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EMA recommends authorisation of Diclofenac Sodium Spray Gel 4% (diclofenac) in the EU

EMA completes review following disagreement among EU Member States

On 15 November 2018, the European Medicines Agency completed a review of Diclofenac Sodium Spray Gel 4% following a disagreement among EU Member States regarding its authorisation. The Agency concluded that the benefits of the medicine outweigh its risks, and the marketing authorisation granted in the United Kingdom can be recognised in other Member States of the EU where the company has applied for a marketing authorisation.

What is Diclofenac Sodium Spray Gel 4%?

Diclofenac Sodium Spray Gel 4% contains the active substance diclofenac, which belongs to the group of non-steroidal anti-inflammatory drugs (NSAIDs). The spray gel is applied on the skin of affected areas to relieve pain and swelling due to trauma in small and medium joints and surrounding tissues.

Why was the medicine reviewed?

MIKA Pharma GmbH requested that the marketing authorisation for Diclofenac Sodium Spray Gel 4% granted by the UK (the 'reference Member State') in 2001, and subsequently granted by Austria, Estonia, Hungary, Ireland, Latvia, Lithuania and Slovenia, be also recognised in Germany, Italy and Spain (the 'concerned Member States').

However, the Member States were not able to reach an agreement and the UK medicines regulatory agency referred the matter to EMA for arbitration on 4 April 2018.

The grounds for the referral were concerns raised by Germany and Spain that the data provided by the company were not sufficient to show that the product was effective at treating joint pain and swelling. In addition, the use of data from the published literature obtained with other diclofenac medicines to demonstrate the benefits of Diclofenac Sodium Spray Gel 4% needed to be further justified.

What is the outcome of the review?

The Agency considered that the data provided by the company show that, when applied to the skin, Diclofenac Sodium Spray Gel 4% produces similar levels of diclofenac in the body to another diclofenac

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gel already authorised for the same use. The company also provided the results of a study indicating that Diclofenac Sodium Spray Gel 4% is effective at reducing joint swelling and relieving pain.

Since Diclofenac Sodium Spray Gel 4% is absorbed in a similar way to other diclofenac medicines applied to the skin and the supporting study demonstrated an effect similar to that of other diclofenac medicines in the published literature, the Agency considered that it was acceptable to use published data on the effectiveness and safety of other diclofenac medicines to support the use of Diclofenac Sodium Spray Gel 4%. The Agency also considered that, although the effectiveness of diclofenac and other NSAIDs applied to the skin is somewhat modest, these medicines have been authorised and used for decades and their safety is not in question.

Overall, the totality of the data provided by the company was considered sufficient to demonstrate that Diclofenac Sodium Spray Gel 4% is effective at treating joint swelling and pain due to trauma. The Agency therefore concluded that the benefits of the medicine outweigh its risks, and therefore the marketing authorisation should be granted in the concerned Member States.

More about the procedure

The review of Diclofenac Sodium Spray Gel 4% was initiated at the request of the United Kingdom under Article 29(4) of Directive 2001/83/EC.

The review was carried out by EMA's Committee for Medicinal Products for Human Use (CHMP), responsible for questions concerning medicines for human use.

The European Commission issued an EU-wide legally binding decision on the marketing authorisation of Diclofenac Sodium Spray Gel 4% on 18/01/2019.