ECL
Association of European Cancer Leagues
Access to Medicines Task Force

STATEMENT
4 April 2018

EUROPEAN COOPERATION ON HTA

An important step toward equal access to high-quality medicines for European patients

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 European HTA which will ultimately improve access to high-quality medicines for all patients in Europe.

Despite promised added value before entering the market, most new medicines proved marginal clinical and quality of life improvements for cancer patients.[1] A high standard joint clinical assessment (REA) is a potential answer to bringing significant benefit to the EU market.

ECL is convinced, joint REA would (i) increase transparency of the assessment process; (ii) enable faster access to medicines for patients; (iii) create more competition and incentivise industry to invest in areas of unmet medical need rather than concentrate on me-too medicines; (iv) pool expertise and provide higher quality assessment for payers; (v) save money in the long-term by preventing unnecessary duplication; and (vi) help payers to make wise reimbursement decisions.

However, due to the numerous questions unanswered by the legislative proposal, and to fully benefit from European HTA cooperation, ECL recommends implementation of the following points:

I. EU HTA HAS TO MEET THE HIGHEST POSSIBLE STANDARDS

Given that the uptake of the REA decisions 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.

II. PROs AND RWE AS A VITAL PART OF THE ASSESSENT

In order to measure the quality of medicines, looking at patient reported outcomes (PROs) and real world evidence (RWE, if available during primary assessment, always in re-assessment phase) should be mandatory in order to recommend the treatment for reimbursement. Clinical outcomes assessed should include both survival, morbidity and PROs reflecting the quality of life.

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[1] 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 2009-13' *BMJ* 2017, vol 359 (4530). http://press.psprings.co.uk/bmj/october/cancerdrugs.pdf;
New products and new indications in 2016: a system that favours imitation over the pursuit of real progress, *Prescrile International*, 2017, vol 26 (182).

It is essential that industry (i) collects PROs as early as possible in clinical trials, not only in Phase III; (ii) delivers its promises to collect RWE after the market approval; and (iii) discloses all available data to the HTA authority, including unpublished data from failed trials, to enable full high quality assessment.

III. PATIENTS TO BE INVOLVED THROUGHOUT THE WHOLE HTA CYCLE

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

IV. ENSURE TRANSPARENCY AND INDEPENDENCE OF EU HTA

While the role of the Stakeholder Network (of patients, healthcare professionals, researchers, industry and payers) in the joint clinical assessment is still to be outlined, it is crucial to act in a transparent manner with no or minimal confidentiality connected to stakeholder meetings. Strong conflict of interest rules should apply for members of the Coordination Group and its subgroups (i.e. experts) and the relationship with all stakeholders should be clearly defined. Given the narrative of the HTA 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.

Furthermore, the EU HTA should be entirely independent from pharmaceutical industry 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, industry 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.

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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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