



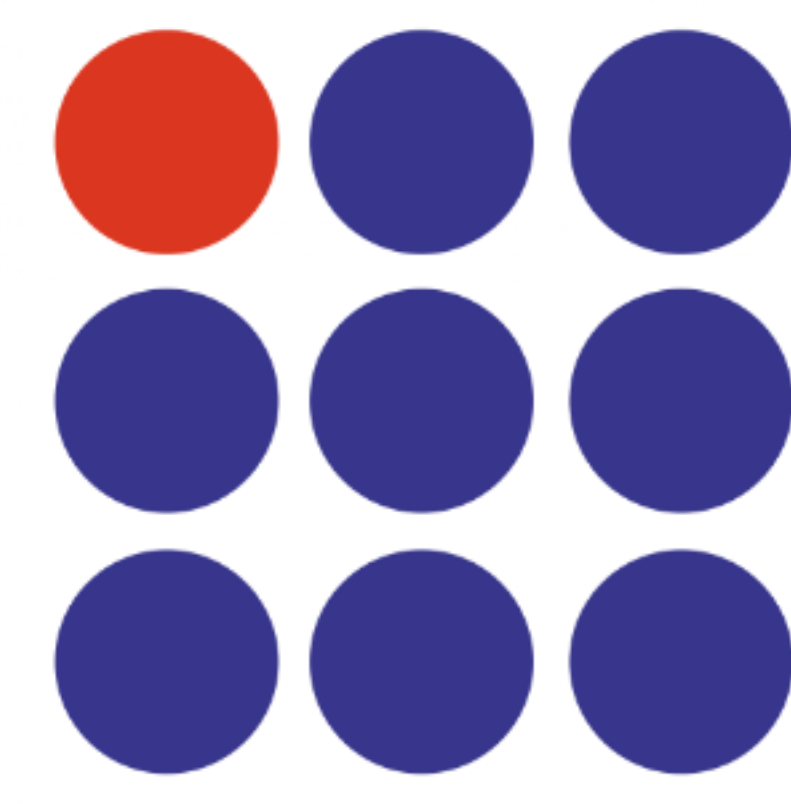
Let's Talk Access!

Tackling challenges in access to innovative cancer medicines

Societal Perspective

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Association of European Cancer Leagues



www.cancer.eu



ACCESS
TO MEDICINES
TASK FORCE

4 WAYS TOWARD A SUCCESSFUL

EUROPEAN COOPERATION ON HTA

AN IMPORTANT STEP TOWARD EQUAL ACCESS TO HIGH-QUALITY MEDICINES FOR EUROPEAN PATIENTS

1. USE HIGH STANDARDS

Given that the uptake of the joint clinical assessment 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.

2. MEASURE PROs & RWE

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.

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to collect RWE after the market approval; and (iii) discloses all available data to the HTA authority, including unpublished data from failed trials, to enable full high quality assessment.

3. INVOLVE PATIENTS

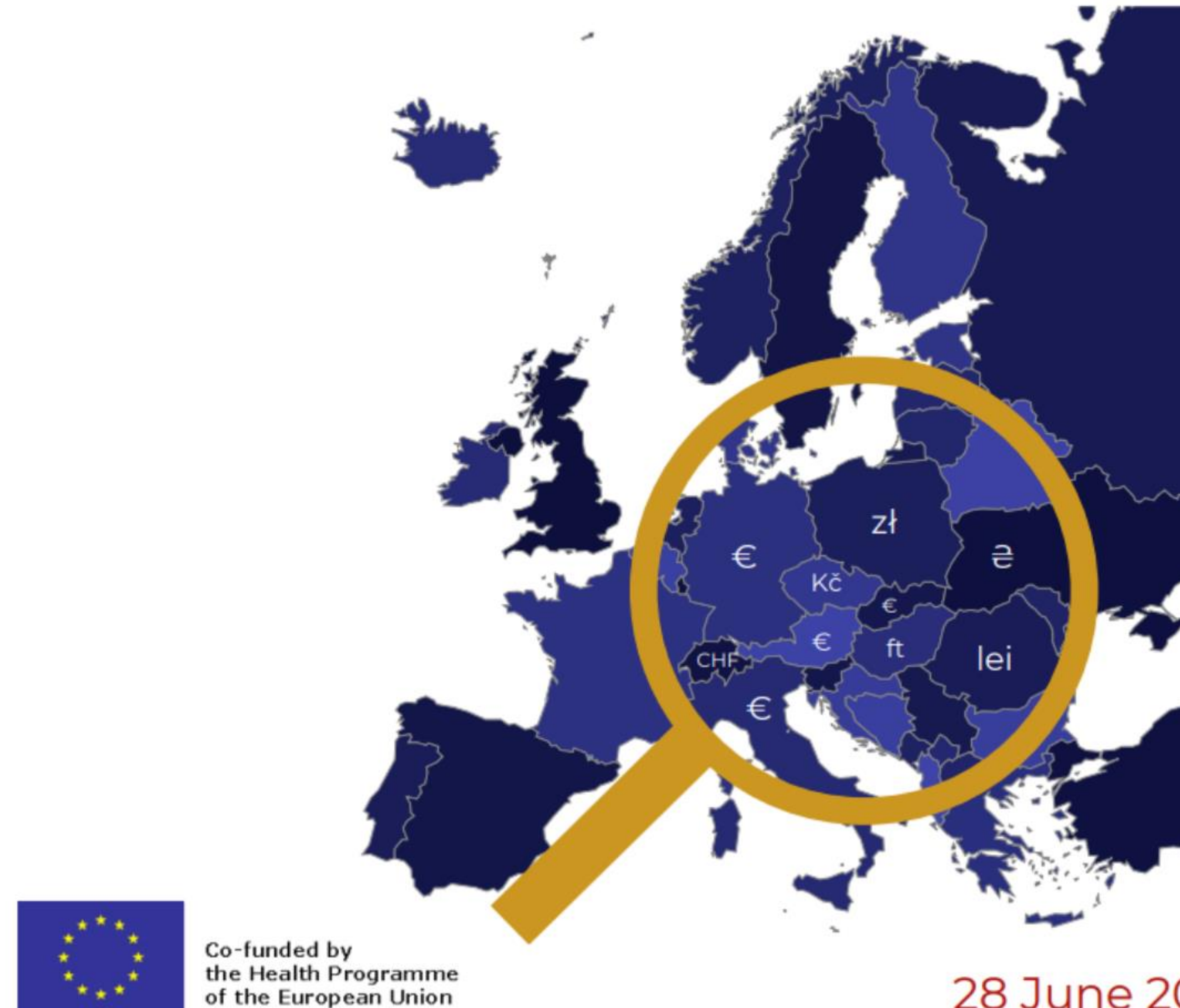
Involving patients in all activities of the EU HTA, including horizon scanning, development of guidelines, joint scientific advice and clinical assessment is key to accurately capture patients' needs while assessing the added value of all treatments.

4. BE TRANSPARENT & INDEPENDENT

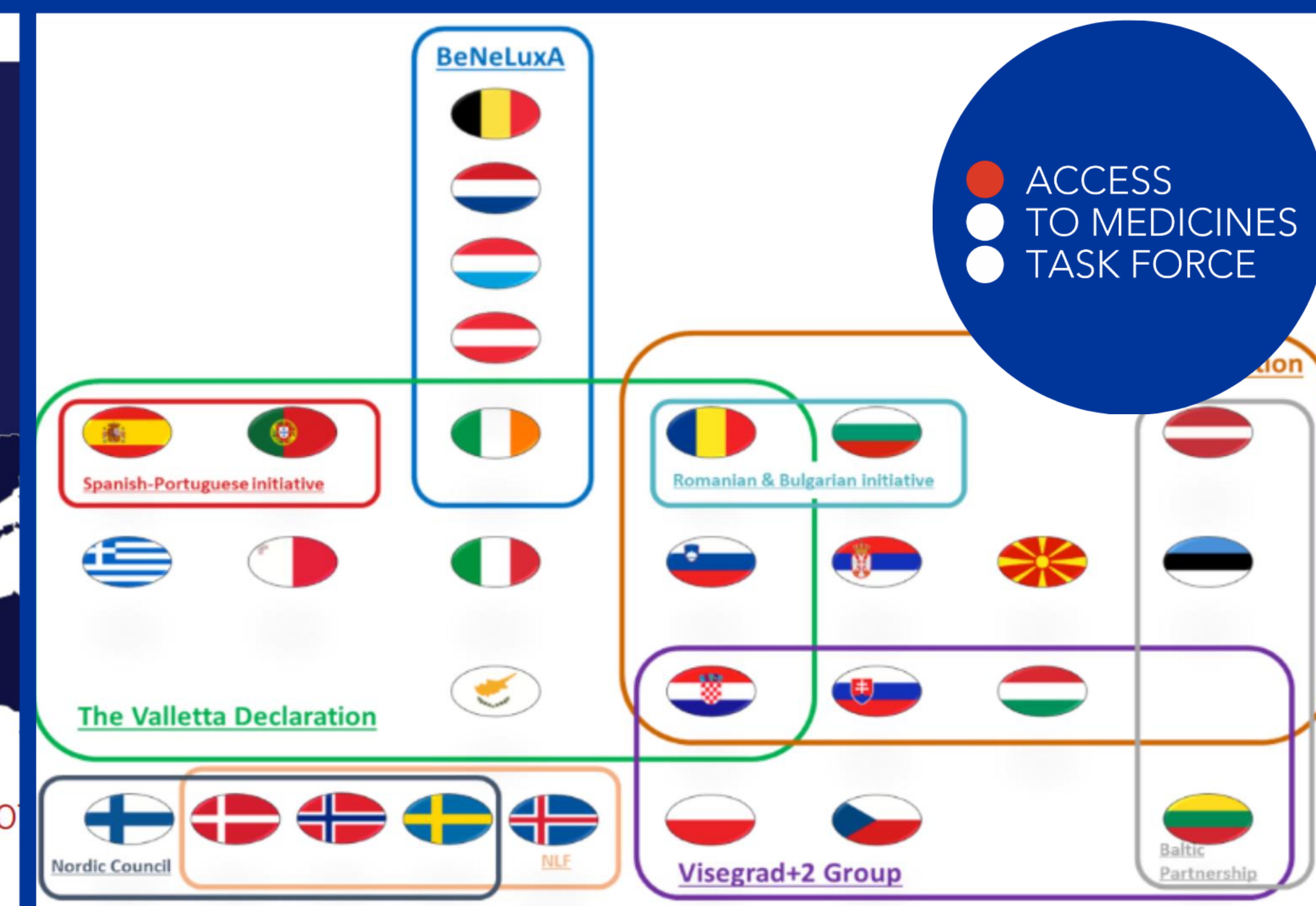
It is crucial to act in a transparent manner with no or minimal confidentiality connected to stakeholder meetings. Strong conflict of interest rules should apply for members of the Coordination Group and its subgroups (i.e. experts) and the relationship with all stakeholders should be clearly defined.

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.

ECL POSITION PAPER



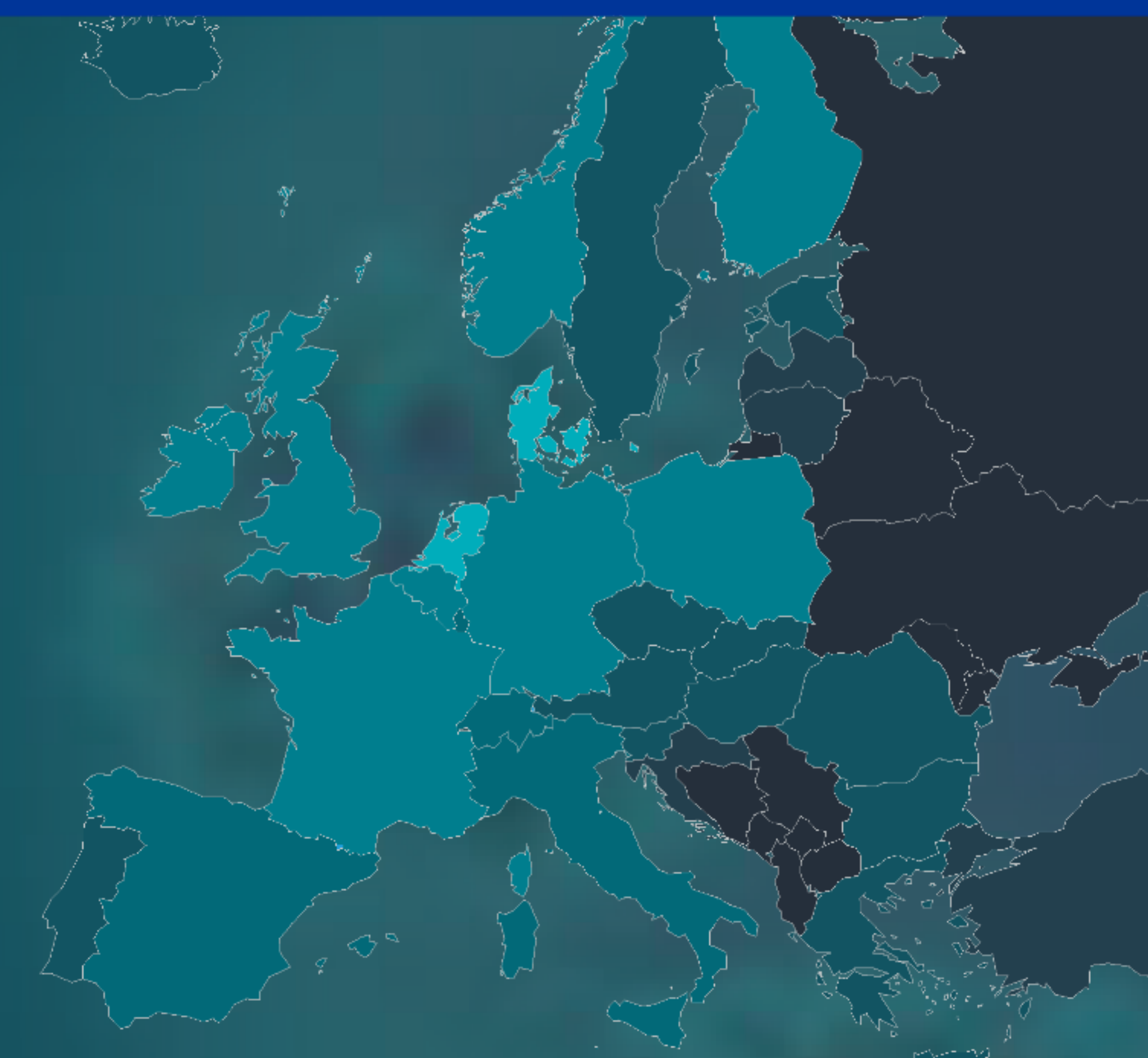
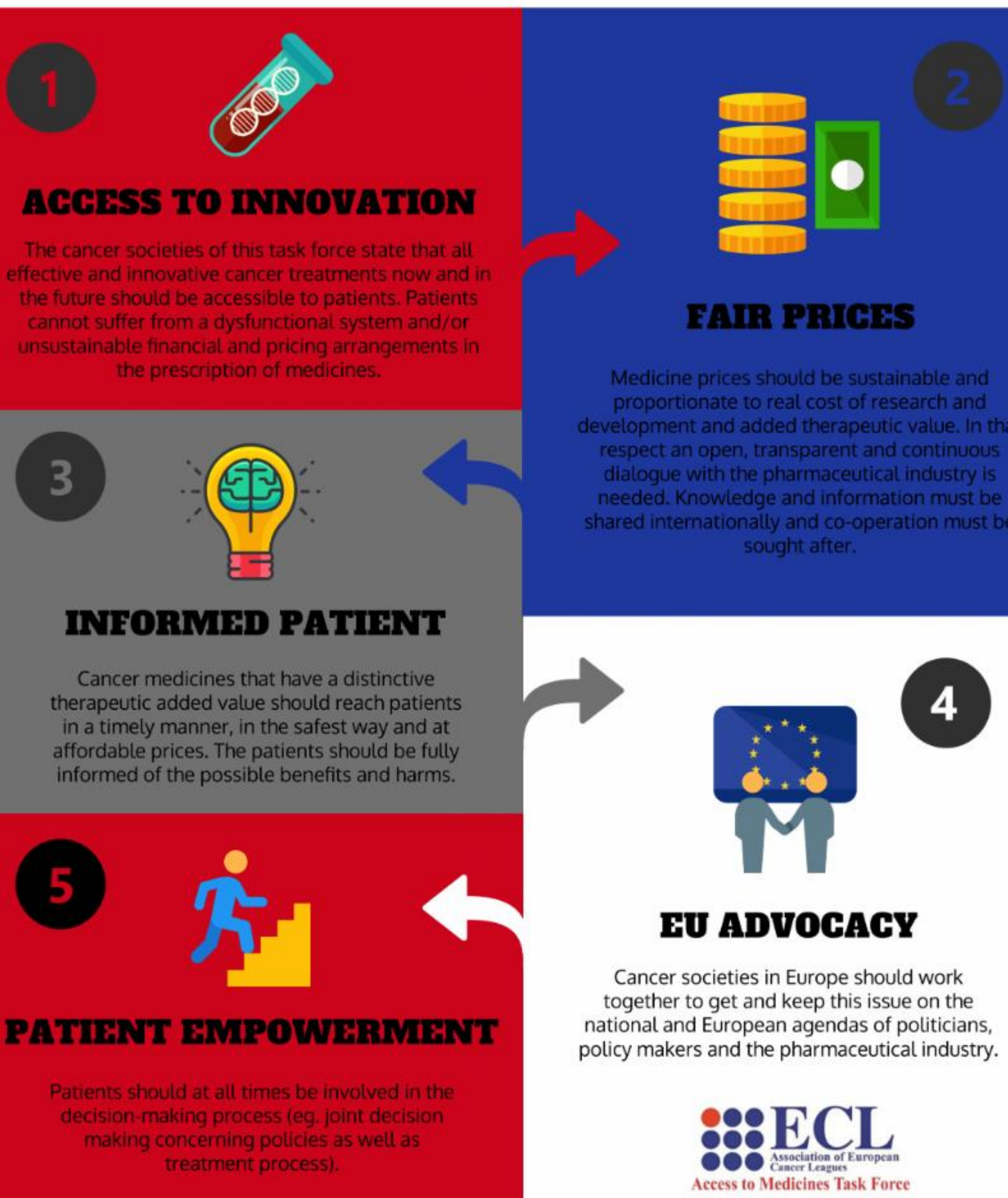
28 June 2018



EMA Regulatory Science to 2025



ACCESSIBLE MEDICINES FOR ALL CANCER PATIENTS!



LET'S TALK ACCESS!

WHITE PAPER ON TACKLING CHALLENGES IN ACCESS TO MEDICINES FOR ALL CANCER PATIENTS IN EUROPE

CAR-T Cell Therapies: How much for survival?

Oncology spending will reach nearly \$240 billion, growing 9–12% through 2023

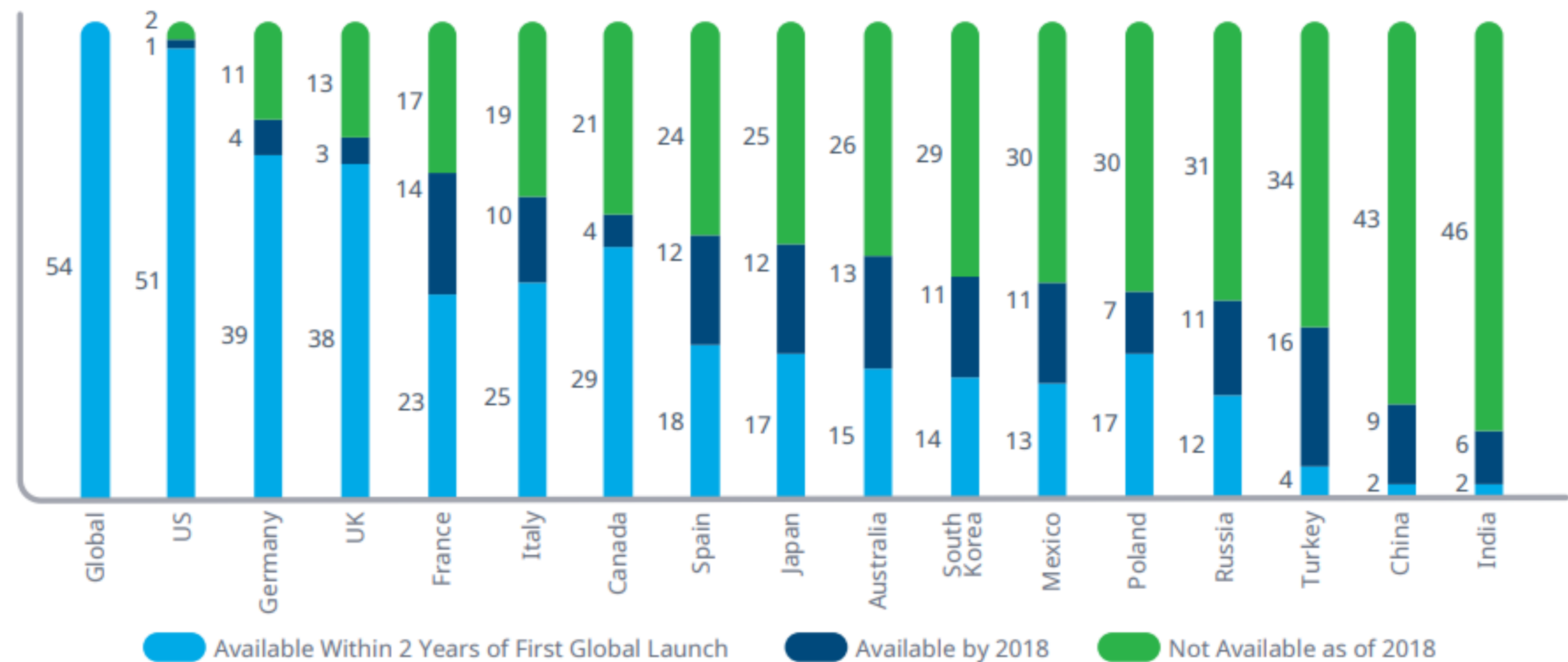
Exhibit 38: Total Spending on Oncology Medicines and Supportive Care and Growth US\$Bn



Source: IQVIA Institute, Apr 2019

Patients in only nine countries have access to more than half of recently launched global cancer medicines

Exhibit 24: Availability in 2018 of Oncology Medicines Launched in 2013–2017

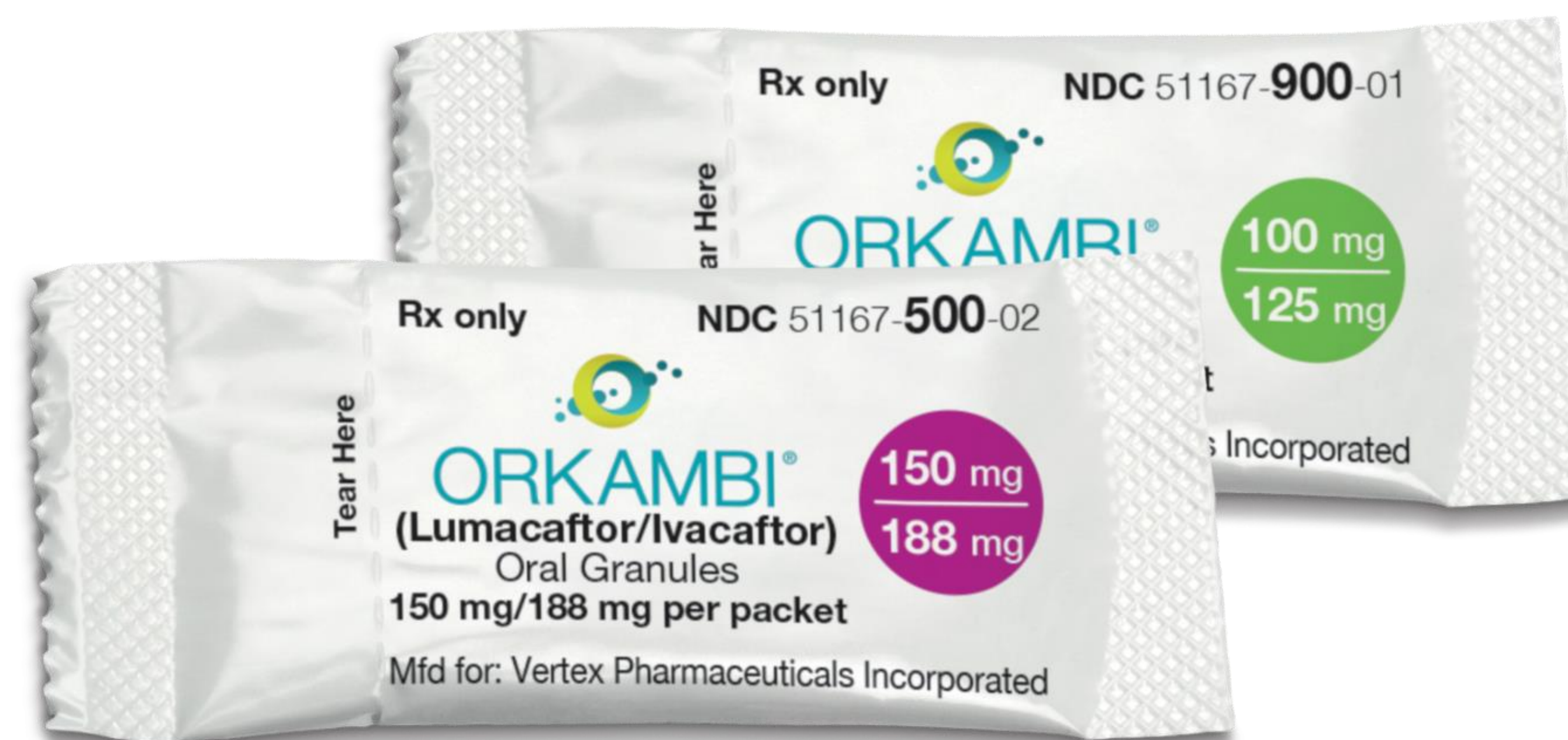


Source: IQVIA MIDAS, Dec 2018; ARK New Product Intelligence, IQVIA Institute, Apr 2019

WHAT IS A HIGH PRICE?



2014
Hepatitis C
€48,000



2015
Cystic Fibrosis
€133,000



2017
Spinal Muscular Atrophy
€600,000/year 1 -
€375,000/year 2-x

WHAT IS A HIGH PRICE?



2018

Acute Lymphoblastic Leukemia
€320,000



2018

Retinal Disease
€425,000 per eye



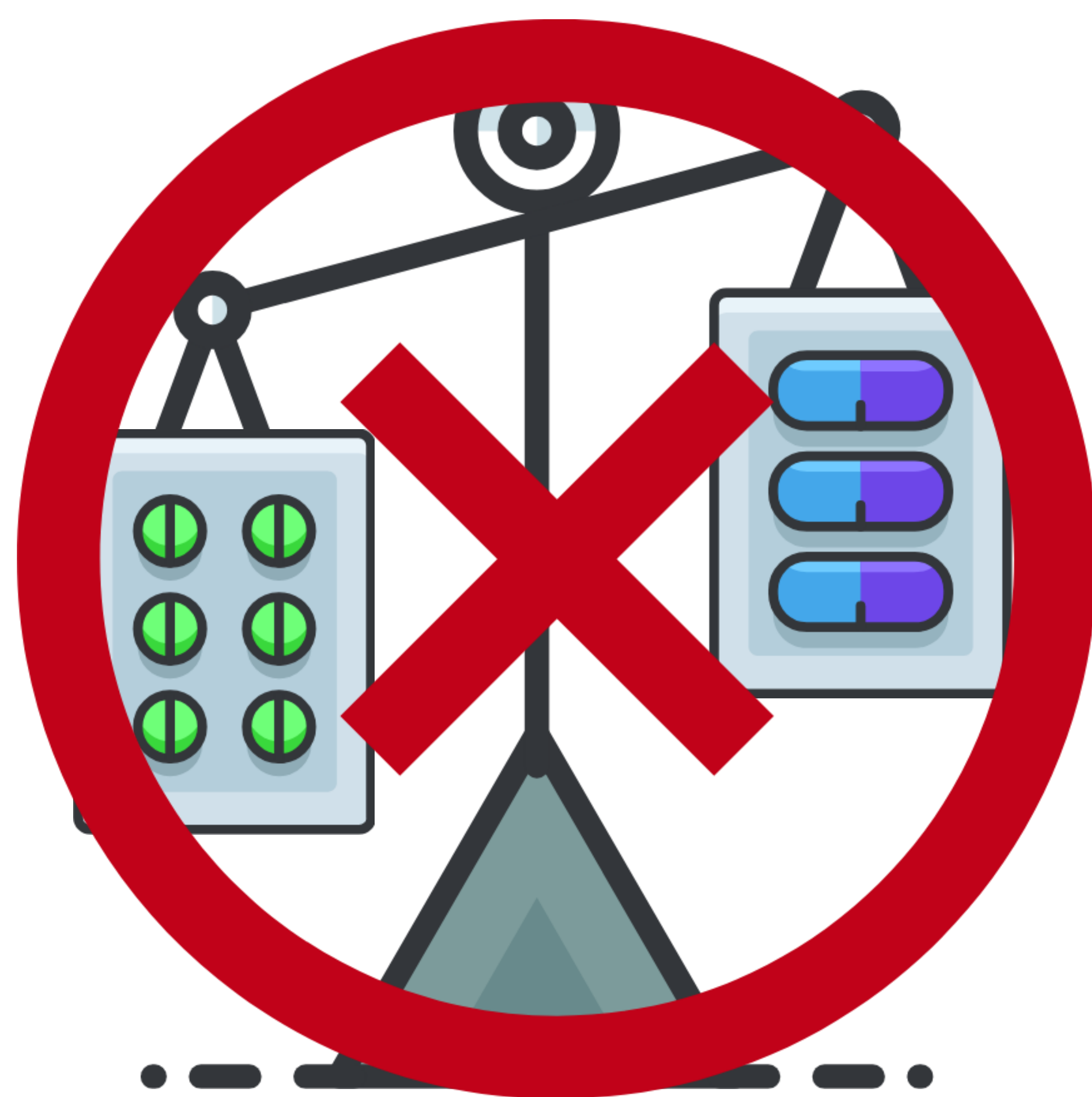
2019

Spinal Muscular Atrophy
€1.9 million

WHY A HIGH PRICE?



R&D



Added value



IP Protection



Speculation

FAIR PRICE DEFINITION 1.0

'A fair price is transparent, understandable, affordable, proportionate and based on objective factors such as R&D investment, delivery, marketing and sales costs, and a clearly defined profit margin connected to the proven therapeutic value (if available compared to other treatments).'

Fair price is profitable enough to steer innovation in the long term, but does not pose a threat to the sustainability of healthcare systems.'

IDEAL PRICING MODEL?

Cost-based pricing

= R&D, marketing, production costs, profit mark up, R&D investment risk

- + Clear components, understandable by wider range of actors
- Dependent on transparency of above mentioned cost components
- Increase in price can only be justified by increase in cost
- Risk companies might now want to enter market with cost-based pricing
- Does not encourage efficiency and does not provide incentives to real innovation based on unmet needs

IDEAL PRICING MODEL?

Value-based pricing

= health gain compared to a current treatment

- + Based on patient and payer relevant outcomes
- + Encourages pharma to be innovative
- Outcomes/value of new therapies often unknown
- Complex analysis requiring highly skilled experts and robust data (clinically relevant end-points based on larger patient populations)
- Pharma-driven concept (omitting the risk of losing money component)
- DILEMA BETWEEN VALUE AND AFFORDABILITY

SO...WHERE DO WE GO FROM HERE?

Competition-based pricing

- What the market can bear
- Confidential discounts based on bargaining power
- Actual price up to 60% difference in the EU

To thinking outside of the box

- ✓ Combine cost-effectiveness and budget impact (willingness to pay for QALY)
- ✓ Use calculated estimates for costs of R&D etc. where transparency is lacking
- ✓ Allow compassionate use where data insufficient for HTA/reimbursement

FAIR PRICE DEFINITION 2.0

'A fair price is justifiable and cost-effective within the aims and priorities of the healthcare systems and the available budget.'

'At the same time, a fair pricing policy takes into account ethical and financial dimensions of patients access to care, affordability and sustainability of healthcare systems.'

CALL FOR MORE TRANSPARENCY



INTERNATIONAL COOPERATION

- Joint Procurement Initiatives
- Information exchange on real prices of medicines (e.g., via EURIPID)
- Implementation on WHO Transparency Resolution



FAIR PRICING

- Definition of a fair price
- Analysis of challenges and advantages of different pricing models
- Establishing a European transparency research network

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;

GET IN TOUCH WITH US!

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