14 July 2017
EMA/275221/2017
Executive Director

Decision of the Executive Director

on a 1-year initiative for fee reductions for notifications of parallel distribution

THE EXECUTIVE DIRECTOR

Having regard to Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Union procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (hereafter 'the Agency') (Founding Regulation) and in particular Article 57(1)(o) thereof,

Having regard to Directive 2001/83/EC of the European Parliament and of the Council of 06 November 2001 on the Community code relating to medicinal products for human use and in particular Article 76(4) thereof,

Having regard to Council Regulation (EC) No 297/95 of 10 February 1995 on fees payable to the European Agency for the Evaluation of Medicinal Products, and in particular Article 9(1) thereof,

Having regard to the Rules for the implementation of Council Regulation (EC) No 297/95 on fees payable to the European Agency for the evaluation of medicinal products, and in particular Annex III, Number 3 thereof,

Having regard to the Financial Regulation of the European Medicines Agency and its implementing rules and in particular Article 29(1) and (2) 2nd sentence,

Having regard to the Executive Director Decision to run a pilot initiative for fee reductions for notifications of parallel distribution in the Maltese language from the 1st of January 2016 until the 31st of December 2016 (EMA/677790/2015) and the corresponding ex-post evaluation (ref: pmjjb001/2016) provided by the Maltese competent authority

Having regard to the eligibility criteria for an application by Member States as set out in Article 4 of this decision

Having regard to the consultation with the competent scientific committee (Committee for Medicinal Products for Human Use 19.06.2017) regarding the exceptional circumstances and the imperative reason of public health for parallel distributions in languages for which the population size speaking the national official EU language is no more than 2 million at the time of application or was no more than 2 million at the time of accession,

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Whereas the Executive Director may, without prejudice to more specific provisions of Union law, in exceptional circumstances and for imperative reasons of public or animal health, grant fee reductions case by case after consultation of the competent scientific committee,

Whereas it is imperative for the health of European citizens that language is not an obstacle to access centrally authorised medicinal products,

Whereas the level of fees charged by the European Medicines Agency for processing notifications for parallel distribution could potentially contribute to the lack of parallel distribution notifications for medicinal products in languages for which the population size speaking the national official EU language is no more than 2 million at the time of application or was no more than 2 million at the time of accession,

Whereas the expected impact of the initiative will not lead to an increase in resources needed at the Agency,

Whereas appropriations shall be used in accordance with the principles of sound financial management whilst respecting the principle of efficiency aiming for the best relationship between resources employed and results achieved,

Whereas for the value of the fee charged for initial notifications of parallel distribution and any subsequent procedure thereof it is not deemed efficient to require case-by-case decisions on potential reduction for a predefined duration (initiative).

HAS DECIDED

Article 1 - Scope of the initiative

In order to enable European citizens to access centrally authorised medicinal products where the fee level might be an obstacle to parallel distributions in their national official language reduced fee levels for parallel distributions shall be introduced as a one-year initiative, having regard to the eligibility criteria for an application by Member States as set out in Article 4 of this decision.

Article 2 - Fee reductions

The applicable fee for parallel distribution shall be reduced as set out below.

Initial notification of parallel distribution	~~3 070 EURO~~ reduced to 450 EURO For each EU presentation of a medicinal product distributed in [..] national official EU language. [..]
Notification of changes	~~580 EURO~~ reduced to 280 EURO For each notification of changes to a notice in the national official EU language that is not submitted as part of the annual update notification and is not a safety update. [..] [..]

Notification of bulk changes	~~3 070 EURO~~ reduced to 450 EURO For one or more changes that affect all of a parallel distributor's initial notifications in the national official EU language, at any point in time after the approval of the initial notification. The scope(s) of the changes are limited to: a change in the name and/or address of a parallel distributor, addition or deletion of a re-packager, and/or a change in the name and/or address of a re-packager.

Article 3 – Other fees for parallel distribution

1. Notifications of changes or notifications of bulk changes applicable to PD notices issued in accordance with this Decision that are submitted after the one year period shall be charged at the regular rates
2. Fees for annual updates will apply at the normal rate once due.

Article 4 – Process and eligibility criteria of new applications by the National Competent Authorities

1. An application shall be made by the interested national competent authority to the Agency's Executive Director with the request of a fee reduction for notifications of parallel distribution in accordance with the eligibility criteria set in paragraph 2.
2. The eligibility shall be assessed by the Executive Director in accordance with the following criteria:
   a) A lack of accessibility to centrally authorised products has been demonstrated (amounting to more than 50% of all authorised ATC codes)
   b) A lack of treatment alternatives available
   c) Demonstrated imperative public health need
   d) Population size speaking the national official EU language is
      i. no more than 2 million at the time of application or
      ii. was no more than 2 million at the time of accession
   e) Wholesalers do not engage in parallel distribution due to the Agency's fees for administrative services
3. Once the fee reduction is granted, the details are published in Annex I of this decision (country, population speaking the language, start/finish date)

Article 5 - Processing of fee reductions

During the initiative, any request for notifications for parallel distribution in the participating member states, submitted to the Agency using the Agency's procedure, will be assigned the applicable reduced fee. No separate request for fee reduction by the applicant is required during this period.

Article 6 - Ex-post evaluation

Within three months of the end of the initiative, the Agency will collect the following data from the (participating) relevant authorities:

- An analysis on the effect that notices for parallel distribution in the national official EU language had on the number of centrally authorised products (CAPs) available on the local market during the period of the initiative
- An analysis on the effect that notices for parallel distribution in the national official EU language had on the availability of ATC codes of CAPs on the locale market during the period of the initiative

The Agency shall supply the (participating) relevant authorities with the details of all notices for parallel distribution issued in the national official EU language during the period of the initiative.

Article 7 - Entry into force

The duration of the initiative shall be one (1) year. This decision will enter into force on 15 July 2017 and shall be valid until 14 July 2018.

London, 14 July 2017

[signature on file]

Guido Rasi
Executive Director

05 March 2018
EMA/373049/2017/Rev1[i]
Executive Director

ANNEX I – List of participating Member States

Having regards to the Decision of the Executive Director

on a 1-year initiative for fee reductions for notifications of parallel distribution

1. **Malta**
   Request: pmjjb001/2016 of 07/03/2017
   Population speaking Maltese: 429, 344
   Start date: 15 July 2017
   End date: 14 July 2018

2. **Latvia**
   Request: No. 1-4/477 of 23/03/2017
   Population speaking Latvian: 1, 986, 096
   Start date: 15 July 2017
   End date: 14 July 2018

3. **Estonia**
   Request: RDH-4/2265-2 of 16/08/2017
   Population speaking Estonian: 1, 315, 635
   Start date: 08 December 2017
   End date: 14 July 2018

4. **Slovenia**
   Request: document number 01-1/2018-1
   Population speaking Slovenian at time of accession: 1,997,004
   Start date: 08 January 2018
   End date: 14 July 2018

[i] End dates for Estonia and Slovenia have been corrected to reflect the end date of the initiative.

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