HEALTH TECHNOLOGY ASSESSMENT

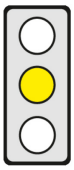
cep**PolicyBrief** No. 2018-15

Centrum für Europäische Politik

KEY ISSUES

Objective of the Regulation: Joint clinical assessments and harmonised assessment procedures will be introduced at EU level for innovative health technology in order to remove barriers in the internal market.

Affected parties: Patients, hospitals, doctors, companies in the health sector, health insurance funds.



Pro: (1) Joint clinical assessments avoid redundant duplication of work both in national assessment bodies and for developers of health technology.

(2) Joint clinical assessments and the harmonisation of assessment procedures reduce costs currently incurred by developers due to differing national assessment concepts.

Contra: (1) Joint clinical assessments and the harmonisation of assessment procedures prevent Member States from designing procedures according to the preferences of their health systems.

(2) The EU currently lacks the competence for harmonising clinical assessments.

(3) Irrespective thereof, the essential assessment criteria must, in view of their importance, be established by the Union legislator and not by the Commission.

The most important passages in the text are indicated by a line in the margin.

CONTENT

Title

Proposal COM(2018) 51 of 31 January 2018 for a **Regulation on health technology assessment** and amending Directive 2011/24/EU

Brief Summary

- **Context and objectives**
  - Health Technology Assessment (HTA) covers [Art. 2 (e) and (f)]
    - "clinical assessment" which, by way of scientific evidence, examines the medicinal benefit – the relative clinical effectiveness and safety – of a health technology as compared with alternative treatments and
    - "non-clinical assessment" which covers economic, social, ethical and other aspects.
  - Health technology means, inter alia, medicines, medicinal products – such as medical instruments or devices – and procedures – such as those used in diagnosis or surgery [Art. 2 (c), Art. 3 (l) Directive 2011/24/EU].
  - The aim of HTA is to inform health-policy decision-making following market approval – primarily regarding reimbursement or pricing of new innovative health technology – in support of the financial viability of national healthcare systems [p. 1, Recital 4].
  - Currently, HTA takes place at national level and clinical assessment concepts sometimes vary significantly [p. 1, 2 and 4]. According to the Commission, this means that [p. 1, 2]
    - resources are wasted because HTAs are duplicated and run in parallel in the Member States,
    - developers of health technology have to comply with varying data and evidence requirements for HTAs which hinder their market access and make the access more costly, thus detrimentally affecting the internal market and damaging developers planning certainty and innovative ability [see also Recital 5] and
    - innovative health technology is delayed or only available in some Member States.
  - Existing cooperation on HTA at EU level is voluntary and – according to the Commission – has not been able to solve the problems which arise [p. e]. In addition, it is project-based and therefore unsustainable [p. 2].
  - In future, the Commission therefore wants
    - to pool the cooperation of Member States on HTA in a "Coordination Group" [Art. 3] and
    - within this framework, in particular [Art. 5 and 20, Recitals 10 and 12]
      - to stipulate "joint clinical assessments" by Member States at EU level and
      - harmonise the procedures, methods and requirements for clinical assessments EU wide.
- **Establish a "Coordination Group" for cooperation**
  - The "Coordination Group" consists of [Art. 3 (2), (4) and (5)]
    - the designated HTA bodies of the Member States and their appointed representatives,
    - a co-chair appointed by the Commission and
    - a co-chair – elected by the members.
  - Decisions of the Coordination Group are reached by consensus or – "where necessary" – by simple majority, and each Member State has one vote [Art. 3 Abs. 3].

Authors: Bastian Sattelberger and Muhammed Elemenler | sattelberger@cep.eu
cep | Kaiser-Joseph-Strasse 266 | 79098 Freiburg | Germany | Telephone +49 (0)761 38693-107 | www.cep.eu

- **"Joint clinical assessments" at EU level**
  - The Coordination Group must carry out joint clinical assessments on [Art. 5 (1)]
    - medicinal products that are – as is generally the case – subject to authorisation by the European Medicines Agency; exempt from this are generic drugs and "biosimilars";
    - specific medical devices classified as high risk – class IIb and III – under the Medicinal Product Regulation [(EU) 2017/745],
    - certain in-vitro diagnostic medical devices (IVD) – such as medicinal products for the analysis of samples derived from the human body in a test tube – classified as class D pursuant to the IVD Regulation [(EU) 2017/746].
  - The assessment is carried out on behalf of the Coordination Group by two members – national HTA bodies. For this purpose, they examine a dossier prepared by the developer, which includes data and evidence to show the added value of the technology, and issue an assessment report [Art. 6 (2)–(4)].
  - The Coordination Group must "approve" the report [Art. 6 (12)].
  - The Commission must examine whether the report satisfies the requirements of the Regulation. If this is the case, the health technology is listed and the report is published on an IT platform [Art. 7 (1) and (6)].
  - Member States are no longer permitted to carry out any clinical or "equivalent" assessments for listed health technologies [Art. 8 (1) (a)] and must apply the joint reports to any continuing HTAs [Art. 8 (1) (b)].

- **EU-wide harmonised clinical assessments**
  - Procedures, methodology and requirements will be harmonised for [Art. 20]
    - joint clinical assessments at EU level and
    - clinical assessments that are still carried out by the Member States for medicines and medical products.
  - The Commission will inter alia adopt rules on this by way of implementing and delegated acts for [Art. 22 and 23]
    - the methods by means of which clinical assessments are made and
    - the contents of the dossiers to be prepared by health technology developers.

- **Other mandatory and voluntary cooperation**
  - Health technology developers may request scientific consultation with the Coordination Group concerning the data and evidence "likely" to be required for the joint clinical assessment [Art. 12 (1)]. The Coordination Group decides, on the basis of selection criteria laid down in the Regulation, which consultation requests it will engage with [Art. 12 (2)].
  - The Coordination Group must annually prepare a study to identify relevant new health technology which is taken into account in the next year's work programme [Art. 18 (1) and (3)].
  - The Commission supports voluntary cooperation in certain other, non-mandatory joint areas of health technology assessment, such as non-clinical assessments [Art. 19 (1)].

Main Changes to the Status Quo

- In future, a Coordination Group will manage cooperation between Member States on HTA [Art. 3].
- Until now, cooperation on HTA between Member States was voluntary. In future, member states will only be permitted to carry out clinical assessments of many health technologies jointly at EU level [Art. 5 and 8 (1) (a)].
- Until now, Member States were free to design the procedures, methods and requirements of their clinical assessments themselves. In future, many of these aspects will be harmonised EU wide [Art. 20, 22 and 23].
- In future, Member States will have to cooperate via the Coordination Group on scientific consultation for health technology developers [Art. 12].

Statement on Subsidiarity by the Commission

Significant conceptual differences in clinical assessment between the Member States result in barriers in the internal market which can only be removed at EU level [p. 4].

Policy Context

In 2014, the Council called on the Commission to continue to support cooperation on HTA in a sustainable manner [Recital 7]. In 2015, the Commission announced its proposal [Communication COM(2015) 550] to increase coordination on HTA [Recital 9]. In 2017, the European Parliament called on the Commission to propose legislation on an EU system for HTA and to harmonise HTA criteria [Recital 8].

Legislative Procedure

31 January 2018	Adoption by the Commission
Open	Adoption by the European Parliament and the Council, publication in the Official Journal of the European Union, entry into force

Options for Influencing the Political Process

Directorates General:	DG Health and Food Safety (leading)
Committees of the European Parliament:	Environment, Public Health and Food Safety (leading), Rapporteur: Soledad Cabezón Ruiz (S&D Group, E)
Federal Ministries:	Health (leading)
Committees of the German Bundestag:	European Union Affairs (leading); inter alia Health
Decision-making mode in the Council:	Qualified majority (acceptance by 55% of Member States which make up 65% of the EU population)

Formalities:

Competence:	Art. 114 TFEU (Internal Market)
Type of legislative competence:	Shared competence (Art. 4 (2) TFEU)
Procedure:	Art. 294 TFEU (ordinary legislative procedure)

ASSESSMENT

Economic Impact Assessment

Joint clinical assessments and the proposed harmonisation of assessment procedures possess a range of desirable features and are basically appropriate. They also have disadvantages, however, which the proposed Regulation fails to address sufficiently.

Joint clinical assessments at EU level **avoid redundant duplication of work, both in national assessment bodies and for** developers **of health technology**, which currently occurs due to the multiplicity of national assessment procedures. This will reduce costs on both sides.

The ban on further clinical assessments at national level at the same time prevents Member States from undertaking simultaneous national clinical assessments – which currently take place in voluntary cooperation. Otherwise, the advantages of joint assessments would be reversed due to the additional work required at EU level.

Joint clinical assessments and the proposed **harmonisation of methods and requirements both for joint and national assessment procedures also reduce the costs currently incurred by developers** of health technology due **to differing national assessment concepts** because – depending on the level of harmonisation – there will be less need for developers to tailor their data and evidence – acquired in costly studies – to varying national requirements. Current national assessments differ for example with regard to accepted evidence procedures and measurement results or the choice of the therapy with which a new technology is compared.

The duty of the Coordination Group to consult with developers of health technology regarding the necessary evidence and data, also helps developers to design their studies for assessment in a targeted and cost-effective way. It reduces the risk that technologies with added value are assessed as poor due to avoidable - evidence deficits. In addition, in the case of medicinal products, cooperation with the authorisation procedure of the European Medicines Agency is possible and gives rise to synergies.

Although restricting consultation to health technology which corresponds to the selection criteria laid down in the Regulation is a disadvantage for technology that does not satisfy these criteria, this is likely to be unavoidable for reasons of efficiency and cost.

Joint clinical assessments and the envisaged harmonisation of assessment procedures ultimately make planning easier for developers who are better able to predict the progress and results of a single and/or uniform assessment procedure than is currently possible with the multiplicity of national processes with varying concepts and results.

Joint clinical assessments and the proposed harmonisation of assessment procedures, however, prevent Member States from designing procedures according to the preferences and particular features **of their national health systems**, such as regarding evidence procedures and the choice of comparative treatments. This is true of any harmonisation that supports the creation of the internal market but in this case it is problematic that the Commission intends to determine the content and thus the level of harmonisation only by way of implementing and delegated acts. Thus it is not possible to predict either the extent of the advantage for developers or the level of interference in national design preferences even though these are fundamental to the proposal. There is also a risk that the Commission will include provisions that are far-removed from the needs of Member States and industry.

Clinical assessments generally remain closely linked to the subsequent decision-making processes on reimbursement and pricing of technology which will continue to take place at national level. Any separation may necessitate considerable adjustments in national systems. Member States may also be anxious to compensate for the resulting restrictions in the design of clinical assessments by way of stricter regulation on reimbursement or pricing. To that extent, the Regulation will not necessarily provide for faster and greater availability of innovative technology for patients.

Harmonised – joint and national – clinical assessments ultimately eliminate the competition between Member States in the methods used by the different assessment concepts which promotes the innovation of these methods.

Legal Assessment

Legislative Competency

The EU lacks the competence for harmonising clinical assessments. Although the internal market competence may apply [Art. 114 TFEU] because the multiplicity of national requirements applicable to HTA is capable of impeding the internal market for health technology (cf. CJEU, Judgement of 4 May 2016, Poland v. Parliament and Council, C-358/14, para. 32-34), the proposal represents interference by the EU in the responsibility of Member States for the management of health services and medical care and the allocation of the resources assigned to them, which is guaranteed under primary law [Art. 168 (7) TFEU]. Although, under the internal market competence, the EU can in principle harmonise situations in which the health sector is a decisive factor (cf. CJEU, Judgement of 14 December 2004, Arnold André, C-434/02, para. 32, 33), **it is not permitted to bypass the Member States' responsibility for health services** [Art. 168 (7) TFEU] **by way of the internal market competence** (cf. CJEU, Judgement of 5 October 2000, Germany v. Parliament and Council, C-376/98, para. 79). The obligation to carry out joint assessments and to apply these harmonised assessments in continuing national procedures means that intervention in the health policies of the Member States is unavoidable because the HTAs that are the subject of the legislation – apart from non-clinical assessments – constitute an essential element of the "management of medical care", the basic approach and design of which is an expression of the preferences of the respective Member States as regards health policy, such as in establishing the scientific standards. The corresponding complaints from the Parliaments of Germany, France and the Czech Republic are justified. An extension of powers under primary law is desirable.

Subsidiarity.

The voluntary cooperation between the EU and Member States which has been ongoing since the 1980s has not led to a convergence of standards. If the EU had the competence, subsidiarity would be affirmed.

Proportionality with Respect to Member States

The proposal is disproportionate in that it does not deal with the national special features of HTA procedures in the social security systems of the Member States. When exercising their powers, however, Member States must comply with Community law (CJEU, Judgement of 28 April 2008, Decker v. Caisse de maladie des employés privés, C-120/95, para. 21, 23), which has not been done sufficiently in the field of health technology due to national special features. In this regard – rather than the proposed Regulation – a Directive with minimum harmonisation of scientific standards would be appropriate.

Compatibility with EU Law in other respects

In view of their importance, the essential assessment criteria must be established not by the Commission but by the Union legislator – Council and Parliament – [Art. 290 et seq. TFEU]. Assessment methods and requirements regarding the content of the required dossiers must not be delegated wholesale to the Commission because only elements that are not "essential" can be transferred to the Commission [Art. 290 (1), sub-para. 2 TFEU; cf. CJEU, Judgement of 5 September 2012, Parliament v. Council, C-355/10, para. 64-66]. Study conditions, real-life conditions, criteria for comparison with standard treatment, and the patient-related outcomes such as mortality, morbidity and quality of life that are applicable thereto, are not non-essential, quasi-"technical" details but crucial and often ethically highly controversial, i.e. "essential", cornerstones of health-policy. Union legislators – Council and Parliament – must therefore establish these cornerstones in their basic guidelines.

Impact on German Law

The assessment rules [Sections 35 et seq. German Social Code (SGB) V], the provisions on the Federal Joint Committee [G-BA; cf. Section 92 SGB V] and on the Institute for Quality and Efficiency in Healthcare (IQWiG) [Sections 139a et seq. SGB V] and the Rules of Procedure of the Federal Joint Committee must be adapted.

Alternative Approach

In view of the economic advantages of joint HTA, a treaty amendment procedure, to create the EU powers that are currently lacking, is desirable.

Conclusion

Joint clinical assessments avoid redundant duplication of work both in national HTA centres and for developers of health technology. Combined with harmonisation of methods and requirements both for joint and national assessment procedures, they also reduce the costs currently incurred by developers due to differing national assessment concepts. However, joint clinical assessments and the proposed harmonisation of assessment procedures prevent Member States from designing procedures according to the preferences of national health systems. The EU lacks the competence for harmonising health technology assessments; an extension of powers under primary law is desirable. Irrespective thereof, the fundamental assessment criteria must, in view of their importance, be established by the Union legislator and not by the Commission.