European Medicines Agency

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# Questions and answers on the referral for Prokanazol capsules containing itraconazole 100 mg

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 Prokanazol. The Agency's Committee for Medicinal Products for Human Use (CHMP) has concluded that the benefits of Prokanazol do not outweigh its risks, and that the marketing authorisation granted in the Czech Republic cannot be recognised in other Member States of the EU. The marketing authorisation in the Czech Republic should also be suspended.
The review was carried out under an 'Article 29' referral[1].

## What is Prokanazol?

Prokanazol is an antifungal medicine. It is used to treat adults with infections caused by fungi. It can be used in local infections, such as infections of the vulva or vagina (female sexual organs) or infections of the skin or the eye. It can also be used in systemic infections (infections that affect the whole body), including tropical infections. Prokanazol can be used against a range of fungi and yeasts, including *Candida*, *Aspergillus* and *Cryptococcus*.
The active substance in Prokanazol, itraconazole, is an antifungal substance that belongs to the group 'triazoles'. It works by preventing the formation of ergosterol, which is an important part of fungal cell walls. Without ergosterol, the fungus is killed or prevented from spreading.
Prokanazol is a generic medicine that is based on a reference medicine authorised in the Czech Republic (Sporanox 100 mg capsules). Prokanazol is also marketed under the name Prokanaz.

## Why was Prokanazol reviewed?

The company PRO.MED.CS Praha a. s. submitted Prokanazol for mutual recognition on the basis of the initial authorisation granted by the Czech Republic on 30 July 2003. The company wanted the authorisation to be recognised in Latvia, Lithuania, Poland, Slovakia and Slovenia (the 'concerned Member States'). However, because the concerned Member States were not able to reach an agreement, the Czech medicines regulatory agency referred the matter to the CHMP for arbitration on 31 July 2008.
The grounds for the referral were that one of the concerned Member States, Poland, did not agree that enough evidence had been presented to show that Prokanazol was 'bioequivalent' to the reference medicine. Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

## What are the conclusions of the CHMP?

Based on evaluation of the currently available data and the scientific discussion within the Committee, the CHMP was of the opinion that bioequivalence to the reference medicinal product has not been shown. The CHMP therefore concluded that the benefits of Prokanazol do not outweigh its risks and recommended that the marketing authorisation should not be granted in the concerned Member States.

[1] Article 29 of Directive 2001/83/EC as amended, referral on the grounds of potential serious risk to public health

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In addition, the Committee has also recommended that the marketing authorisation for Prokanazol in the Czech Republic should be suspended.

The European Commission issued a decision on 14 July 2009.

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| Rapporteur: | Prof Pirożynski (Poland) |
| Co-rapporteur: | Dr van Zwieten-Boot (Netherlands) |
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| Company responses provided on: | 15 December 2008 |
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