SÉNAT

RÉPUBLIQUE FRANÇAISE

EUROPEAN AFFAIRS COMMITTEE

Paris, 25 June 2020

POLITICAL OPINION

on the Proposal for a Regulation on health technology assessment – COM(2018) 51 final

The Senate European Affairs Committee,

Having regard to Articles 114 and 168 of the Treaty on the Functioning of the European Union,

Having regard to the Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU of 2 February 2018, COM/2018/51 final,

Having regard to the European Parliament legislative resolution of 14 February 2019 on the Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU,

Having regard to Senate resolution no. 87 of 3 April 2018 delivering a reasoned opinion on the Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU,

Whereas the harmonisation powers given to the European Commission by Article 114 of the Treaty on the Functioning of the European Union may justify questioning the powers that the same Treaty also confers on the Member States;

Whereas Article 168(7) of the Treaty on the Functioning of the European Union provides that "Union action shall respect the responsibilities of the Member States for the definition of their health policy and for the organisation and delivery of health services and medical care. The responsibilities of the Member States shall include

the management of health services and medical care and the allocation of the resources assigned to them";

Whereas the assessment of a health technology is a comparative assessment whose aim is to determine the conditions of reimbursement of that technology within the Member States;

Whereas clinical assessments are an essential component of the assessment of a health technology;

Whereas, to provide patients with the most effective technologies, joint clinical assessments must be based on all the reliable and objective studies available on the one hand, and the assessment must be performed in a transparent and independent manner;

Whereas implementing acts and delegating acts cannot define the essential elements of a piece of legislation and whereas the issues relating to the transparency and independence of assessments are essential;

Whereas, furthermore, the COVID-19 pandemic has revealed the limits of the cooperation between Member States in the health field and whereas that cooperation must be reinforced;

Asks that the Regulation be adopted on the basis not only of Article 114, but also of Article 168(4)(c) of the Treaty on the Functioning of the European Union;

Recommends that the scope of the technologies to be assessed jointly should be limited initially to enable the establishment of practices guaranteeing the quality of the assessments;

Asks that the Regulation provide that the Member States "use" and not "apply" joint clinical assessments to assess a health technology;

Asks that the Member States be authorised to perform a complementary clinical assessment if they consider that certain objective and reliable studies have not been taken into account or that the studies taken into account have not been conducted under the expected conditions of transparency and independence;

Asks that it be specified in the text that the outcomes of the joint clinical assessments may not prejudge the outcome of the overall assessment performed by a Member State;

Considers that the conditions relating to the quality, transparency and independence of joint clinical assessments must be defined in the

Regulation itself and not by means of implementing acts or delegating acts;

Hopes that the joint scientific consultations for technologies in development will take place under conditions of transparency and independence capable of guaranteeing their objectivity and their interest for greater health safety;

Commends the Commission's intention to encourage voluntary cooperation between Member States in the area of health technology assessment, in particular concerning non-clinical assessments;

Deems it necessary to identify emerging health technologies at a very early stage in their development when they could have a major impact on the health of patients, particularly in the event of a pandemic.