EMA/475432/2012

# European Medicines Agency decision

P/0163/2012

of 23 July 2012

on the agreement of a paediatric investigation plan and on the granting of a waiver for misoprostol (EMEA-001159-PIP02-12) in accordance with Regulation (EC) No 1901/2006 of the European Parliament and of the Council

**Disclaimer**

This Decision does not constitute entitlement to the rewards and incentives referred to in Title V of Regulation (EC) No 1901/2006.

**Only the English text is authentic.**

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# European Medicines Agency decision

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The European Medicines Agency,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No. 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004[1],

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency[2],

Having regard to the application submitted by Ferring Pharmaceuticals A/S on 4 April 2012 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 6 July 2012, in accordance with Article 18 of Regulation (EC) No 1901/2006, and Article 13 of said Regulation,

Having regard to Article 25 of Regulation (EC) No 1901/2006,

Whereas:

(1) The Paediatric Committee of the European Medicines Agency has given an opinion on the agreement of a paediatric investigation plan and on the granting of a waiver.

(2) It is therefore appropriate to adopt a decision agreeing a paediatric investigation plan.

(3) It is therefore appropriate to adopt a decision granting a waiver.

[1] OJ L 378, 27.12.2006, p.1.
[2] OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

***Article 1***

A paediatric investigation plan for misoprostol, vaginal delivery system, vaginal use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby agreed.

***Article 2***

A waiver for misoprostol, vaginal delivery system, vaginal use, the details of which are set out in the opinion of the Paediatric Committee of the European Medicines Agency annexed hereto, together with its appendices, is hereby granted.

***Article 2***

This decision is addressed to Ferring pharmaceuticals A/S, Kay Fiskers Plads 11, DK 2300 Copenhagen S, Denmark.

Done at London, 23 July 2012

For the European Medicines Agency
Guido Rasi
Executive Director
(Signature on file)

EMA/PDCO/389507/2012

# Opinion of the Paediatric Committee on the agreement of a Paediatric Investigation Plan and a waiver

EMEA-001159-PIP02-12

## Scope of the application

**Active substance(s):**

Misoprostol

**Condition(s):**

Labour induction

**Pharmaceutical form(s):**

Vaginal delivery system

**Route(s) of administration:**

Vaginal use

**Name/corporate name of the PIP applicant:**

Ferring Pharmaceuticals A/S

## Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, Ferring Pharmaceuticals A/S submitted for agreement to the European Medicines Agency on 4 April 2012 an application for a paediatric investigation plan for the above mentioned medicinal product and a waiver under Article 13 of said Regulation.

The procedure started on 15 May 2012.

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## Opinion

1. The Paediatric Committee, having assessed the proposed paediatric investigation plan in accordance with Article 17 of Regulation (EC) No 1901/2006 as amended, recommends as set out in the appended summary report:

   - to agree the paediatric investigation plan in accordance with Article 18 of said Regulation,
   - to grant a waiver for one or more subsets of the paediatric population in accordance with Article 13 of said Regulation and concluded in accordance with Article 11(1)(b) of said Regulation, on the grounds that the disease or condition for which the specific medicinal product is intended does not occur in the specified subset(s) of the paediatric population.

The Norwegian Paediatric Committee member agrees with the above-mentioned recommendation of the Paediatric Committee.

2. The measures and timelines of the agreed paediatric investigation plan and the subset(s) of the paediatric population and condition(s) covered by the waiver are set out in the Annex I.

This opinion is forwarded to the applicant and the Executive Director of the European Medicines Agency, together with its annex(es) and appendix.

Langen, Germany, 6 July 2012

On behalf of the Paediatric Committee
Dr Daniel Brasseur, Chairman
(Signature on file)

# Annex I

# The subset(s) of the paediatric population and condition(s) covered by the waiver and the measures and timelines of the agreed Paediatric Investigation Plan

# 1. Waiver

Not applicable.

## *1.1. Condition: Labour induction*

The waiver applies to:

- all male subsets of the paediatric population from birth to less than 18 years of age;
- all prepubertal girls;
- for vaginal delivery system, vaginal route;
- on the grounds that the specific medicinal product does not represent a significant therapeutic benefit as clinical studies(s) are not feasible.

# 2. Paediatric Investigation Plan

## *2.1. Condition: Labour induction*

### 2.1.1. Indication(s) targeted by the PIP

Induction of labour when medically indicated.

### 2.1.2. Subset(s) of the paediatric population concerned by the paediatric development

Postpubertal adolescent girls.

### 2.1.3. Pharmaceutical form(s)

Vaginal delivery system, vaginal use.

### 2.1.4. Studies

| Area | Number of studies | Description |
|---|---|---|
| Quality | 0 | Not applicable. |
| Non-clinical | 0 | Not applicable. |
| Clinical | 1 | Efficacy and safety literature review to support extrapolation of adult data to adolescent population. |

## 3. Follow-up, completion and deferral of PIP

| | |
|---|---|
| Concerns on potential long term safety and efficacy issues in relation to paediatric use: | No. |
| Date of completion of the paediatric investigation plan: | By December 2012. |
| Deferral for one or more studies contained in the paediatric investigation plan: | No. |