



ECL POSITION ON EU HTA COOPERATION

The Association of European Cancer Leagues (ECL) endorses the European Commission’s legislative proposal on health technology assessment (HTA) published on 31 January 2018, and calls for an adoption of a regulation establishing European HTA cooperation which will ultimately improve access to high-quality medicines for all patients in Europe.

In the past decade, the prices of cancer medicines have increased by up to 10 times beyond their therapeutic value. Despite promised added value before entering the market, most new cancer medicines proved marginal clinical and quality of life benefits for patients.² A high-standard European joint clinical assessment is needed to identify real innovation in treatment of complex diseases, such as cancer.

In the context of rising costs of innovative treatments, issues connected to sustainability of healthcare systems and proliferation of me-too medicines bringing negligible therapeutic advances, **ECL wishes to underline the connection between implementation of a strong European cooperation on HTA and access to high quality treatment for European patients**, as recognised by the 2016 Council Conclusions about the functioning of the pharmaceutical system.

ECL is convinced, enhanced mandatory cooperation on HTA would:

- (i) enable faster and improved access to high value treatments for patients in Europe;
- (ii) strengthen quality of clinical assessment by pooling expertise from all EU Member States;
- (iii) reduce duplication and ensure efficient use of resources;
- (iv) help payers make wise decisions on pricing and reimbursement by providing high-quality assessment;
- (v) increase transparency in all aspects of the joint HTA process;
- (vi) steer innovation in areas of unmet medical need and improve business predictability.

1 Kelly, R., and Smith, T., 'Delivering maximum clinical benefit at an affordable price: engaging stakeholders in cancer care.' *The Lancet Oncology*, vol.15(3), (2014), p. 112-18.

2 Davis, C. et al., 'Availability of evidence of benefits on overall survival and quality of life of cancer drugs approved by European Medicines Agency: retrospective cohort study of drug approvals 2009-2013.' *BMJ* vol. 359 (4530), (2017).

'New products and new indications in 2016: a system that favours imitation over the pursuit of real progress,' *Prescrire International*, vol 26 (182), (2017).

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ECL recommends 4 ways toward a successful European HTA cooperation:

I. Use highest possible standards

Given that the uptake of the joint clinical assessment will be mandatory, there is a clear need for high standard assessment with high quality endpoints. Hence, EU Member States would not feel the need to re-assess decisions met by the Coordination Group.

1. Methodology and relevant endpoints should be defined by the Coordination Group after a consultation with stakeholders;
2. Reference to high-quality standards shall be elaborated on in the regulation text to increase confidentiality in the system and prevent Member States' concern about signing a blank check;
3. The role of the Coordination Group and the Commission (scientific vs. administrative) shall be clearly defined in the regulation text to ensure national experts play the key role in the assessment;
4. Multiple representatives shall be allowed to act as assessors and co-assessors to increase the Coordination Group's expertise and workload management, they shall only have 1 vote per Member State;
5. The Coordination Group shall act by consensus or where necessary by 2/3 majority to prevent potential disputes over debatable decisions;
6. Technology developers shall submit full data file (including negative results) and declare in writing they have submitted all data available. If not done so, there shall be a sanction mechanism in place;
7. Assessors and co-assessors shall use data submitted by technology developers as well as other available studies/evidence to conduct their assessment;
8. Where relevant, comparative trials (comparing medicine to existing and possibly best available therapies rather than placebo) shall be encouraged during scientific consultation.

II. Measure PROs and RWEs

In order to assess the value of new treatments, it is necessary to look beyond surrogate endpoints measured during clinical trials. As many cancer treatments offer only limited extension of survival, it is crucial to look at quality of life indicators. In addition, it can be expected that medicines will be performed less in the real world settings, as patients selected for clinical trials tend to be older, less healthy and more diverse. Therefore, we need to demand proper collection of patient reported outcomes (PROs) during clinical studies and real world evidence (RWE) following medicines' market access.

1. During joint scientific consultation, the Coordination Group shall demand collection of PROs as early as possible in clinical trials, not only in Phase III;
2. Technology developers shall disclose all available data to the HTA authority, including unpublished negative data from failed trials, to enable full high-quality assessment;
3. Technology developers and providers shall collect RWE after treatments' market access;
4. Re-assessment shall be performed once new substantial data is available with no unnecessary delay, no later than 5 years after the initial joint assessment, to prevent investment where a technology becomes obsolete.

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III. Involve patients in the whole HTA cycle

Involving patients in all activities of the EU HTA, including horizon scanning, development of guidelines, joint scientific consultation and joint clinical assessment is key to accurately capture patients' needs while assessing the added value of all treatments.

1. Stakeholders and non-profit interested parties (namely patients, patient advocates, healthcare professionals, consumer organisations, public health NGOs and academia) shall be involved in all aspects of the European HTA cooperation (from horizon scanning, scientific consultation, joint clinical assessment to voluntary cooperation);
2. Stakeholders shall be independent (non-profit-making entities, which shall not receive funding from technology developers higher than 50% of their annual income).

IV. Ensure transparency and independence

While the role of the Stakeholder Network in the joint clinical assessment is still to be outlined, it is crucial to act in a transparent manner with minimal confidentiality connected to stakeholder meetings. Strong conflict of interest rules should apply for all members of the Coordination Group and its subgroups (i.e. national experts). Given the narrative of the HTA process and its aim to objectively assess the value of new treatments, it is necessary to keep all HTA personnel independent from the industry's influence.

EU HTA body should be entirely independent from the influence of technology developers and financed by public sources rather than industry fees. In case EU HTA would gradually become an EU agency where such fees would be needed, such fees should not represent the majority source of funding.

Last but not least, there should be a clear separation between the HTA and the European Medicines Agency (EMA) mandates.

TRANSPARENCY

1. Highest possible level of openness shall be applied: results of scientific consultation, clinical data, methodology, positive and negative assessment results, results of voting in the Coordination Group including minority opinions, stakeholder consultations excluding confidentially sensitive information, etc. shall be made available to public;
2. Published REA summary report should include at least: clinical data compared, the end-points used, the comparators, the methodology, the clinical evidence used, conclusions regarding efficacy, safety and quality indicators, limits of the assessment and diverging views, summary of consultations carried out in the process, and positive or negative opinion with key reasoning including minority opinions.

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INDEPENDENCE

Independence and public confidence in the new EU HTA body need to be ensured, therefore:

1. Members of the Coordination Group providing scientific advice to health technology developers shall be different persons from members serving as assessors and co-assessors in the joint clinical assessment (mandates appointed by Art. 13(3) and 6(3) shall not overlap);
2. Members of the Coordination Group shall have no financial interest in any health technology, shall act independently and annually declare their conflict of interest; the Commission shall monitor the independence of members of the Coordination Group and its subgroups; if a conflict of interest is found, the member of the Coordination Group shall leave their post;
3. Role of the EMA and the HTA body shall be separated given the different purpose of the assessment they perform; Cooperation between the HTA body and the EMA shall not reach beyond timeline synchronisation;
4. ECL recognises that due to the future workload and financial situation, the work of the HTA body may move from the secretariat provided by the European Commission to a separate agency and industry fees for scientific consultation may be needed to address the growing expense. However, given the sensitivity of the HTA process and its connection to pricing and reimbursement decisions at the national level, industry fees shall never serve as the main source of funding of the new agency (ECL suggests 30% threshold).

About ECL



The Association of European Cancer Leagues (ECL) is a non-profit, pan-European umbrella organisation of national and regional cancer societies, currently representing 26 cancer leagues in 23 European countries.

The ECL Access to Medicines Task Force aims to make cancer medicines available for all cancer patients in Europe by insisting on accessibility, sustainability of the healthcare system and transparency of medicines prices. Today, 25 national/regional cancer leagues, representing over 450 million Europeans, have signed the Task Force's Declaration of Intent.

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