Public consultation on strengthening EU cooperation on Health Technology Assessment (HTA)

Statement of the Representation of the French Social Security

The Representation of the French Social Security institutions to the European Union (REIF) was created in May 2003 to represent the French social security agencies to the EU institutions.

Since April 2015, REIF gathers all the Branches of the general scheme together with the scheme for farmers and self-employed people: the health insurance (CNAMTS), the old-age insurance (CNAV), the Family fund (CNAF), the social security collection body (ACOSS), the farmer scheme (CCMSA), the self-employed scheme as well as the French University for Social Security (EN3S) and the Union of the National social security funds (UCANSS).

The Representation of the French Social Security (REIF) is pleased to answer to the public consultation on EU cooperation on Health Technology Assessment launched by the European Commission.

As an association representing the French compulsory health insurance (the National health insurance fund for salaried workers, CNAMTS, the Central health insurance fund for farmers, CCMSA and the National health insurance fund for independent workers, CNRSI), the REIF expresses its strong interest for Health Technology Assessment as a basis for the pricing and reimbursement decision.

In principle, the REIF welcomes the goal of improving and strengthening the cooperation on Health Technology Assessment at European level. We strongly support the activities of the HTA network and the three joint actions implemented under EUnetHTA. This cooperation has allowed the national Health Technology Assessments bodies to share best practices, better knowledge of procedures and methodologies.

In October 2014, the Member States representatives in the HTA network unanimously adopted their *Strategy for EU cooperation on HTA*[1]. In this strategy paper, they invite all stakeholders, and especially the European Commission, *"to explore models for long term sustainability of the cooperation by considering relevant funding opportunities and by including joint work in national and regional HTA activities, as appropriate and in line with national requirements"*.

The REIF also thinks that it is necessary to secure the joint action and cooperation on HTA in the long-term. We recognize the importance of a well-functioning HTA framework at European level.

Please find below our main observations and comments on the current cooperation and the next HTA framework beyond 2020.

1. Differences on HTA procedures and methodologies for the clinical and economic assessment and outcomes

First, the REIF agrees with the statements of the public consultation (cf. Part 3 "State of play") which declare that there are differences between HTA procedures and methodologies for clinical and economic assessment among EU Member States.

This heterogeneity is linked to the fact that Member States have their own organisation and structure, which are justified by specific health needs and economic settings within their respective territories. Methodologies and

[1] *Strategy for EU cooperation on Health Technology Assessment*, EU Health Technology Assessment Network, October 2014
http://ec.europa.eu/health//sites/health/files/technology_assessment/docs/2014_strategy_eucooperation_hta_en.pdf

outcomes need to take into account the local economic, social and health context.

Nevertheless, improvements have been made on methodologies for clinical assessment. Indeed, the first two joint actions EUnetHTA established a common methodology and a degree of consensus as regards data requirements, choice of comparators, acceptable endpoints and way of expressing added therapeutic benefit, and gave evidence of the feasibility of joint reports.

2. *Type of financing system*

In the public consultation, the European Commission asks stakeholders to give their opinion on the type of financing system to implement in case EU cooperation beyond 2020.

As it is very important to implement good governance based on transparency and independence, the REIF would not support a financing system based on industry fees. To preserve the independency of the HTA process, the financing system should rely on public funding (national and/or UE budget).

3. *Secretariat/organisational support*

In case EU cooperation on HTA will continue beyond 2020, one option considered is to give the task of organisational support to the European Medicines Agency (EMA).

However, we think that the scope of Health Technology Assessment is wider than the scope of EMA. Indeed, Health Technology Assessment does not only refer to a medicinal product but also to a medical device or medical and surgical/radiation procedures as well as measures for disease prevention, diagnosis and treatment used in healthcare. In this perspective, it would not have any sense to give this mission to EMA.

In addition, we recall that the process of HTA should remain separate and independent from that of market authorisation, and thus be entrusted to an independent HTA bodies.

4. *Type of cooperation and activities in a EU cooperation on HTA beyond 2020*

In the public consultation (part 4 – "EU cooperation on HTA beyond 2020"), the European Commission asks to the stakeholders to give their opinion on activities and type of cooperation on HTA which have to be considered beyond 2020.

We think that an EU initiative should serve towards the long term sustainability of national healthcare systems by driving innovation towards patient access to

technologies that demonstrate relevant benefit for the patients and healthcare systems.

On the other hand, we share the view of the strategy paper of the Member States representatives in the HTA Network which recall that the measures *"adopted to implement the HTA Network (…) shall aim at strengthening cooperation and shall not interfere with areas of Member States' competence in deciding on the implementation of HTA conclusions and shall not harmonise national laws or regulations of the Member States. Cooperation at EU level shall fully respect their responsibilities to organise and deliver health services and medical care".*

The HTA cooperation has to respect the competencies of the Member States, especially their responsibility to organise and deliver health services and medical care and to set prices and reimbursement conditions for health products.

We recall that the measures of EU cooperation on HTA beyond 2020 have to respect article 15 of *Directive 2011/24/EU relative to the application of patients' rights in cross-border healthcare*. From article 15, the *«network shall be based on the principle of good governance including transparency, objectivity, independence of expertise, fairness of procedure and appropriate stakeholder consultations»*[2].

The reuse and uptake of the common work must not be binding for national pricing and reimbursement decisions. The national HTA bodies should always have the possibility to carry out complementary or specific assessments in line with national public health priorities, regulation settings and legal obligations.

Finally, the REIF calls on the European Commission to make sure that payers are involved in the implementation of the cooperation beyond 2020. Indeed, payers have a key role in ensuring the accessibility and sustainability of national health care systems, and especially in the reimbursement setting process.

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[2] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:088:0045:0065:en:PDF