



Ms Sorina Pinte
Ministry of Health
Intr. Cristian Popișteanu, nr. 1-3
Sector 1
010024 București
Romania

Brussels, 21 January 2019

Dear Minister,

On 1st January 2019 Romania took over the Presidency of the Council of the European Union and we would like to highlight the importance of a topic on the agenda of the EU institutions since January 2018: **the proposal for a regulation on Health Technology Assessment (HTA)**. Cooperation on HTA has the potential to **positively affect the treatment of patients and the long-term sustainability of Member States' healthcare systems**, and thus could demonstrate the **direct benefits of European cooperation to EU citizens**.

As you are aware, the aim of this proposal is to set up a European cooperation on HTA, in order to consolidate and expand the work currently performed by the European Network for Health Technology Assessment (EUnetHTA), a voluntary cooperation financed by the EU Health programme since 2006 and whose funding will cease in 2020.

The European Social Insurance Platform (ESIP) represents the national statutory social insurance organisations in 16 Member States and Switzerland covering 250 million insured persons. As public health care payers, at the forefront of ensuring universal access to an adequate level of healthcare based on the principle of solidarity, we have been supporting cooperation in this field¹. **HTA is an essential tool for Member States to make evidence-based decisions on pricing and reimbursement of health technologies.**

HTA supports decisions on where best to allocate public resources, ensuring that patients benefit from high-quality, added-value medicines and medical devices. Cooperation in HTA offers the possibility to pool resources and knowledge and to support countries in developing capacities in this field.

¹ See the ESIP position on Access to innovative medicines from 13 October 2015: <https://esip.eu/publications-intranet?id=104>.

ESIP aisbl

Maison Européenne de la Protection Sociale
Rue d'Arlon 50 • 1000 Bruxelles • ☎ +32 2 282 05 60 • 📠 +32 2 282 05 98
✉ esip@esip.eu • 🌐 www.esip.eu • 🐦 @ESIP_EU • VAT: BE 0808.072.950



As expressed in our positions² on the topic, we still think that the EC proposal could be substantially enhanced, e.g. by improving the governance of the cooperation and, defining strong quality requirements regarding joint clinical assessments in the regulation itself (as opposed to in tertiary legislation) while allowing sufficient flexibility for Member States to perform their own clinical evaluation if deemed necessary.

Although the European Parliament has pushed forward some interesting ideas to improve the Commission's proposal³, the Council has not yet been able to define a common position on this issue.

We are concerned about this situation as **the absence of legislation before 2020 could undermine the EU cooperation in HTA and the important work done for over a decade within EUnetHTA.**

For this reason we encourage the Presidency to foster fruitful discussions on the HTA file within the Council.

We hope you will take our views into consideration and remain at your disposal for further information.

Sincerely

Arnaud Emériaux
ESIP President



In copy: Commissioner for Health and Food Safety Vytenis Andriukaitis

About the European Social Insurance Platform (ESIP)

The European Social Insurance Platform (ESIP) represents over **40 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-

² See the ESIP position on the regulation on Health Technology assessment from 23 April 2018:

https://esip.eu/new/details/2/50-Ensuring%20quality%20?independence_at_the_core_of_the-HTA_Regulation=.

³ See the European Parliament position from 3 October 2018:

<http://www.europarl.europa.eu/sides/getDoc.do?type=TA&language=EN&reference=P8-TA-2018-0369>.



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.

Note: ESIP members support this position in so far as the subject matter lies within their field of competence.

ESIP aisbl

Maison Européenne de la Protection Sociale

Rue d'Arlon 50 • 1000 Bruxelles • ☎ +32 2 282 05 60 • 📠 +32 2 282 05 98

✉ esip@esip.eu • 🌐 www.esip.eu • 🐦 @ESIP_EU • VAT: BE 0808.072.950

