



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/388981/2020

## European Medicines Agency decision P/0308/2020

of 12 August 2020

on the agreement of a paediatric investigation plan and on the granting of a deferral and on the granting of a waiver for darunavir / ritonavir (EMEA-002537-PIP02-19) 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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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<sup>1</sup>,

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<sup>2</sup>,

Having regard to the application submitted by PharOS - Pharmaceutical Oriented Services Ltd on 9 September 2019 under Article 16(1) of Regulation (EC) No 1901/2006 also requesting a deferral under Article 20 of said regulation and a waiver under Article 13 of said Regulation,

Having regard to the opinion of the Paediatric Committee of the European Medicines Agency, issued on 26 June 2020, in accordance with Article 17 of Regulation (EC) No 1901/2006 and Article 21 of said Regulation 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 deferral 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 deferral.
- (4) It is therefore appropriate to adopt a decision granting a waiver.

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<sup>1</sup> OJ L 378, 27.12.2006, p.1.

<sup>2</sup> OJ L 136, 30.4.2004, p. 1.

Has adopted this decision:

**Article 1**

A paediatric investigation plan for darunavir / ritonavir, film-coated tablet, oral 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 deferral for darunavir / ritonavir, film-coated tablet, oral 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 3**

A waiver for darunavir / ritonavir, film-coated tablet, oral 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 4**

This decision is addressed to PharOS - Pharmaceutical Oriented Services Ltd, Lesvou Str. (end), Thesi Loggos, Industrial Zone, 14452 - Metamorfossi Attikis, Greece.



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

EMA/PDCO/217809/2020  
Amsterdam, 26 June 2020

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

EMA-002537-PIP02-19

### Scope of the application

**Active substance(s):**

Darunavir / ritonavir

**Condition(s):**

Treatment of human immunodeficiency virus (HIV-1) infection

**Pharmaceutical form(s):**

Film-coated tablet

**Route(s) of administration:**

Oral use

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

PharOS - Pharmaceutical Oriented Services Ltd

### Basis for opinion

Pursuant to Article 16(1) of Regulation (EC) No 1901/2006 as amended, PharOS - Pharmaceutical Oriented Services Ltd submitted for agreement to the European Medicines Agency on 9 September 2019 an application for a paediatric investigation plan for the above mentioned medicinal product and a deferral under Article 20 of said Regulation and a waiver under Article 13 of said Regulation.

The procedure started on 15 October 2019.

Supplementary information was provided by the applicant on 23 March 2020. The applicant proposed modifications to the paediatric investigation plan.



## 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 17(1) of said Regulation;
- to grant a deferral in accordance with Article 21 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)(a) of said Regulation, on the grounds that the specific medicinal product is likely to be ineffective or unsafe in part or all 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 and appendix.

## **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 (PIP)**

# 1. Waiver

## 1.1. Condition:

Treatment of human immunodeficiency virus (HIV-1) infection

The waiver applies to:

- the paediatric population from birth to less than 3 years of age;
- film-coated tablet, oral use;
- on the grounds that the specific medicinal product is likely to be unsafe.

# 2. Paediatric investigation plan

## 2.1. Condition:

Treatment of human immunodeficiency virus (HIV-1) infection

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

Treatment of human immunodeficiency virus (HIV-1) infection in paediatric patients from the age of 3 years and at least 15 kg body weight

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

From 3 to less than 18 years of age

### 2.1.3. Pharmaceutical form(s)

Film-coated tablet

### 2.1.4. Measures

Area	Number of measures	Description
Quality-related studies	1	Study 1: Development of a lower strength film-coated tablet
Non-clinical studies	0	Not applicable
Clinical studies	1	Study 2: Open-label, randomised, single dose, crossover bioequivalence study of the 800 mg darunavir /100 mg ritonavir fixed-dose combination film-coated tablets compared to 800 mg darunavir film-coated tablets co-administered with 100 mg ritonavir film-coated tablets in healthy adults under fed conditions
Extrapolation, modelling and	1	Study 3: Modelling and simulation study to support the use of the

simulation studies		lower strength film-coated tablet in children from 3 years of age
Other studies	0	Not applicable
Other measures	0	Not applicable

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

Concerns on potential long term safety/efficacy issues in relation to paediatric use:	No
Date of completion of the paediatric investigation plan:	By September 2023
Deferral for one or more measures contained in the paediatric investigation plan:	Yes