 500mg/150mg film-coated tablets and associated names (tablets containing 500 mg paracetamol and 150 mg ibuprofen)

Outcome of a procedure under Article 29(4) of Directive 2001/83/EC

On 18 May 2017, the European Medicines Agency completed an arbitration procedure following a disagreement among Member States of the European Union (EU) regarding the authorisation of the medicine Paracetamol/ibuprofen 500mg/150mg film-coated tablets. The Agency's Committee for Medicinal Products for Human Use (CHMP) concluded that the benefits of Paracetamol/ibuprofen 500mg/150mg film-coated tablets outweigh its risks, and the marketing authorisation can be granted in the United Kingdom and in the following Member States of the EU: Austria, Belgium, Croatia, France, Germany, Ireland, Luxembourg, the Netherlands, Portugal and Spain.

What is Paracetamol/ibuprofen 500mg/150mg film-coated tablets?

Paracetamol/ibuprofen 500mg/150mg film-coated tablets is a medicine for use in adults for the short-term treatment of mild to moderate pain.

Paracetamol/ibuprofen 500mg/150mg contains the active substances paracetamol and ibuprofen. Both are well known medicines that work in different ways to relieve pain. Combinations of paracetamol and ibuprofen containing 500 mg paracetamol and 150 mg ibuprofen or similar doses are already available in many EU countries.

Why was Paracetamol/ibuprofen 500mg/150mg film-coated tablets reviewed?

Vale Pharmaceuticals Limited submitted Paracetamol/ibuprofen 500mg/150mg film-coated tablets to the United Kingdom for a decentralised procedure. This is a procedure where one Member State (the 'reference Member State', in this instance the United Kingdom) 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 Austria, Belgium, Croatia, France, Germany, Ireland, Luxembourg, the Netherlands, Portugal and Spain).

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However, the Member States were not able to reach an agreement and the United Kingdom referred the matter to the CHMP for arbitration on 21 October 2016.

The grounds for the referral were that the rationale for use of this medicine for the short-term treatment of mild to moderate pain without medical supervision was not sufficiently justified. There were concerns about potential long-term use which is not authorised and whether the dose used was the best one to choose. In addition, concerned Member States felt that benefits for this fixed-dose combination over the individual components had not been consistently shown across studies and that safety in the intended population, including elderly patients, had not been sufficiently proven.

What are the conclusions of the CHMP?

The CHMP assessed the available data from studies and from the scientific literature provided by the company to support the use of this combination in the short-term treatment of pain. The data showed that the use of the fixed-dose combination of 500 mg paracetamol and 150 mg ibuprofen is safe and effective in adults, including the elderly. The CHMP concluded that this combination was more effective than the individual components, while its safety profile was similar. Using the combination may avoid having to use stronger painkillers such as opioids which have risks of abuse and misuse. To address the risk of potential long-term use the applicant provided data obtained after marketing to show that similar combinations have not led to significant long-term use or increased safety concerns.

Based on evaluation of the currently available data and the scientific discussion within the Committee, the CHMP concluded that the benefits of Paracetamol/ibuprofen 500mg/150mg film-coated tablets outweigh its risks, and therefore the marketing authorisation for Paracetamol/ibuprofen 500mg/150mg film-coated tablets should be granted in all concerned Member States.

The European Commission issued an EU-wide legally binding decision to implement the CHMP recommendations on Paracetamol/ibuprofen 500mg/150mg film-coated tablets on 07/08/2017.