EUROPEAN SOCIAL INSURANCE PLATFORM

The Social Insurers of Europe

Brussels, 12 October 2015

Concerning: Position of the *European Social Insurance Platform* on the proposed EU Regulation on medical devices [COM (2012) 542]

Dear Sir or Madam,

I am addressing you on behalf of the *European Social Insurance Platform* (ESIP), which is a strategic alliance of over 40 national statutory social security organisations in 15 EU Member States and Switzerland.

ESIP has been in favour of the establishment of a central marketing authorisation procedure for high-risk medical devices in order to avoid a repetition of the health scandals that have been arising because of defective medical devices (e.g. breast and hip implants). Regrettably the amendments on the draft regulation still rely on decentralised notified bodies.

Nevertheless ESIP welcomes the improvements proposed by the European Parliament and the Council to make medical devices as safe and effective as possible for patients. On the eve of the trilogue negotiations, ESIP wants to bring some important issues to your attention.

ESIP asks for:

1. Adoption of the proposals of the Council (e.g. Art. 28, 29, 32,33, 35, Annex VI) and the European Parliament (Art. 43a and Annex VI) regarding the assessment of high-risk devices by notified bodies. These proposals strengthen the independence and the expertise of the notified bodies and set provisions aimed at reinforcing their surveillance and monitoring by competent authorities. However, stricter **provisions are needed to ensure that notified bodies are sufficiently qualified and have the relevant expertise within their organisation with "Permanent in-house staff"** (see European Parliament proposal for Annex VI).

2. **A stronger assessment of high-risk medical devices in which safety, efficacy and a positive risk-benefit balance must be proven by the results of high quality clinical investigations**. ESIP supports the position of the Council in which medical devices of class IIa, IIb and III are subject to the conformity assessment procedure (Art. 42 – paragraph 2, 3 and 4) and manufacturers shall perform clinical investigations for high-risk medical devices (Art. 49 – paragraph 2a). In this regard, **ESIP recommends compulsory clinical investigations for all class III devices and class IIb implantable medical devices.** Moreover **randomised controlled investigations should be privileged** as proposed by the European Parliament (Annex XIV – Part II – point 1 – point 1.11).

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ESIP also welcomes the consultation of external experts during the assessment (Council proposal for Art. 42 2a, European Parliament proposal for Article 44a) but asks for **more demanding provisions regarding the functioning of the expert panel. In addition, notified bodies should not be allowed to deliver the certification to high-risk medical devices if this expert panel has given a negative opinion**, as it is the case within the procedure for devices incorporating a medicinal substance (Council proposal for Annex VIII – point 6 – point 1(e)).

ESIP welcomes the provision that the intended purpose must be clearly reflected by the results of clinical evaluation.

3. **Stronger provisions regarding transparency, which should be the rule and not the exception.** Particularly, **clinical data, including the full results of clinical investigations irrespective of their outcome** (European Parliament proposal for Article 53 – paragraphs 2a and 57 - paragraph 3) as well as any information that may be useful to ensure the independence of decision-making and to improve patient safety, should be made publicly available.

4. **The obligation of compulsory liability insurance for medical device manufacturers** as proposed by the European Parliament in its position (Article 8 – point 10(a)). Indeed, the text proposed by the Council (Article 8) where this liability insurance remains optional is insufficient. Only mandatory liability insurance guarantees that patients harmed can enforce their rights in the event of insolvency of the manufacturer.

For more details on our recommendations, please see the annex to this letter.

We would be pleased if you could take the recommendations of ESIP into account in your forthcoming discussions. For any questions and information please do not hesitate to contact us.

Yours faithfully,

F. Terwey

Franz Terwey, President ESIP

About ESIP - European Social Insurance Platform

ESIP represents a strategic alliance of over 40 statutory social security organisations in 15 EU Member States and Switzerland. ESIP's mission is to preserve high profile social security for Europe, to reinforce solidarity based social insurance systems, and to maintain European social protection quality.