EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

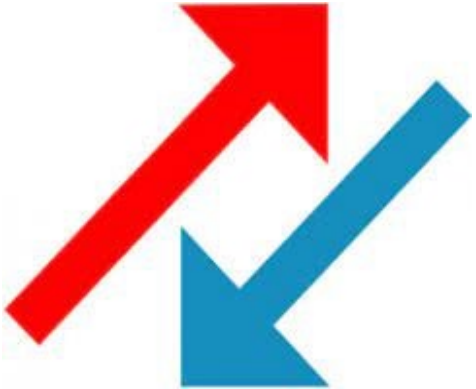
Third party interventions

Presented by Fabrizio Boccacci
Joint PCWP and HCPWP meeting, 27 February 2024

Can third parties intervene in marketing authorisations procedures? How can the intervener and the applicant/MAH exercise their respective rights?

MAH- Marketing Authorisation Holder

Aspects to be considered



1. Bilateral nature of marketing authorisation procedures

2. Need to ensure a high level of human health protection

3. Strict deadlines identified in EU pharmaceutical legislation

1. Bilateral nature of marketing authorisation procedures

Article 3(1) of Regulation (EC) 726/2004

Article 4(1) of Regulation (EC) 726/2004

Article 6(1) of Regulation (EC) No 726/2004

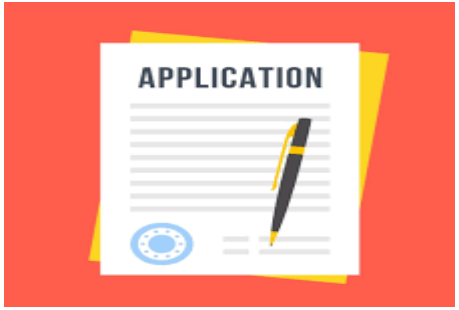
Article 7 of Regulation (EC) No 726/2004

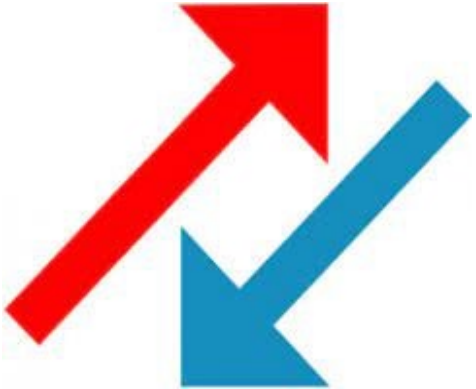
Article 17 of Regulation (EC) No 726/2004

Article 12 of Regulation (EC) No 726/2004

Article 16(3) of Regulation (EC) No 726/2004

Annex II to Regulation (EC) No 726/2004





2. Need to ensure a high level of human health protection

Article 168 of the Treaty on the Functioning of the European Union (ex Article 152 TEC)

1. ***A high level of human health protection shall be ensured in the definition and implementation of all Union policies and activities.*** *Union action, which shall complement national policies, shall be directed towards improving public health, preventing physical and mental illness and diseases, and obviating sources of danger to physical and mental health.* [….]

3. Strict deadlines identified in EU pharmaceutical legislation

- Article 6(3) of Regulation (EC) No 726/2004: "*The Agency shall ensure that the opinion* […] *is given within 210 days after receipt of a valid application*".
- Article 14(9) of Regulation (EC) No 726/2004: "*When an application is submitted for a marketing authorisation in respect of medicinal products for human use which are of major interest from the point of view of public health […], the time-limit laid down in Article 6(3), first subparagraph, shall be reduced to 150 days*".
- Article 9(2) of Regulation (EC) No 726/2004: "*Within 60 days following receipt of the grounds for the request, the said Committee shall re-examine its opinion*".

Relevant judgments of the European Court of Justice (ECJ)

- Court of First instance, 18 December 2003, in Case T-326/99, *Dr Olivieri / EC*
- General Court, 5 May 2021, in Case T-611/18, *Pharmaceutical Works Polpharma / EMA*
- General Court, 26 January 2022, in Case T-303/16, *Mylan IRE Healthcare Ltd / EC*

Principles stemming from the judgments of the ECJ

- Information from a third party must be taken into account where such a course of action is indispensable in order to safeguard public health. (para. 73, Court of First instance, 18 December 2003, in Case T-326/99 Olivieri v Commission and EMEA)
- *Third parties are not entitled to participate in a regulatory procedure or set themselves up as interlocutors of the CHMP and of the Commission in regard to the assessment of the scientific data relating to the medicinal product in question*. (para. 117, General Court,5 May 2021, Pharmaceutical Works Polpharma / EMA, case T-611/18)
- *Although the intervener is entitled to make sure that the CPMP and the EC examine the information, that right ends at the moment when that information is examined and taken into account in the course of that assessment procedure (*para. 91, Court of First instance, 18 December 2003, in Case T-326/99, Olivieri v Commission and EMEA)

Principles stemming from the judgments of the ECJ cont..

- *There is no provision in Directive 2001/83/EC, applicable to this case, which prohibits the Commission, before issuing an MA, from following a procedure during which persons other than the applicant for the MA are able to submit their observations to it so as to enable it to fulfil its duty to check, in the interests of public health, whether all the information relating to the scientific assessment of the medicinal product in question, whether it be favorable or unfavorable to the product, has indeed been made available to it. The fact that those rules do not contain any provision to that effect cannot prevent the Commission from obtaining information from a third party where such a course of action is indispensable in order to safeguard public health (see para. 73 of the judgment of the Court of First instance, 18 December 2003, in Case T-326/99 Olivieri v Commission and EMEA and para. 164 of the Judgment of the General Court of 26 January 2022, Mylan IRE Healthcare / Commission, case T-303/16)*

MA- Marketing Authorisation

How the Agency handles third party interventions?

1. Third parties can submit written observations.
2. Third party interventions, **if considered relevant** by the concerned Scientific Committee, should be taken into account during the scientific assessment.
3. The addressees of the decisions should be given the opportunity to have **access to** (an eventually **redacted** version of) the third-party **intervention.**
4. The addressees of the decisions should be entitled to provide **comments** to the third-party intervention.
5. Third-party interventions are reflected in the assessment report.

Any questions?

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