Deutscher Bundestag

D E C I S I O N

The German Bundestag, acting on the basis of Bundestag printed paper 19/1296, adopted the following decision at its 23rd sitting, held on 22 March 2018, regarding

the proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU, COM(2018) 51 final; Council document 5844/18:

Reasoned opinion within the meaning of Article 6 of Protocol No 2 to the Treaty of Lisbon (application of the principles of subsidiarity and proportionality)

Noting the communication contained in point A. 25 of Bundestag printed paper 19/1053, the Bundestag adopts the following decision in accordance with Protocol No 2 to the Treaty of Lisbon, taken in conjunction with section 11 of the Parliamentary Responsibility for EU Integration Act (*Integrationsverantwortungsgesetz*), in which it asserts a breach of the principles of subsidiarity and proportionality:

On 31 January 2018, the European Commission presented a proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU. In that document it proposes full harmonisation of health technology assessment (HTA) in the realm of clinical assessments of all new medicinal products that are subject to the central marketing authorisation procedure and of certain medical devices. Participation in the joint clinical assessments and the subsequent use of the assessment reports as a basis for national decisions on pricing and reimbursement are to be compulsory. Member States will not be permitted to conduct assessments of their own in the aforementioned areas. The proposal provides for the following four areas of cooperation:

1. joint clinical assessments,

2. joint provision of scientific advice to manufacturers of medicinal products and medical devices,

3. identification of emerging health technologies, and

4. voluntary cooperation in areas that are not to be harmonised, e.g. clinical assessment of health technologies other than medicinal products and medical devices and non-clinical assessment of health technology.

I. With regard to the compatibility of the proposal for an HTA regulation with the principles of subsidiarity and proportionality, the Bundestag notes:

1. On compatibility with the subsidiarity principle

   The proposed HTA regulation lays the foundations for national decisions on health policy, such as those concerning pricing and reimbursement. The proposal encroaches – at least as regards the obligation contained in Article 8 – on the legally protected responsibilities of Member States for the definition of their health policies and for the organisation and delivery of health services and medical care (Article 168(7) TFEU). Since the proposal from the European Commission thus lays down binding rules in the EU framework which will affect the shaping of national health systems, the Bundestag considers that it infringes the principle of subsidiarity.

   The production of HTA reports and, in particular, the assessment decisions taken on the basis of those reports determine to a great extent the outcome of decisions on eligibility for reimbursement and on pricing in the Member States. Accordingly, decisions on reimbursement and pricing in the Member States will be hampered by the fact that Member States will be prohibited from undertaking their own assessments if a joint EU assessment already exists and that they will be under an obligation to adopt such joint assessments (see Article 8(1) of the proposal).

2. On compatibility with the proportionality principle

   Comprehensive harmonisation of HTA within the EU with an obligation to adopt joint clinical assessments is a very far-reaching measure. The Bundestag has reservations and wonders whether the aims of avoiding duplication of effort and making the single market work better by removing administrative obstacles to manufacturers of health technology cannot also be achieved through voluntary cooperation at EU level, for which provision has already been made in Directive 2011/24/EU on the application of patients' rights in cross-border healthcare (OJ L 88 of 4 April 2011, p. 45).To this end, an expanded organisational framework for enhanced voluntary cooperation on clinical assessments within the EU, for instance, could be productive.

   Even though the proposal indicates that Member States will remain responsible for the non-clinical assessment of more context-specific HTA domains, such as economic, organisational and ethical issues, and for decision-making on pricing and reimbursement, it is essential to emphasise the fundamental importance of the clinical side of HTA. It is on the basis of the outcome of clinical assessments that decisions on pricing and reimbursement

are made. Accordingly, when making these decisions, Member States will not be able to draw on anything but the clinical assessments conducted in the EU framework on the basis of common standards.

The details of the shape of the procedure are not convincing and introduce numerous uncertainties. The fact that Member States cannot carry out a clinical or equivalent assessment of any health technology that is included in the list of assessed health technologies or for which a joint clinical assessment has been initiated unless there are grounds related to the need to protect public health in the Member State concerned must be regarded as a clear encroachment on the national competence of Member States.

If the proposal from the European Commission is implemented, there is an inherent danger that it will devalue the standards of benefit assessment in Germany. This constitutes an interference with the tried and tested procedure for testing medicinal products under the Pharmaceutical Market Reform Act (AMNOG). A centralised health technology assessment cannot take proper account of the diversely structured healthcare systems of the Member States. The German HTA institutions, namely the Institute for Quality and Efficiency in Health Care (IQWiG) and the Federal Joint Committee (*Gemeinsamer Bundesausschuss*), must not be obstructed in their benefit assessment under Book Five of the German Social Code. They must be able to operate on the basis of the HTA standards that have been prescribed for them.

3. Lastly, the Bundestag welcomes the fact

   that the European Commission attaches great importance to assessing the benefits of health technologies. At the present time, there are 50 active HTA authorities in 26 EU Member States; these authorities have been engaging in project-related European cooperation that is not regulated by legislation. The German IQWiG and Federal Joint Committee have been involved in this cooperation. EU-wide exchanges and recording of benefit assessments of health technologies through EUnetHTA are useful and should be continued. The framework for future cooperation in the realm of HTA within the EU framework must be made as flexible as possible and must uphold the subsidiarity principle for the benefit of the Member States.

II. The Bundestag reserves the right to express its views on other aspects of the proposed regulation in a separate opinion in the course of the legislative procedure.

III. The Bundestag asks its President to forward this Decision to the European Commission, the European Parliament and the Council of the European Union and to bring it to the attention of the Parliaments of the Member States.