

Italian Resolution:

# WHAT'S NEXT ON TRANSPARENCY?

Outcomes of the WHO resolution on 'Improving the transparency of markets for medicines, vaccines and other health-products' and possible implementation in EU Member States



## SUMMARY OF RECOMMENDATIONS:

- ① Use the EURIPID database to share net prices of medicines;
- ② Work together with the European Medicines Agency (EMA) and national authorities towards transparent and robust criteria for marketing authorisation;
- ③ Support open science and make sure research results of all clinical studies and collected real world data (RWD) are publicly available.
- ④ Work together with the EMA and the European Commission to ensure incentives (e.g., orphan designation) and related/other patent protection are transparent and not misused;
- ⑤ Insist on greater accountability and reporting on investments of public funding in R&D;
- ⑥ Support European collaboration on health technology assessment (HTA) and ensure high quality cost-effectiveness analysis of approved treatments.
- ⑦ Participate in joint procurement initiatives to further share information on health products and increase the governments' bargaining power in pricing negotiations;

## ITALIAN RESOLUTION: WHAT'S NEXT ON TRANSPARENCY?

On the last day of the 72nd session of the World Health Assembly (WHA) which took place in Geneva between 20 and 28 May 2019, Member States adopted the **resolution** on 'Improving the transparency of markets for medicines, vaccines and other health-products'.

The final resolution is clear about public transparency on real medicine prices. Member States are urged to 'take appropriate measures to publicly share information on net prices of health products'. The ECL Access to Medicines Task Force believes that this is an important step to restore the balance in pricing and reimbursement negotiations between governments/payers and multinational pharmaceutical companies. Currently, there exists an informational asymmetry, where the industry knows the product prices in all countries, but national payers do not have access to such data beyond their borders.

Regarding other aspects of transparency mentioned in the initial draft (i.e., R&D costs, marketing costs, subsidies and incentives and patent status), the wording in the adopted resolution is vague and very soft. Member States are not urged to take measures, but to 'take necessary steps, as appropriate', 'work collaboratively to improve' or 'facilitate' greater transparency on these issues. Moreover, transparency about the results of clinical studies has disappeared completely, although it is important step towards safeguarding patients and open science.

## ITALIAN RESOLUTION: WHAT'S NEXT ON TRANSPARENCY?

The ECL Access to Medicines Task Force calls on EU Member States to work closely together to guarantee a swift implementation of the resolution throughout the Union. We recommend to:

- 1 Use the EURIPID database to share net prices of medicines; use EURIPID and/or similar tools to share net prices in the hospital setting, net prices of vaccines and other health technologies, information on purchasing agreements (conditions of managed entry agreements etc.) and other relevant information (e.g., cost of R&D, public investments, marketing, patent status).
- 2 Work together with the European Medicines Agency (EMA) and national authorities towards transparent and robust criteria for marketing authorisation. Ensure medicines entering the EU market are safe and at the same time bring significant clinical benefit to patients compared to existing treatments.
- 3 Support open science and make sure research results of all clinical studies and collected real world data (RWD) are publicly available.
- 4 Work together with the EMA and the European Commission to ensure incentives (e.g., orphan designation) and related/other patent protection are transparent and not misused;
- 5 Insist on greater accountability and reporting on investments of public funding in R&D (including research grants, subsidies, tax breaks, in kind contributions etc.) and ensure publicly funded products, in particular, are set at an affordable price level and available to patients.
- 6 Support European collaboration on health technology assessment (HTA) and ensure high quality cost-effectiveness analysis of approved treatments.
- 7 Participate in joint procurement initiatives to further share information on health products and increase the governments' bargaining power in pricing negotiations.

The ECL Access to Medicines Task Force, representing 26 national and regional cancer societies in 23 European countries, welcomes this resolution as an important step towards more transparency in pharmaceutical markets and development. The adopted resolution caters to several of the concerns laid down in the Task Force's **Let's Talk Access** white paper on tackling challenges in access to medicines for all cancer patients in Europe'.

The Task Force would like to thank the leading European delegations, particularly Italy, Spain and Portugal, for their strong support for this resolution. The ECL Task Force hopes a larger alliance at the EU level will be formed to work together towards implementation of the resolution. This is as a great opportunity to join forces with as many countries as possible through a work program to enforce transparency on net prices of health products, costs of clinical trials, R&D, sales revenues, marketing costs, subsidies, incentives and patent status information.

## About ECL

The Association of European Cancer Leagues (ECL) is a non-profit, European umbrella organisation of national and regional cancer societies, currently representing 29 cancer leagues in 24 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 drug prices. The Task Force strongly believes in the power of dialogue. We urge all stakeholders to push for innovative improved treatments, improving both survival and the quality of life of cancer patients, instead of investments in me-too products. Currently, 25 national/regional cancer leagues, representing over 450 million Europeans, have signed the Task Force's **Declaration of Intent**.

For more information, please contact Anna Prokupkova, Policy & Project Officer at ECL (Anna(at)europcancerleagues.org).

#LetsTalkAccess @cancerleagues cancer.eu



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