SÉNAT

RÉPUBLIQUE FRANÇAISE

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COMMITTE FOR
EUROPEAN AFFAIRS

# Proposal for a regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU: reasoned opinion

① The proposal for a regulation COM (2018) 51 final aims to coordinate the health technology assessment. This technology, comprising medicinal products, medical device or medical and surgical procedures, is now assessed by Member States, on medical, economic, social or ethical aspects. These assessments serve as a basis for Member States, in particular to define the price of the technology and the repayment conditions.

② This text proposes to implement a joint clinical assessment of health technologies, non-clinical assessments remain a matter of national competence. To this aim, a coordination group made up of member states representatives and co-chaired by the European Commission will be in charge of defining which clinical assessments have to be carried out in common under the European Commission control. Member States will be able to carry out clinical technology assessments un-registered in the coordination group's work program, but they will have to respect a procedure defined by the European Commission.

③ Once approved by the European Commission, the joint clinical assessment of a health technology will have to be taken over by Member States realizing an overall assessment of this technology. Member States shall notify to the Commission the results of the overall assessment of a health technology that has been subject to a joint clinical assessment within 30 days following its conclusion.

④ The Commission will determine, through implementing acts, the rules of procedure, the methodology and the file contents to allow joint clinical assessments and those realized by Member

States. It will also by this mean set the conditions of cooperation with the European Medicines Agency. Thus, the Commission wishes to associate this agency, in charge of processing the marketing authorization files, with the work of the coordination group.

⑤ Having regard to the article 88-6 of the French Constitution,

⑥ The French Senate makes the following observations :

⑦ – The Commission relies on article 114 of the Treaty on the functioning of the European Union to justify this proposal for a regulation. It enables it to take measures allowing the rapprochement of the provisions in force in Member States for health, taking as a base a high level of protection. The standard of protection offered by this text cannot be evaluated. Indeed, provisions concerning the methodology for the realization of clinical assessments are not yet known and will only be defined later on implementing acts. It is then essential to recall that implementing acts are free from the subsidiarity check ;

⑧ – The article 6 of the Treaty on the functioning of the European Union specifies that the European Union only have authority to take supportive actions regarding the protection and improvement of human health. Its role is to complement and to coordinate the action of Member States. In fact, this text provides that the coordination group will set the program of the clinical assessments that will be carried out in common. Those joint clinical assessments shall necessarily be taken over by Member States without being able to conduct new assessments. The coordination group then seeks to replace Member States, which is contrary to the Treaty ;

⑨ – The article 168 of the Treaty on the functioning of the European Union, in paragraphs 2 and 5, makes it clear that the Union encourages cooperation between Member States in the field of public health. It cannot then enforce a cooperation in this field ;

⑩ – The article 168 of the Treaty on the functioning of the European Union, in paragraph 7, stipulates that the Union shall respect the responsibilities of the Member States for the definition of their health policy. It shall include the management of health

services and medical care and the allocation of the resources assigned to them. Clinical assessments are essential to Member States for the definition of pricing and repayment policies for health technologies. It then falls within the responsibility of Member States ;

⑪ – The European Commission wants to associate the European medicines agency with the evaluation works of the coordination group. But this agency has been created to ensure high standards on safety and medicine quality, which complies with the provisions of article 168 paragraph 4 of the Treaty on the functioning of the European Union. Currently, its mission is not to realize assessments necessary for the implementation of national health policies. These are two missions referring to distinct purposes, one falling under the European Union and the other under Member States.

⑫ For these reasons, the French Senate considers that the proposal for a regulation COM (2018) 51 final does not comply with the subsidiarity principle.