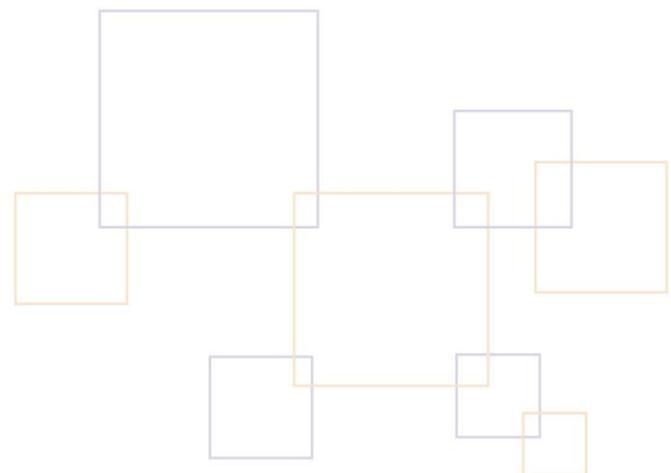


***Proposal for a Regulation on Health Technology Assessment***

**Statement supporting the inclusion of a broad scope of medical devices in the proposed Regulation**

**European Social Insurance Platform (ESIP)**

**6 July 2018**



**ESIP aisbl**

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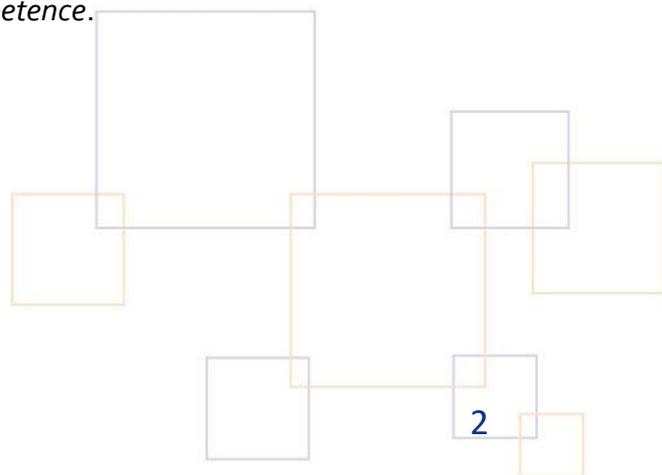
## About the European Social Insurance Platform (ESIP)

The *European Social Insurance Platform (ESIP)* represents over **50 national statutory social insurance organisations** (covering approximately **250 million citizens**) in **16 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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Some voices are advocating that the clinical assessment of medical devices should be kept out of the scope of the joint assessment at EU level foreseen in the EU Proposal for a Regulation on Health Technology Assessment (HTA)<sup>1</sup>. In view of the forthcoming votes in the committees of the European Parliament, **the European Social Insurance Platform (ESIP), representing healthcare payers, strongly advocates in favour of their inclusion in the scope of the proposed HTA regulation.** Further, **we believe the scope for joint clinical assessments of medical devices should be broadened.**

## **Medical devices need to be included in the scope of the HTA regulation**

### **The need for better clinical evidence**

In our view, the clinical evidence needed for assessment and decision-making concerning medical devices should be improved. This is also the view of the rapporteur of the Committee on the Environment, Public Health and Food Safety, MEP Soledad Cabezón Ruiz.

### **The need to increase knowledge of their efficacy and cost-effectiveness**

The recently approved Medical Devices Regulation that will enter into force in May 2020<sup>2</sup> concerns only the CE marking of medical devices. It covers the aspects of their safety and transparency only; it does not cover the aspects of efficacy and cost-effectiveness. These aspects can only adequately be addressed by their inclusion in the scope of the proposed HTA regulation.

### **The importance of medical devices for healthcare systems**

The budget impact of medical devices<sup>3</sup> as well as their impact on patients and on the organisation of healthcare systems requires the inclusion of medical devices in the scope of HTA at EU level, according to objective criteria of impact on populations' health.

## **The scope of medical devices to be assessed at EU level should be broadened**

We believe that the selection of topics **should not be limited to the medical devices and in-vitro diagnostics mentioned in article 5, 1 (b) - (c).** Instead, all medical devices and other relevant topics such as services that include medical devices (referred to as "other health technologies" in article 3) should be subject to a selection mechanism following the criteria mentioned in article 5, 2 (a) – (e). We would like to highlight three examples of joint

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<sup>1</sup> See for instance the [amendments](#) submitted to the Committee on the Environment, Public Health and Food Safety, on 15.06.18 and 18.06.18.

<sup>2</sup> [Regulation \(EU\) 2017/745, of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation \(EC\) No 178/2002 and Regulation \(EC\) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.](#)

<sup>3</sup> Committee on the Environment, Public Health and Food Safety 2018/0018(COD) 4.5.2018, Amendment 3: EUR 110.000 million expenditure.

assessments of medical devices which have a high added-value but would be excluded according to the current text of article 5 of the Proposal.

### **Blood glucose monitoring**

In EUNETHTA Joint Action 3 (JA3) an assessment on “continuous blood glucose monitoring (devices)” is ongoing. The topic has a high potential impact on patients, public health, or healthcare systems. A joint assessment of the clinical value is therefore of major EU-wide added value<sup>4</sup>.

### **Screening of foetal aneuploidies by non-invasive prenatal test**

In EUNETHTA JA3 an assessment on “Screening of foetal aneuploidies by non-invasive prenatal test” was carried out. This is of significant interest in any case of pregnancy. Thus, the topic also has a high potential impact on patients, public health, or healthcare systems. A joint assessment of the clinical value is therefore of major EU-wide added value<sup>5</sup>.

### **Renal denervation systems for treatment-resistant hypertension**

In EUNETHTA JA 2, a rapid assessment on the use of “renal denervation systems for treatment-resistant hypertension” was carried out. Patients with this condition suffer from the lack of treatment alternatives, which led to an increasingly widespread use of this technology throughout Europe. Trial results published in 2014 showed a lack of effectiveness of the treatment. Preliminary data of recent studies<sup>6</sup> with very restricted inclusion criteria using a different product indicated some clinical effects which remain to be confirmed. As the underlying ablation catheters are not subject to the requirements currently suggested by the proposal of the European Commission, this example of a medical device with a lack of efficacy at least for the first developed model at the time of its widespread use in combination with a potential of risk in patients due to irreversible destruction of nerve tissue, underlines the necessity to open up the scope of the HTA regulation<sup>7</sup>.

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<sup>4</sup> <https://www.eunetha.eu/continuous-glucose-monitoring-cgm-real-time-flash-glucose-monitoring-fgm-personal-standalone-systems-patients-diabetes-mellitus-treated-insulin/>

<sup>5</sup> <https://www.eunetha.eu/wp4-otca03-screening-fetal-trisomies-21-18-13-non-invasive-prenatal-testing-now-available/>

<sup>6</sup> Kandzari DE, Böhm M, Mahfoud F et al, Lancet 2018; 391: 2346–55

<sup>7</sup> <https://www.eunetha.eu/second-pilot-rapid-assessment-on-renal-denervation-systems-for-treatment-resistant-hypertension/>