

## Revision of Regulation (EC) No 726/2004

### Position of the *European Social Insurance Platform (ESIP)*

FINAL

25 November 2016

### **About the *European Social Insurance Platform (ESIP)***

The *European Social Insurance Platform (ESIP)* represents over 40 national statutory social insurance organisations (covering approximately 240 million citizens) in 15 EU Member States and Switzerland, active in the field of health insurance, pensions, occupational disease and accident insurance, disability and rehabilitation, family benefits and unemployment insurance. The aims of ESIP and its members are to preserve high profile social security for Europe, to reinforce solidarity-based social insurance systems and to maintain European social protection quality. ESIP builds strategic alliances for developing common positions to influence the European debate and is a consultation forum for the European institutions and other multinational bodies active in the field of social security.

**Statement regarding positions submitted by ESIP:** *ESIP members support this position in so far as the subject matter lies within their field of competence.*

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#### Background

On 10 September 2014, the European Commission (EC) submitted a proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (EMA). On 23 February 2016, the Members of the European Parliament (EP) adopted a report on the proposal in the Environment, Public Health and Food Safety Committee, in which they proposed a number of amendments. The proposed amendments were accepted in plenary on 10 March 2016. The initial proposal was aimed at a better regulation of *veterinary products*, however, in the course of the legislative proceedings, amendments have been included that have significant **consequences for medicinal products for human use**.

#### **1. ESIP objects to a centralised evaluation of comparative efficacy that will impinge upon Member States competences in the field of pricing and reimbursement**

The European Parliament proposed several amendments (cf. the amendments listed in annex I) aimed at conducting an evaluation of the comparative efficacy of medicinal products for human use in the context of EMA's marketing authorisation. According to the proposals put forward by the EP, the Committee for Medicinal Products for Human Use (CHMP) is to include a comparative evaluation of the medicinal product (for human use) with the authorisation, if a positive opinion is issued. According to amendment No. 9, the Member States' power to set the prices of medicinal products, as well as to include such products in their national health insurance systems, on the basis of health, economic and social conditions, only remain unaffected if they take this evaluation of comparative efficacy "into due consideration".

While the early **assessment of comparative efficacy** is important for Member States when making their pricing and reimbursement decisions, this assessment **must be independent and free from conflict of interest**. Currently it is not clear in the text who will be responsible for carrying out the comparative assessment **in the context of the centralised marketing authorisation**. In the case that this will be EMA itself **ESIP strongly objects to the amendments**. Currently, comparative assessments are conducted on the Member State level by independent HTA (health technology assessment) bodies. Notwithstanding numerous differences in national procedures and practices, which are justified by the specificities of each Member State's local needs and settings, these assessments are an essential pillar of **national pricing and reimbursement decisions** for medicinal products. Derogating from the EMA assessment would only be possible by stating the grounds for the derogation, entailing a significant **burden** for pricing and reimbursement institutions. Further, it would considerably intensify the discussions, which are already underway, as to the selection of an expedient comparative therapy. Bearing in mind the existing mandatory time

limits and appeal proceedings foreseen in the so-called Transparency Directive (89/105/EEC), this may easily lead to a *de facto* obligation to accept EMA's assessment. As a result, the amendments would significantly **harmonise the benefit assessment** on a European level and transfer an essential element of national price setting to the EU level. Pricing and reimbursement is and should remain a **national competence**.

Moreover, the current proposal does not provide for any **standards or methodology** to be applied by the EMA when carrying out the benefit assessment. The amendments do not take into account that the medicinal products used as reference (**comparators**) for assessments vary due to national particularities linked to medical, economic and availability issues.

Lastly, ESIP and its member organisations are already supporting ongoing initiatives aimed at further **streamlining existing national HTA procedures**. In particular, EUnetHTA provides a sound framework for national institutions to work together on a voluntary basis to develop common standards and conduct common assessments using a bottom-up approach. The proposed amendments **jeopardise** those ongoing developments by imposing a top down solution inconsiderate of **possible disruptions** for existing national procedures. Accordingly, they risk predetermining and undermining DG SANTE's Inception Impact Assessment on Strengthening of the EU cooperation on Health Technology Assessment. In addition, more work still needs to be done on a voluntary basis to identify areas of possible convergence and to assess to what extent the reuse of common reports is possible at national level.

## **2. ESIP stresses caution in authorising delegated acts in view of the current debate on accelerated market access schemes**

Already in the initial proposal the European Commission intends to align the powers conferred to it under Regulation (EC) No 726/2004 to Articles 290 and 291 of the TFEU, establishing the possibility to authorise the Commission to adopt delegated or implementing acts to amend or supplement certain non-essential elements of a legislative act. Accordingly, the Commission shall be empowered to adopt delegated acts in certain *non-essential aspects* of Regulation 726/2004. This includes, inter alia, the power to lay down provisions and requirements for granting marketing authorisations subject to certain specific obligations as well as the power to determine the situations in which post-authorisation efficacy studies may be required (cf. Annex II).

**Conditional marketing authorisation** in conjunction with **post-marketing obligations** currently provide the regulatory framework for various initiatives aimed at implementing an accelerated market access (e.g. via so called "adaptive pathways"). Authorisation on the basis of incomplete data and **limited evidence** entails significant risks for patients. Current experiences show that post-marketing obligations are often not fully satisfied or are subject to considerable delays and are therefore not suitable to replace pre-market evidence. Despite the lack of available evidence, national health care systems may be forced to bear the costs after conditional marketing authorisation has been granted. Thus, delegation in this case touches upon one of the **most sensitive** issues in the current debate on adaptive pathways for marketing authorisation. In our view, the underlying ethical and political questions directly affect **essential parts of the regulation**. In any case, it has to be ensured that approvals on the basis of limited evidence are made possible only in **exceptional circumstances** where a clearly **defined unmet medical need** has been identified.

Annex I:

Extracts from the report on the proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (Committee on the Environment, Public Health and Food Safety): Amendments 8, 9, 13 and 16.

No	Amendment
8	<i>(6e) Member States have developed an evaluation of the comparative efficacy of medicinal products aimed at positioning a new medicinal product with respect to those that already exist in the same therapeutic class. Similarly, the Council, in its conclusions on medicinal products and public health, adopted on 29 June 2000, emphasised the importance of identifying medicinal products that presented an added therapeutic value. That evaluation should be conducted in the context of the marketing authorisation.</i>
9	<i>2a) In Article 1, the second paragraph is replaced by the following:</i> "The provisions of this Regulation shall not affect the powers of Member States' authorities as regards setting the prices of medicinal products or their inclusion in the scope of the national health system or social security schemes on the basis of health, economic and social conditions, <b>provided that Member States take into due consideration the reference comparative evaluation of human medicinal product as referred to in Article 9(4).</b> In particular, Member States shall be free to choose from the particulars shown in the marketing authorisation those therapeutic indications and pack sizes which will be covered by their social security bodies."
13	<i>(5b) In Article 9(4), the following point is inserted:</i> " <b>(da) the comparative evaluation of the human medicinal product;</b> "
16	<i>(10c) In Article 57(1), the first subparagraph is replaced by the following:</i> "1. The Agency shall provide the Member States and the institutions of the Community with the best possible scientific advice on any question relating to the evaluation of the quality, safety, efficacy <b>and comparative assessment</b> of medicinal products for human or veterinary use which is referred to it in accordance with the provisions of Community legislation relating to medicinal products."

Annex II:

Extracts from the proposal for a regulation of the European Parliament and of the Council amending Regulation (EC) No 726/2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (COM/2014/0557 final).

*Article 1*

Regulation (EC) No 726/2004 is amended as follows:

(7) Article 10b(1) is replaced by the following:

‘The Commission shall be empowered to adopt measures, by means of delegated acts in accordance with Article 87b, to determine the situations in which post-authorisation efficacy studies may be required under point (cc) of Article 9(4) and point (b) of Article 10a(1).’;

(8) Article 14(7) is replaced by the following:

‘7. In the interests of public health a marketing authorisation may be granted subject to certain specific obligations, to be reviewed annually by the Agency. Those obligations and, where appropriate, the time limit for compliance shall be specified in the conditions to the marketing authorisation. The summary of product characteristics and the package leaflet shall clearly mention that the marketing authorisation for the medicinal product has been granted subject to those obligations.

By way of derogation from paragraph 1, such authorisation shall be valid for one year, on a renewable basis.

The Commission shall be empowered to adopt delegated acts in accordance with Article 87b in order to lay down provisions and requirements for granting such marketing authorisation and for its renewal.’ ;

(9) Article 16(4) is replaced by the following:

‘4. The Commission shall be empowered to adopt delegated acts in accordance with Article 87b establishing procedures for the examination of applications for variations to the terms of marketing authorisations and for the examination of applications for the transfer of marketing authorisations.’;

(20) Article 87b is replaced by the following:

‘Article 87b

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.

2. The delegation of power referred to in Articles 3(4), 10b (1), 14(7), 16(4) and 84(3) shall be conferred on the Commission for an indeterminate period of time from the date of entry into force of this Regulation.

3. The delegation of power referred to in Articles 3(4), 10b (1), 14(7), 16(4) and

84(3) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the European Union* or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.

5. A delegated act adopted pursuant to Articles 3(4), 10b (1), 14(7), 16(4) and 84(3) shall enter into force only if no objection has been expressed either by the European Parliament or the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.’;