Joint position statement

German Network for Evidence-based Medicine (DNEbM) and German Society for Technology Assessment in Health Care (HTA.de)

On the Proposal for a Regulation of the European Parliament and of the Council on health technology assessment and amending Directive 2011/24/EU, published on 31.01.218

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Harmonization at all costs? Evidence-based health care takes priority over single market and commercial interests.

Background

On January 31st, 2018 and under the heading "Strengthening EU cooperation beyond 2020", the European Commission issued a proposal for regulation that foresees, among other things, a far-reaching harmonization of the assessment of patient benefit provided by pharmaceuticals and certain medical devices within the context of increased cooperation in Health Technology Assessment (HTA) between Member States. In this harmonized evaluation, a central role is to be adopted by a newly established Coordination Group consisting of representatives from Member States' national authorities and bodies responsible for HTA. The Commission will both co-chair Coordination Group meetings and host a Secretariat tasked with providing continuous administrative, scientific and IT support.

More specifically, the draft regulation includes the following measures:

1. **Joint clinical assessments** of new pharmaceuticals as well as certain medical devices and in vitro diagnostics. Following a phase-in period of three years, participation in the centralized assessments and use of the joint clinical assessment reports at Member State level will be mandatory.
2. **Joint scientific consultations**: these will allow developers of pharmaceuticals and medical devices to seek advice from the Coordination Group on the data and evidence likely to be required as part of a potential joint clinical assessment in the future. These consultations can potentially be held in conjunction with scientific advice from the European Medicines Agency or expert panels on medical devices regarding marketing authorization of the same technology. After the phase-in period, equivalent consultations at the Member State level are not to take place for technologies covered by the joint scientific consultation.
3. Identification of **emerging health technologies** ("horizon scanning"): the Coordination group is to carry out an annual study to ensure that health technologies expected to have a major impact on patients, public health or healthcare systems are identified at an early stage in their development and included in the joint work of the Coordination Group.
4. Support for continuing **voluntary cooperation** and information exchange on non-clinical aspects of HTA and for other technologies than pharmaceuticals and medical devices not covered by European law.

Based on the arguments that national HTA processes “impede and distort market access” to innovative technologies while leading to considerable duplication of work and that the current, project-based cooperation in HTA at EU level is unsustainable, a central, European evaluation of all new pharmaceuticals and certain medical devices in risk classes IIb and III is to be introduced, precluding separate assessments at national level. This joint assessment will only comprise the evaluation of clinical elements; other dimensions of HTA, such as the economic or ethical implications of the technology in question, will remain subject to (additional) assessments at Member State level. The Commission states that the Proposal is based on Article 114 of the Treaty on the Functioning of the European Union (TFEU); Article 114 “allows for the (…) approximation of the provisions laid down by law, regulation or administrative action in the Member States, provided they are necessary for the establishment or functioning of the internal market (…)”.

Position of DNEbM and HTA.de

It is the opinion of the DNEbM and HTA.de that the intention of the European Commission to foster EU-wide cooperation in technology assessment is fundamentally welcome. Both joint scientific consultation processes as well as the intended identification of innovative technologies and the endorsement of information exchange should be supported. DNEbM and HTA.de advocate for a stronger acknowledgement of joint assessments at European level than before. For example, they could be a substitute for national assessments in Member States without own HTA bodies or be adopted as needed by Member States with established HTA processes.

However, DNEbM and HTA.de take an extremely critical view of the intended mandatory centralized benefit assessment as a component of the Commission´s proposed regulation. In the perspective of DNEbM and HTA.de, the Proposal allows for assessments shaped by commercial interests to be authorized by the Commission. In the interest of a smoothly functioning single market, divergent interpretations of the (clinical) evidence on assessed technologies in individual health systems would no longer be permissible.

The Commission reserves far-reaching influencing rights for itself. For example, it is to adopt implementing acts for the proposed regulation concerning both procedural and methodological rules for joint assessments, thus substantially influencing assessment methodology. It also retains Co-Chairmanship and Secretariat functions for the Coordination Group. Finally, it is entitled to comment on and demand amendments to joint evaluations, including the removal (blacking out) of “commercially sensitive” passages before assessment reports are published. What is more, the proposed regulation does not foresee any mechanism for ensuring an adequate evidence base for evaluation. For instance, there is no obligation for the industry to provide a complete data basis that would include unpublished information.

Joint assessments for pharmaceuticals are supposed to be available around the time of the product’s marketing authorization. Marketing authorization is also the responsibility of the Commission, through the European Medicines Agency. This introduces the potential for conflict of interest: due to a lack of comparative data, the Commission could be put in the position of having to issue negative assessment results for a medicine it just authorized for sale. Especially in conjunction with the developers’ right to provide input during assessments

and the insufficient demarcation from the centralized marketing authorization process at the EMA, this could compromise the evaluation's independence. Furthermore, the level of transparency achieved so far in certain health systems is endangered, as passages can be removed or blacked out at the instigation of the manufacturers before final joint assessment reports are published.

The assessment of newly authorized (i.e. marketable) pharmaceuticals and medical devices in Europe does not compromise their availability on the German market, as pharmaceuticals in Germany are reimbursable immediately after market entry to begin with. The assertion of the European Commission that only a centralized HTA process under its own jurisdiction could remedy the fragmented single market in this area is thus not really meaningful, at least for Germany. In contrast, in some Member States the implementation of the proposed regulation could have the opposite effect than the one intended, namely the introduction of new types of inquiry (such as economic evaluations, known as the fourth hurdle).

There is good reason to retain the possibility of separate assessments in different health systems in the EU. For example, certain outcomes (e.g. surrogate outcomes) are evaluated differently in various countries, and the standard of treatment (with relevance to comparator therapies for the assessment) can vary. This inevitably leads to divergent assessments of the evidence base, which stem from the decision-making culture of each health care system. Replacing these with one centralized evaluation can lead to inadmissible exertion of influence in the health systems of Member States.

The intended obligation for Member States to consider the joint assessment could potentially involve having to accept evidence of insufficient quality. The authority of most HTA organizations is grounded in their scientific competence and in the high quality of their evaluation processes, not in a legal obligation to adopt other assessments.

Subsequent to the consultations in the European Parliament, the German Federal Government should exert its influence in the Council of the European Union to amend this component of the regulation in such a manner that the competence for evaluation remains with the Member States, who should be nevertheless entitled to adopt the results of joint assessments as needed. Given that many EU Member States are indeed without their own HTA institutions, this would already benefit numerous countries. This stance reflects that of the German President Steinmeier, who recently stressed that science should never become an indulgence of powerful commercial or political interests. Against this backdrop, we urge the Federal Government to not agree to the Commission's proposed regulation in its current form. In particular the obligatory consideration of joint assessments precluding supplementation at national level and the lack of any provisions obliging manufacturers to make complete data available for assessment should be opposed.

and health sciences faculties, practicing physicians as well as representatives from other health professions (www.ebm-netzwerk.de).

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HTA.de promotes knowledge exchange on the direct and indirect consequences of the adoption of medical procedures and technologies in health care (technology assessment). This includes among others advancing scientific methods for the evaluation of health technologies, organizing events, providing advice for decision-makers and contributing to specialist and continuing education (www.health-technology-assessment.de)

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