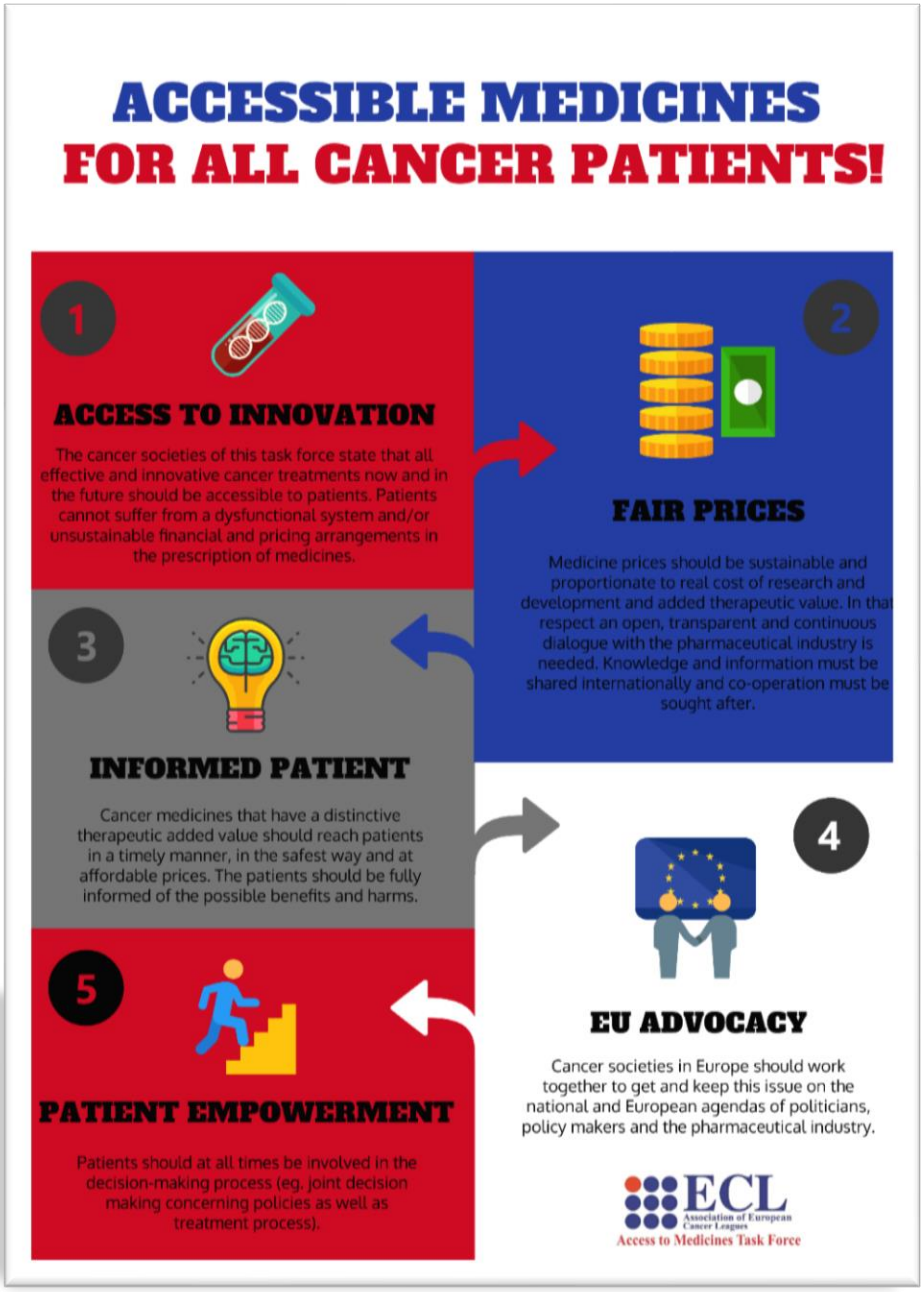
ECL ACCESS TO MEDICINES TASK FORCE



ACTION PLAN 2021

Co-funded by
the Health Programme
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NOTE FROM THE CHAIR

Brussels, October 2020

The times are exciting for the Access to Medicines Task Force. The new European Commission launched several policy initiatives that touch the core of our remit. The initiatives will shape the pharmaceutical market and the cancer policy in the coming decade. The Europe's Beating Cancer Plan is going to promote actions at every key stage of the disease (prevention, diagnosis, treatment, survivorship). The Pharmaceutical Strategy strives to guarantee that new medicines are available quickly and under all circumstances to patients across Europe.

We grabbed the opportunity to influence these initiatives. We published a position paper on Europe's Pharmaceutical strategy and are advocating for the recommendations in the paper. A meeting with the European Commissioner of Health is scheduled. Due to the work and expertise of the Task Force, ECL's position paper about Europe's Beating Cancer Plan contains an important chapter about access to and development of medicines.

An unforeseen challenge is the COVID-19 crisis. The Task Force should come to grips with its consequences. The rush for an effective vaccine may change the role of governments in pharmaceutical markets and their attitude towards international collaboration. The consequences for cancer drug development and affordability are still unclear. We need to stay on top of these developments so that we are able to answer the consequences as soon as possible.

Thanks to the expertise of the members of the Task Force, we can approach the future with confidence. The publication of the position paper 'What is a fair price?' has proven this. The thorough analysis in this paper is very inspiring for discussions about price and pricing. This became clear during the launch of the paper and in the invitations of several pharmaceutical firms to discuss the contents of the paper. The workshop on international collaboration and public procurement that will take place in spring 2021 is the next opportunity to influence the pharmaceutical policy in Europe.

All of the above has been achieved in difficult circumstances. The last time that we met in person was in Dublin, in the Autumn of 2019. Communication since then has been purely online, which makes it more difficult to have thorough discussions and develop creative ideas. Our organisations are under stress because all our activities, from fundraising to patient support, have to be re-thought. It is more difficult than usual to break into the agenda of officials who have to deal with an unseen public health crisis.

The mission of the A2M TF is not yet accomplished. A new case of cancer is diagnosed in the EU every 9 seconds. Many of these patients need new treatments, which offer hope of a longer and better life. But there are many hurdles to making these treatments quickly available to every new patient. Prices of new generations of therapies, e.g. gene therapy and cell therapy, reach a new order of magnitude and range from $100.000 to $800.000. Many countries experience increasing issues with drug shortages. I'm convinced that we can make a difference. We are a small but dedicated group of people. 30 cancer societies from 25 countries are members of the Task Force. Together, these societies represent more than 500 million Europeans. If we make our voice heard, we will have an impact.

Ward Rommel
Chair, ECL Access to Medicines Task Force

OBJECTIVES OF THE TASK FORCE

"To achieve equal access to medicines for all cancer patients in Europe."

GOAL 1: Increase access to all essential and innovative cancer medicines with proved added value for patients across Europe, now and in the future.

By advocation for priorities set in the ECL's Vision for EU Pharma Strategy, covering:

(i) prevention and management of medicine shortages;

(ii) achieving sustainable innovation;

(iii) ensuring robust regulatory pathway from R&D, clinical trials to market approval;

(iv) supporting international collaboration in horizon scanning (HS), health technology assessment (HTA) and pricing and reimbursement (P&R); and

(v) promoting our definition of a fair price and advocating for the uptake of a sustainable pricing model.

GOAL 2: Increase transparency throughout the pharmaceutical system, including:

(i) transparency of research data (open science);

(ii) transparency and accountability of public spending in medical R&D

(iii) transparency in pricing and prices of medicines, including making prices understandable and justifiable by disclosing costs related to medicine development, manufacturing and marketing, and added value margin based on patient outcomes;

(iv) transparency in decision-making processes including decisions on marketing authorisations, orphan/paediatric status, HTA and P&R decision.

GOAL 3: Increase patient empowerment and ensure the voice of patients and civil society is reflected in all decision-making processes throughout the medicine development and access pathway, by:

(i) Advocating for patient/consumer engagement in decision-making, including medicines development, the work of the European institutions, European Medicines Agancy (EMA), HTA and P&R bodies, etc.;

(ii) Having the patient voice represented at key events, meetings, initiatives of the A2M TF.

ORGANISATION

The ***Task Force's Chair***, with the support of the ECL Secretariat, is responsible for the overall management and development of the A2M TF activities, including providing the themes and agendas for, deciding on the venue of, and chairing of all A2M TF meetings. The Chair is further responsible for reporting on the group's developments and future plans to the Board upon request. The Chair is elected for a period of three years by the members of the Task Force, as per procedure described in the Terms of Reference. *The time commitment needed for this position is on average four hours per week.*

Chair: *Ward Rommel, PhD, Head of Care and Treatment, Stand up to Cancer, Flanders*

The ***Steering Committee*** defines the strategy of the Task Force under the leadership of the Chair. It decides on key aspects and ensures that all WG s are working toward a common goal. The Chair, and designated members of the Task Force and the Secretariat are members of the Steering Committee. Each Steering Committee member has an area of responsibility (see details below) and decides on endorsements of other organisation's initiatives within that remit. Aside from the two Task Force meetings, the Steering Groups meets in person at least one time per year and organises at least three online meetings per year. In the absence of the TF Chair, designated Steering Group members can substitute the role of the Chair and act as Vice-Chair.

Members of Steering Committee:

- ***Ward Rommel****, PhD, Head of Care and Treatment, Stand up to Cancer, Flanders (Chair),* responsible for: **TF overall strategy and visibility, R&D models**
- ***Linda Aagaard Thomsen****, PhD., Head of Research Governance, Danish Cancer Society Research Center,* responsible for: **medicine's evaluations and fair pricing**
- ***Dimitri Kohler****, PhD., Research Associate, Pricing & Reimbursement, Swiss Cancer League,* responsible for: **international collaboration on horizon scanning, HTA and procurement**
- ***Guy Muller****, International Public Affairs Adviser, Dutch Cancer Society,* responsible for: **orphan and paediatric medicines**
- ***Amandine Courtin****, Advocacy Manager, French League Against Cancer,* responsible for: **medicine shortages**
- *Policy officer, ECL (Observer),* responsible for: **functioning of the TF, advocacy strategy, activity planning and output delivery**

Every working group has ***leaders*** responsible for specific tasks, supporting its members to ensure progress. Leadership on specific activities is assigned based on the person's experience and expertise.

***Members of the working group*:**

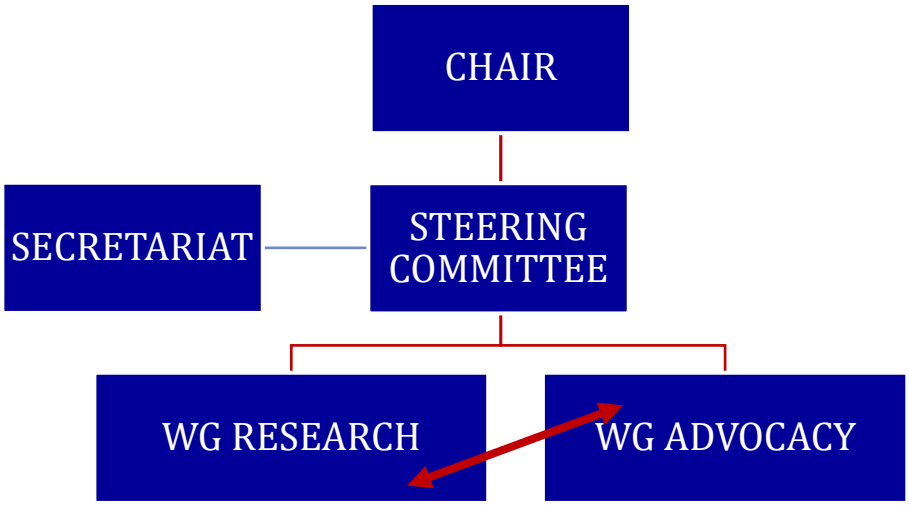
- Work together with other WG members toward implementation of the A2M TF Action Plan, specifically to reach the objectives set up by the relevant working group;
- Are willing to dedicate (at least) one hour per week (average) to the WG's cause;
- Provide feedback to the WG's outputs, upon request;
- Are present during Task Force meetings and WG calls.

Any staff or board member of ECL member leagues can become a *member of the A2M* TF and join any of the TF meetings. Members should endorse the *Declaration of Intent* and preferably join one of the A2M TF working groups in order to be able to contribute in a constructive manner to the aims of the Task Force. All members shall act in the spirit of the Declaration and refrain from actions which are contrary to it. Where possible, members should publish the declaration on their league's website.

ECL functions as the ***Secretariat*** by providing logistical support, advising on content, and acting as a contact point between Task Force members. ECL also monitors EU policies, advises on working group content, advocates at the European level and supports members in their advocacy activities in the capitals.

Up to date overview of all active members of the task Force and their roles and expertise in available here.

Structure



WG RESEARCH

Members of the Research working group are responsible for analysing topics related to access to medicines by conducting literature review and use other methods (e.g., interviews) to identify and assess the extent of the problems and how to overcome them. They work closely with members of WG Advocacy to develop policy recommendations which will be provided to national, European and international decision-makers.

Activities

1. International Collaboration in Medicines Policy and Joint Procurement Initiatives

1.1 By conducting research (white and grey literature review and interviews), map international cooperation and joint procurement initiatives, the extent of their success, what is needed for the success to be achieved and what are the main issues and obstacles to success.

1.2 Organise a workshop (Q1/2 2021) with Member States representatives discussing best practices, challenges and opportunities of international cooperation in horizon scanning, HTA and pricing negotiations; use workshop conclusions as a part of the above-mentioned research.

1.3 Publish paper on International Collaboration & Joint Procurement Initiatives by Q3 2021, with policy recommendations with short-, medium- and long-term actions which should be undertaken by public authorities in order to fulfil the potential of regional initiatives.

1.4 Share best practice in Europe – advocate for recommendations published in above mentioned paper and encourage governments to join the initiatives.

- *Theme leader: Dimitri Kohler, Swiss Cancer League*
- *Supporting members: TBC: PLEASE STATE YOUR INTEREST HERE*
- *Work Timeline: June 2019-September 2021 (paper development, workshop organisation); followed by advocacy action in 2021 and 2022*

2. Draft a position paper on improving regulatory incentives related to orphan and paediatric medicines development

2.1 Research functioning of current framework and its shortcomings (also based on available assessments of Technopolis)

2.2 Draft a position paper on how to address the shortcomings if orphan and paediatric legislation gets re-opened (foreseen in 2022)

- *Theme leader: Guy Muller, Dutch Cancer Society*
- *Supporting members: TBC: PLEASE STATE YOUR INTEREST HERE*
- *Work timeline: Q2-Q3 2021*

WG ADVOCACY

Members of the Advocacy working group are responsible for the dissemination, public communication and lobbying based on the Task Force's output. They work closely with members of WG Research to develop policy recommendations which will be provided to national, European and international decision-makers.

Anna Prokupkova and Ward Rommel are responsible for smooth functioning of all advocacy activities stated below. Please state your interest here to show your willingness to support them.

Activities

3. Promote established definition of a fair price

4.1 Promote 'What is a fair price?' paper in meetings and conferences.

- Identify and create a list of meetings and conferences where the Task Force should proactively reach out to explore a possibility to present

- Keep track of public appearances by TF members who presented the topic *(each appearance needs to be in line with the ethical code and reported in advance to Anna)*
- Please see Communications and Advocacy Toolkit provided to you by Anna to help you navigate through advocacy activities related to the ECL Task Force

4.2 Explore collaboration with WHO, its working groups and the upcoming Fair Pricing Forum. Take part in the Oslo Initiative of WHO EURO.

4.3 Continue open dialogues with pharmaceutical industry re fair pricing strategy.

5. Promote messages from ECL's Vision for EU Pharma Strategy

5.1 Promote policy recommendations stated in ECL's Vision for the EU Pharma Strategy at the national, European and international level.

5.2 Schedule face to face meetings with MEPs, representatives of health ministries and the Commission re ECL's Position Paper.

- Meeting with Commissioner Kyriakides and DG Sante in January 2021 (A2M TF SC)
- MEPs – ECL Secretariat engagement on blue and pink weeks, Members on Green weeks
  - EP Calendar 2021
- Government representatives – ministries, medicine agencies, HTA agencies, P&R agencies, responsible officials who are preparing the response to Council of the EU
- International organisations e.g., OECD, WHO – take part in stakeholder meetings, where possible
- *Please inform Anna of any relevant meetings with decision-makers that should be noted and share the meeting outcomes*
- Please see Communications and Advocacy Toolkit provided to you by Anna to help you navigate through advocacy activities related to the ECL Task Force

5.3 Publish a 1-2page reflection on the final text of the Pharma Strategy stating ECL's priorities (Commission Communication prospected on 24 November 2020)

5.4 Provide input and amendments to the EP report on EU Pharma Strategy of the ENVI Committee (report timing TBC).

5.5 Provide input and amendments to the EP report on cancer of the BECA committee in the field of access to medicines (Q1/Q2 2021).

6. Respond to urgent upcoming policy inquiries of the European and global decision-making bodies (incl. Commission, EP, WHO, OECD, EMA etc.)

6.1 Monitor opportunities to provide input (letters, consultations, meetings) linked to the Pharmaceutical market, including medicine shortages, extended mandate of the EMA, European Health Union, Cross-border Healthcare Directive, establishment of the EU Agency for Biomedical Research (HERA), establishment of the European Health Data Space (EHDS) and others.

7. Build and maintain relationships with decision-makers and stakeholders [CONTINUOUS]

7.1 Build strong and maintain relationships with European and national policy-makers, including members of the MEPs Against Cancer, European Commission officials, representatives of national governments and executive agencies.

7.2 Build and maintain relationship with the EMA by responding to ad-hoc requests of the Agency, participating in Patients and Consumers Working Party and other stakeholder meetings, take part in EMA's public consultations.

7.3 Monitor and explore opportunities for cooperation with initiatives of other organisations active in access to medicines (EFPN, EPHA, BEUC, HAI, MSF, MdM, EPF, AIM, EORTC, ESMO etc.).

7.4 Lead constructive dialogue with pharmaceutical industry on access to medicines and fair pricing and participate in multi-stakeholder meetings, in accordance with ECL's ethical code.

7.5 Strengthen relationship with international organisations on access to medicines, particularly with the WHO and OECD; attend relevant stakeholder meetings.

8. Ensure public visibility of the Task Force [CONTINUOUS]

8.1 Strive to have a representative of the TF speak at public conferences, e.g., at the European Parliament, ECCO Summit, EPHA A2M Forum, etc.

Other activities [CONTINUOUS]

- Maintain a knowledge platform with academic and grey literature on access to medicines.
- Maintain a list of experts to with a knowledge on specific topics relevant to the Task Force. Experts will be consulted for advice and invited to relevant meetings/ conference panels.

WG MEMBERS

Overview of active members of the Task Force, their role and expertise.