INTERNAL DOCUMENT

ECL ACCESS TO MEDICINES TASK FORCE

COMMUNICATIONS & ADVOCACY STRATEGY

ECL's Vision for EU Pharmaceutical Strategy &
What is a Fair Price? Position Papers

November 2020

CONTENTS

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1. ABOUT THIS STRATEGY

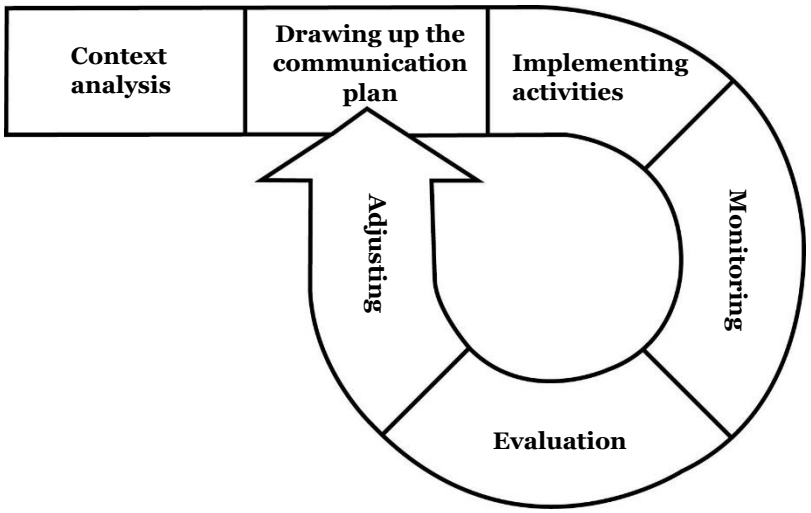
This strategy covers activities to communicate about and advocate for priorities stated in the ECL Access to Medicines Task Force (A2M TF)'s latest publications: the Vision for the EU Pharma Strategy and the 'What is a Fair Price?' position paper.

The A2M TF Communication & Advocacy Strategy aims to take an operational action-based approach that maximises the impact of the limited resources available to ECL and its members. The communication plan should be flexible and dynamic and help ECL secretariat and members navigate effectively through the realm of EU lobbying.

The communication plan shall include the following:

a) **Context Analysis** – SWOT analysis
b) **Objectives** (what we want to accomplish)
c) **Target Groups** (who we need to talk with) – primary and secondary audiences
d) **Communication actors**, their resources and key roles – the people responsible for implementation information and publicity measures and indicative budget for implementation of the plan;
e) **Key Messages** & Message House (what we want to say and to whom)
f) **Tools & Channels** (how we will communicate) - strategy, tactics and content of the information and publicity measures to be taken;
g) **Engagement Calendar** (when we will communicate) – key EU timelines and pressure points for advocacy as well as key events, meetings, webinars, etc.
h) **M&E** (how we will measure progress) - an indication of how the information and publicity measures are to be evaluated in terms of visibility and awareness.

The drawing up of the document must be considered as a cycle composed of six major steps, as shown in the figure below:



2. CONTEXT ANALYSIS

A SWOT analysis examining strengths, weaknesses, opportunities and threats helps to identify potential areas where the communication plan should concentrate.

STRENGTHS	OPPORTUNITIES
• Strong relationship of the Task Force with EU institutions • High expertise within the network (public affairs, health economy, research, patient perspectives...) • Good reputation as independent and credible stakeholder • Task Force Coordinator committed to strategic planning	• Cancer is a priority at the EU level in the 2019-2024 legislature • Availability and affordability of medicines is a hot topic at the EU level • Many NGOs and decision-makers keen to push for access to medicines and create partnerships • Room to develop stronger relationships with national Health Ministers and agencies
To boost strengths: ➢ Be in regular contact with decision-makers to present your views ➢ Ensure dedicated engagement of ECL members in the Task Force ➢ Promote evidence-based policy messages ➢ Ensure hands-on proactive Coordinator	**To boost opportunities:** ➢ Profile yourself as to-go-to organisation on cancer policy and access to medicines in Brussels and capitals ➢ Use COVID-19 to further stress the need to address affordability and budgetary constraints and need to cooperate to address availability issues ➢ Build partnerships with like-minded organisations and draft joint statements
LIMITATIONS	**THREATS**
• Lack of time • Budget constraints • Lacking a strong network of communication officers within member leagues • Asymmetry in the level of engagement of ECL members in the A2M TF activities • Lacking number of members with dedicated engagement in the work of the Task Force • Limited amplification of common messages at national/regional level	• Resistance of pharmaceutical industry to change • Hesitancy of some large European countries to cooperate in pharmaceutical policy/health • Stagnating communications and outreach to decision-makers between output launches and events • Lack of support from national and regional leagues, stakeholders (e.g., pharma sponsored patient organisations or medical societies not willing to talk about prices) and governmental institutions
To overcome limitations: ➢ Ensure effective prioritisation of issues addressed by the TF ➢ TF members should ensure to communicate about the TF within their organisations ➢ Chair and Coordinator should dedicate more resources to present the TF to leagues who are not as active and get them on board ➢ Better alignment with priorities of national leagues (advocacy strategy) needed	**To prevent threats:** ➢ Keep an open dialogue with industry, in accordance with the ethical code, and stress views of patients and civil society ➢ Show evidence re advantages achieved with enhanced cooperation in policy papers ➢ Plan policy engagement and output delivery throughout the year, look for continuous opportunities to engage ➢ Better connect engagement with European umbrellas and their national members

3. OBJECTIVES

The ECL Access to Medicines Task Force strives to:

i. **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.

ii. **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.

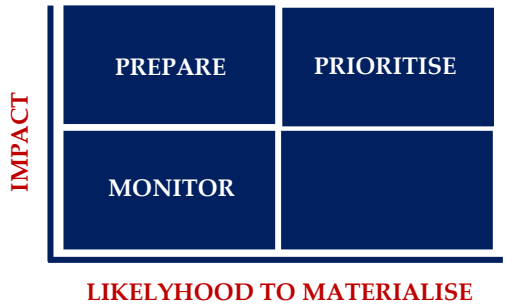
iii. **Increase patient empowerment and ensure the voice of patients and civil society is reflected in all decision-making processes throughout the medicine development and access pathway**, by:
(i) Advocating for patient/consumer engagement in decision-making, including medicines development, the work 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.

To achieve the above-stated goals, the Task Force should:

a. Ensure that the A2M TF is sufficiently well-known among those concerned with cancer, medicines and health issues, so as to attract partners, collaborators and supporters;
b. Ensure that the A2M TF, its outputs and contributions to the cancer and medicines policy as well as the implementation and development of relevant policies are sufficiently well-known within the EU institutions and other decision-makers, so that to receive an appropriate level of political support;

c. Build and maintain beneficial long-lasting relationships with national, European and international decision-makers;
d. Enable publications, projects and campaigns to communicate about their results to raise the awareness of the general public on cancer and medicines issues and on the contribution of the EU in this field.

PRIORITISATION



A2M TF prioritises based on the urgency of issues and political agenda.

4. TARGET GROUPS

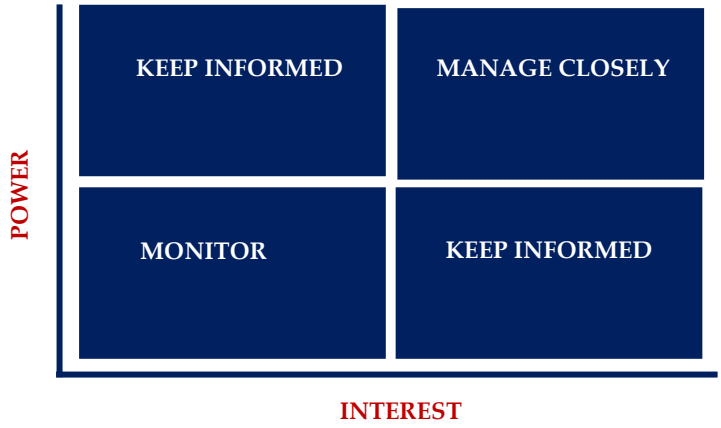
To achieve the above-stated advocacy goals and operational objectives, priority should be given to two main target groups:

1. **Policy-makers**
    a. in the European Institutions and Agencies: European Commission, European Parliament, the Council of the European Union (ministries, attachés) and the European Medicines Agency (EMA)
    b. International decision-making bodies including the WHO and the OECD

2. **Key Stakeholders involved in medicine policy**
    a. Pharmaceutical industry
    b. Public and private payers/insurers
    c. Patient and consumer organisations
    d. Healthcare professionals and academia/non-profit research

The general public is an indirect target group, as it is difficult to reach a significant amount with specific actions in the various countries (in different languages) and from the secretariat. Communicating with the general public is best achieved by national/regional cancer leagues.

STAKEHOLDER MAPPING



It is important to talk to appropriate persons who are particularly relevant to the given topic.

5. ACTORS, ROLES & RESOURCES

These are essentially the members of the A2M TF, supported by the ECL Secretariat, the Chair of the TF and the Steering Committee.

Members of the A2M TF are best placed to:

- ✓ Communicate with their decision-makers (regionally, nationally and to a lesser extent internationally), including relaying the key messages and asks at the EU level
- ✓ Raise the awareness of the A2M TF amongst national and regional stakeholders
- ✓ Communicate to the general public
- ✓ Communicate with local, regional and national media

The members of the A2M TF are highly encouraged to communicate about the A2M TF and its outputs. Typical activities include, amongst others, including a section about the A2M TF on their organisation's website and using available communications channel (e.g., newsletter, social media) to promote the work of the TF. Members are also encouraged to attend and speak at conferences and meetings, arranging meeting with relevant *stakeholders (please let ECL know if you are representing the TF externally)*. Members should actively take part in the drafting of position papers and reports, including translating papers and reports in their national language. Members are encouraged to share such activities with their peers during A2M TF meetings.

The ECL Secretariat is best placed to:

- ✓ Provide basic information about the A2M TF and all outputs to all interested parties
- ✓ Raise the awareness about the A2M TF amongst European and global stakeholders and decision-makers
- ✓ Contribute to the dissemination of outputs at the EU and international level
- ✓ Ensure exchange with the EU and to a lesser extent national policy-makers

- ✓ Coordinate, promote and provide guidance on A2M TF advocacy and communications to its members

ECL typically spends 20% of its budget on communication and advocacy related to access to medicines, addressing primarily EU policy-makers and Brussels-based stakeholders. Typical activities include, amongst others, a detailed website section, brochures/leaflets, press releases presenting new outputs, publicising the outputs of the A2M TF various ways (press, website, mailings, etc), preparing dissemination plans and social media toolkits, promoting/organising launch events and meetings, making presentations about A2M TF to various stakeholders, social media accounts, and networking and lobbying at the EU level.

The Task Force meets twice a year to discuss the past and upcoming activities. Further strategy, advocacy and communication coordination take place every three months with the A2M TF's Steering Committee, to identify pressure points for communication and advocacy activities, and review ongoing and future strategies and activities. All key activities are provided to members in an annual Action Plan.

6. KEY MESSAGES

Communication should tell policy-makers and stakeholders why it is necessary to secure affordable access to high quality essential and innovative medicines. Moreover, communication messages should focus on promoting key publications and recommendations.

ECL ACCESS TO MEDICINES TASK FORCE

The **ECL Access to Medicines Task Force** aims to secure access to all essential and innovative cancer medicines with proved added value for patients across Europe, now and in the future.

MESSAGE 1	MESSAGE 2	MESSAGE 3
Secure availability of well-established medicines for all patients in Europe.	**Ensure sustainable innovation in medicine development.**	**Achieve affordability of novel cancer medicines.**
PROBLEMS 1	PROBLEMS 2	PROBLEMS 3
a) Growing number of (cancer) medicine shortages b) Shortages impair patient outcomes c) Lack of coordinated response in shortage prevention and management	a) Mismatch between R&D investment and unmet need b) Lack of robust evidence for medicine evaluation c) Not all new treatments are innovative in terms of added patient benefit d) Lack of data transparency prevents additional research	a) Growth in healthcare spending b) Negative impact of IP protection on products' affordability c) Unequal capacity to support uptake of new treatments

		d) Information asymmetry related to medicines prices and pricing practices
SOLUTIONS 1	SOLUTIONS 2	SOLUTIONS 3
1) Strengthen EU legislation to improve notification and early warning system of medicines shortages 2) Require medicine shortages management and prevention plans 3) Launch an EU Joint Action on prevention of, and solutions to, medicine shortages	1) Support independent (non-profit) clinical research 2) Set up rigorous design of clinical trials using real world data and demand systematic additional of evidence (post marketing) 3) Ensure high quality benefit-risk assessments of patient-relevant endpoints for MA/HTA/P&R	1) Pool resources and enhance collaboration throughout the medicines access pathway 2) Ensure right balance between awarding R&D/IP incentives and preventing unintended effects on affordability 3) Attach conditions to funding to ensure publicly funded products are affordable 4) Ensure application of fair prices and pricing policies 5) Improve transparency through the pharma system
See ECL Pharma Vision pg 5-7.	*See ECL Pharma Vision pg 8-17.*	*See ECL Pharma Vision pg 17-21 and 'What is a fair price' paper*

7. COMMUNICATION TOOLS

TOOLS	TARGET GROUP(S)	DESCRIPTION
Organisation of teleconferences / meetings for ECL A2M TF	**Cancer leagues**	(Virtual) meetings for cancer leagues to discuss operational aspects with TF members will be organised by ECL. Meetings and teleconferences offer the opportunity for the co-production of outputs, strategy building, for ECL to disseminate outputs/information directly to cancer leagues, and for members to share experiences with peers.
Events and Webinars (for promoting outputs and highlighting policy issues)	**Cancer leagues, external stakeholders, policy-makers**	Public events and webinars to launch new outputs, disseminate existing ones and reiterate the key messages of the A2M TF will be organised by ECL. All stakeholders invested in a given topic or sub-topic and decision-makers will be invited to speak and participate.
Newsletters	**Cancer leagues, external stakeholders, policy-makers**	ECL will continue including links to key outputs produced by the A2M TF in its periodic newsletters. Members of the TF are encouraged to periodically include info about the TF's work, events and outputs in their organisations' newsletters. On occasion, key outputs will be promoted via newsletters of third parties, namely European Public Health Alliance (EPHA) and European Cancer Organisation (ECCO).
Websites	**Cancer leagues, external stakeholders, policy-makers**	ECL will keep the A2M TF's webpages on its website up to date. Members of the TF are encouraged to ask their organisations to include info about the TF on their websites. ECL will also upload all A2M TF's outputs onto the European Commission's Health Policy Platform for wide dissemination among public health groups.
Social media channels	**Cancer leagues, external**	ECL will continue to regularly share posts about the work of the TF on Twitter, Facebook and LinkedIn, as well as engaging with stakeholders and influencers on topics of current concern. Members of the TF are encouraged to like and share ECL's posts and create their own content

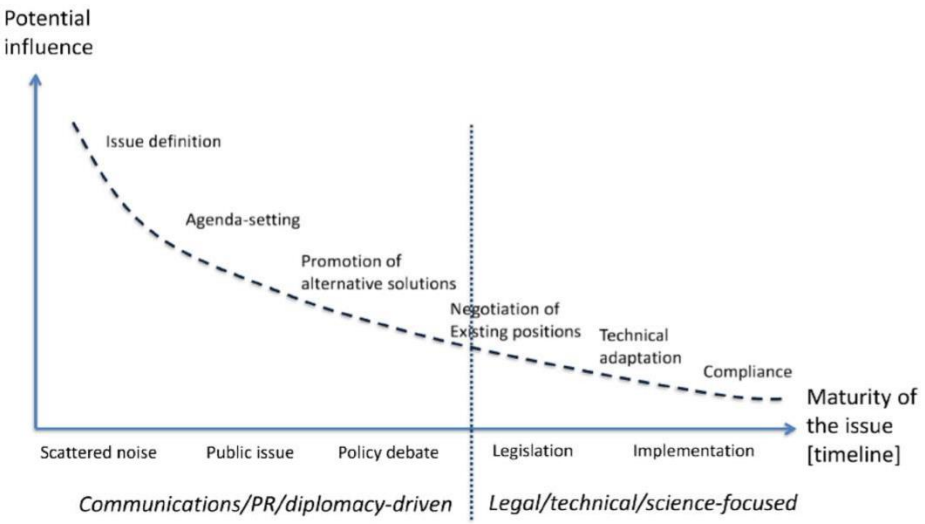
	stakeholders, policy-makers	tailored to their context and in their national languages. Coordinated mini social media campaign and dissemination plans will be created for each new outputs' publications.	
Emails	**Cancer leagues, external stakeholders, policy-makers**	ECL will continue mass mail outs to EU stakeholders and policy-makers via email when new events are organised and papers are published. Members of the TF are encouraged to disseminate news about events and outputs in their networks at the national and regional level.	
Media Kits	**External stakeholders, general public (via media)**	ECL will promote new publications and events of the TF via specific press releases targeted to the main media outlets operational at the European level (Politico, Euractiv, Euronews). Members are encouraged to disseminate nationally by member leagues to national media outlets.	Engagement with Journalists.docx

8. INFLUENCE ON DECISION-MAKING

This chapter elaborates on how and when to engage with different levels of governance, which tools are available and how to successfully influence health decision-making. The chapter particularly zooms into the current state-of-play in pharmaceutical policy.

LOBBYING RULES

1. Lobbying needs to be a conscious and planned process.
2. The earlier you join a debate, the more influence you will have.
3. Understand the processes at national level to achieve success in European and global decision-making
4. Understand the timing and windows of opportunity



i. European Institutions

ECL's primary objective is to influence decision-making of the EU institutions and agencies. Below, we elaborate on the opportunities different EU bodies provide to shape **European medicines policy.**

EU LEGAL NORMS

1. Treaties (TEU, TFEU, ToL)
2. Legislation (Regulations, Directives, Decisions)
3. Implementing and delegated acts (secondary legislation, comitology)
4. Other EU law (inter-institutional agreement, rules of procedure, code of conduct)
5. Soft law (recommendations, guidelines)

EUROPEAN COMMISSION

Role: Approval and regulation of medicines in the EU; functioning of the internal market; measures to encourage innovation. Initiates legislation based on mandate given by the Council. Provides funding opportunities for research and health systems' functioning.

Key DGs, files and persons

DG SANTE (HEALTH & FOOD SAFETY)

- **Key Files and Legislation**
  - EU Pharmaceutical Strategy, Commission Communication (2020)
  - Europe's Beating Cancer Plan, Commission Communication (2020)
  - Evaluation of medicines for rare diseases and children (2020)
  - 2018 Regulation proposal cooperation on health technology assessment (HTA)
  - Directive 2001/83/EC governing rules of production, distribution and use of medicines
  - Regulation 726/2004 on authorisation and supervision of medicines and establishing of the European Medicines Agency (EMA)
  - Paediatric medicines: Regulation 1901/2006 and related documents
  - Orphan medicines: Regulation 141/2000, Commission Regulation 847/2000 laying criteria for orphan designation and related documents
  - Advanced therapies: Regulation 1394/2007 and related documents
  - Clinical trials: Directive 2001/20/EC, Regulation 536/2014 (to replace the Directive) and related documents
  - EU4Health Programme
  - Medical Devices and In-Vitro Diagnostics: all documents
  - European Health Data Space (EU Directive in the pipeline for 2021)

- **Key DG SANTE Officials** (see full organigram)
  - Stella Kyriakides, Commissioner
  - Anne Bucher, Director-General

- Sandra Gallina, Deputy Director General for Health, Directorates B and C
- Andrzej Rys, Head of Directorate B (Health systems, medical products and innovation)
- Ioana-Maria Gligor, Head of Unit B3 – Digital Health and European Reference Networks
- Sylvain Giraud, Head of Unit B4 – Medical Products: Quality, Safety, Innovation
- Olga Solomon, Head of Unit B5 – Medicines: Policy, Authorisation and Monitoring
- Anna Eva Ampelas, Head of Unit B6 – Medical Devices, Health Technology Assessment
- Glora Giorgio, Team Leader HTA (B6)
- Dirk van den Steen, Policy Officer (B4)
- Head of Unit, Secretary General and the legal service represent the Commission in the trilogues

** All Commission emails have the following format: name.surname@ec.europa.eu*

◎ **Expert Groups & Committees**

Expert groups give scientific non-binding advice to the Commission. The groups typically consist of scientists, academics and other experts on the topic. Committees consist of Member States' experts representing the government who have a right to vote.

- The Pharmaceutical Committee = senior experts in public health matters from the Member States' administrations
- Commission Expert Group on Safe and Timely Access to Medicines for Patients ("STAMP")
- Expert Panel on effective ways of investing in health = 17 experts (3yr mandate) providing non-binding independent advice on matters related to effective, accessible and resilient health systems

◎ **Joint Actions/Networks**

- EUNetHTA = collaboration of HTA agencies
- EURIPID = collaboration of public health institutes and medicine agencies on maintaining a database with information on national prices and pricing regulations of medicinal products (reference price baskets, list prices)
  - ECL member of EURIPIS Stakeholder Platform
- iPAAC = collaboration of health ministries and oncology institutes on cancer control (WP9 on innovative therapies)
- ERN = virtual networks involving healthcare providers to facilitate discussion on complex or rare diseases (incl rare and paediatric cancers) and conditions that require highly specialised treatment, and concentrated knowledge and resources

DG RTD (RESEARCH & INNOVATION)

- **Key Initiatives**
  - Horizon 2020 (80bn research programme, 2014-20)
  - Horizon Europe, Cancer Mission (2021-27)
  - European Research Area (ERA)

- **Key DG RTD Officials** (see full organigram)
  - Mariya Gabriel, Commissioner
  - Jean-Eric Paquet, Director-General
  - Irene Norstedt, Acting Head of Directorate E (People), Head of Unit E6 – Economic and Social Transitions
  - Barbara Kerstiens, Head of Unit E2 – Combatting Diseases
  - Maria Pilar Aguar Fernandez, Head of Unit E3 – Health Innovations
  - Ioannis Vouldis, Scientific Policy Officer (E2)
  - Jan-Willem van de Loo, Scientific Policy Officer (E2)
  - Annika Nowak, Policy Officer (E6)

- **Expert Groups**
  - HEU Cancer Mission Board
  - HEU Cancer Mission Assembly

DG CNECT (COMMUNICATIONS, TECHNOLOGY)

- **Key Initiatives**
  - E-Health and digital transformation of health care, Commission Communication (2018)
  - European Digital Strategy (2020)
  - Artificial Intelligence

- **Key DG CNECT Officials** (see full organigram)
  - Thierry Breton, Commissioner
  - Margaret Vestager, VP Commission (A Europe Fit for Digital Age)
  - Roberto Viola, Director-General
  - Khalil Rouhana, Deputy Director-General
  - Lucia Sioli, Head of Directorate A – Artificial Intelligence and Digital Industry
  - Juha Heikkila, Head of Unit A1 – Robotics and Artificial Intelligence
  - Gail Kent, Head of Directorate G – Data
  - Yvo Volman, Head of Unit G1 – Data Policy and Innovation
  - Head of Directorate H – Digital Society, trust & Cybersecurity
  - Jakub Boratynski, head of Unit H2 – Cybersecurity and Digital Privacy Policy
  - Marco Marsella, Head of Unit H3 – eHealth, Well-being and Ageing

- **Expert Groups**
  - E-Health Stakeholder Group ran by Unit H3 (ECL Member)

DG COMP (COMPETITION)

- **Key Initiatives**
  - Competition issues related to pharmaceuticals
    - Antitrust, Mergers, State Aid, Competition breaches (e.g., pay-for-delay deals)
  - Report on Competition enforcement in the pharmaceutical sector (2009-2017)
- **Key DG COMP Officials** (see full organigram)
  - Margaret Vestager, Commissioner (VP)
  - Olivier Guersent, Director-General
  - Paul Csiszar, Head of Directorate E - Markets and cases IV: Basic Industries, Manufacturing and Agriculture
  - Rainer Becker, Head of Unit E1 – Antitrust, Pharma and Health services
  - Tom Viebig, Case Handler (E1)
  - Pinelopi Stamou, Case Handler (E1)
  - Harald Mische, Case Handler (E1)

- **Networks**
  - European Competition Network (ECN) = collaboration of national competition agencies

DG GROW (INTERNAL MARKET & INDUSTRY)

- **Key Initiatives**
  - Industrial Policy
  - A new Industrial Strategy for Europe, Commission Communication (2020)
  - Intellectual Property
  - Sustainable economy and Corporate Social Responsibility

- **Key DG GROW Officials** (see full organigram)
  - Thierry Breton, Commissioner (VP)
  - Kerstin Jorna, Director-General
  - Joaquim Nunes de Almeida, Head of Directorate B – Goods in the Single Market
  - Carlo Pettinelli, Head of Directorate D – Chemicals and Consumer Industries
  - Hubert Gambs, acting Head of Directorate E – Services in Single Market and Digitalisation
  - Slavomir Tokarski, Head of Directorate F – Industrial policy and Innovation
  - Salvatore D'Acunto, Head of unit D4 – Consumer Industry
  - Mark Niclas, Head of Unit F1 – Industrial Strategy and Value Chains
  - Ulla Engelmann, Head of Unit F2 – Social Economy
  - Amaryllis Verhoeven, Head of Unit F3 – Intellectual Property

How to engage with the Commission?

I. Asking for regular meetings

Meetings with Commissioners and Commission Staff on regular basis is key in order to understand the current priorities and state of play on different policies and legislative activities. It is of utmost importance for Commission official to be aware of who you are and what you do and how can you contribute to different policies in order to be regularly approached to provide feedback, where necessary.

Proactively asking for a meeting with the Commission is advised when:

- New Commissioner assumes the office
- New relevant (non)legislative activity is announced and you want to make sure your voice will be among the loudest
- You published a report and wish to discuss its impact and follow up

II. Taking part in consultations

The Commission is running countless consultations related to all levels of policy and legislative files. By taking part in Commission consultations you amplify your voice and ensure it was at least assessed if not reflected in the final text.

There are different levels/types of consultations, these typically include:

- **Open feedback** to initiatives where commission uploads a document and stakeholders can freely comment on their intention and stress key points (e.g., roadmaps, pilot projects, etc.), examples: Pharma Strategy Roadmap ; Market Launch Pilot Project ; Aspen Case Commitments ; Intellectual Property Action Plan
- **Public consultations** in the form of online questionnaires is used to understand the key issues and priorities of different files, example: Pharma Strategy Consultation
- **Targeted consultations** usually take place face to face alongside the public consultation where commission gathers feedback based on stakeholder group (e.g, patient advocates, HCPs, industry etc.)
- **Bilateral meetings** with main players in the field
- **Expert interviews** where more clarity/technical knowledge is needed
- **Submissions by stakeholders** - files sent to Commission officials by email during the consultation periods are also taken into account
- **Official events** the Commission organises stakeholder events in different formats and its conclusions are reflected in the files, e.g., Pharma Strategy workshop on 14-15 July 2020

See the A2M TF's website for input provided by different consultations:
https://www.europeancancerleagues.org/a2madvocacy/

III. Participating in stakeholder groups

The Commission regularly publishes call for interest to take part in established stakeholder groups to co-create policies and give feedback on different files.

IV. Engaging in public events

If you are organising an event, it is useful to have the voice of the Commission represented. That way the speaker gets familiar with your case and can provide practical information on how it is relevant to the work the Commission is currently doing and subsequently include your input in their work.

Networking with Commission officials alongside events organised by other entities is also useful, particularly if you get to discuss the progress on different files informally during the coffee breaks.

When to engage with the Commission?

1. Setting the Political Agenda

1.1 Defining political priorities – largest influence via political parties in the election year (success of Weber's cancer campaign)

1.2 Big Political Initiatives – large frames for the mandate (e.g., European Green Deal)

1.3 Strategies & Action Plans – Sub-points of big initiatives, up for public consultation, if established as a key stakeholder to feed in the concrete plan, the EC will reach out for additional input

2. Political goes Technical

2.1 Roadmaps – Key issues and initial solutions laid out, possibility to provide feedback

2.2. Studies – ordered by the EC, done externally (e.g., Technopolis for Orphan Medicines), influence can be done by providing feedback and taking part in interviews

2.3 Consultations – different levels (see above), provide input to as many as possible to gain influence

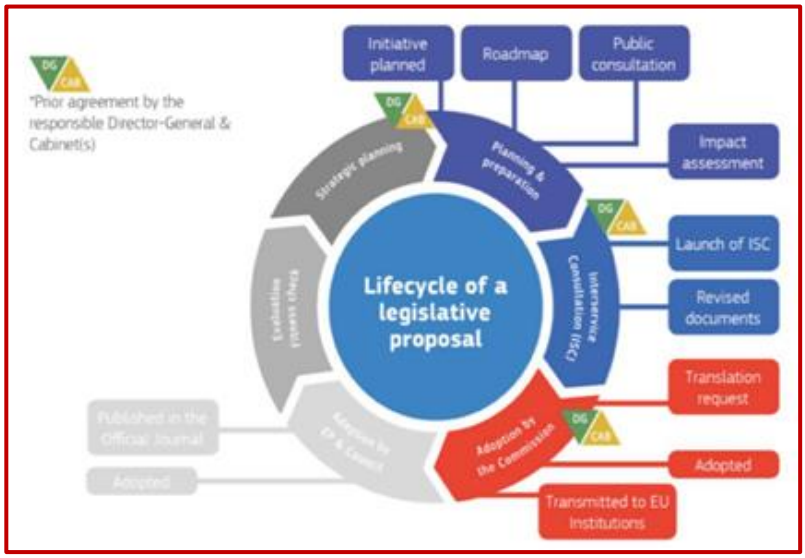
2.4 Impact Assessment - lays out thinking for (non)legislative interventions, basically last stage where external influence is 'easy'

2.5 Regulatory Scrutiny Board – Commission experts, base opinions on the impact assessment, cannot be lobbied

2.6 Interservice Consultation & Proposal – Need to look at other DGs who contribute to the document(legislation) and send them your input to influence their feedback (look for allies in other DGs who share your views)

2.7 Cabinet – approval by the Commissioner of the responsible DG

2.8 College – difficult to influence, Commissioners would only intervene if anything is a red flag, but after the procedure described above that would rarely be the case



2.9 Approval and publication of the legislative proposal – 95% of legislative proposals of the go through and become a law, only rarely the Commission withdraws the proposal (e.g., Transparency Directive). Typically, EC does not legislate where MS support could not be reached.

COMMISSION: KEY TAKEAWAYS

1. **Position paper** needs to be ready before the Policy Officers start drafting the legislation
2. **Data and studies** for impact assessment needs to be planned in advance and ready as soon as possible (e.g., surveys done among members etc.)
3. **Take every opportunity to provide input.** Do not miss consultations even when it is within tight deadlines, take every opportunity to put your name on the map.

EUROPEAN PARLIAMENT

Role: Co-legislator, budgetary powers, executive control and democratic scrutiny of the European Commission (approval of Commissioners suggested by the Council), supervisory powers (inquiries into agencies, budget allocation etc.). The European Parliament largely responds to the actions of the European Commission.

Key Committees, files and persons

ENVI (Health & Environment)

◎ **Initiatives relevant for 2019-2024 Mandate**

- 2017: Own initiative report (INI) Access to Medicines (sets general frame of A2M) https://www.europarl.europa.eu/doceo/document/A-8-2017-0040_EN.html

- 2018: Health Technology Assessment: https://www.europarl.europa.eu/doceo/document/A-8-2018-0289_EN.html (relevant again if file goes to trilogue, Tiemo Wölken = rapporteur)
- 2020: INI Medicine Shortages (rapporteur Nathalie Colin-Oesterlé): https://www.europarl.europa.eu/doceo/document/A-9-2020-0142_EN.html
- 2020: Regulation on EU4Health Programme (to be voted on in October, rapporteur Cristian Silviu Busoi)
- 2021: Pharmaceutical Strategy (rapporteur tbc)
- Health Working Group: https://www.europarl.europa.eu/committees/en/product/product-details/20151006CDT00381

◎ **Relevant Studies**

- Strengthening Europe in the Fight against Cancer (2020): https://www.europarl.europa.eu/RegData/etudes/STUD/2020/642388/IPOL_STU(2020)642388_EN.pdf
- Treatment optimisation in drug development (2020): https://www.europarl.europa.eu/RegData/etudes/STUD/2020/641511/EPRS_STU(2020)641511_EN.pdf

◎ **Key Persons**

- Members: https://www.europarl.europa.eu/committees/en/empl/home/members
- Coordinators : https://www.europarl.europa.eu/cmsdata/197940/ENVI%20COORDINATORS%209th%20leg%20-%2024_02_2020.pdf
- Political Advisors:
  - EPP: Spela Cole spela.cole@europarl.europa.eu
  - S&D Andrew Flagg andrew.flagg@europarl.europa.eu
  - RE Sissel Kvist sissel.kvist@europarl.europa.eu
  - Greens/EFA: Anna Prokupkova anna.prokupkova@europarl.europa.eu (as of 1 January 2021) and Axel Singhofen axel.singhofen@europarl.europa.eu
  - ECR: Jaroslava Chaloupkova jaroslava.chaloupkova@europarl.europa.eu
  - GUE/NGL: Stavros Mavrogenis stavros.mavrogenis@europarl.europa.eu
- Rapporteur, shadow rapporteurs, political group stuff and EP secretariat represent the Parliament in the trilogues

ITRE (Industry & Research)

◎ **Initiatives relevant for 2019-2024 Mandate**

- 2020: Strategic Planning of Horizon Europe
- Common topics with ENVI: vaccines, shortages, health data space…

◎ **Key Persons**

- Members: https://www.europarl.europa.eu/committees/en/itre/home/members

IMCO (Internal Market)

- **Initiatives relevant for 2019-2024 Mandate**
  - Opinion committee for health-related issues linked to the single market incl pharmaceuticals (shortages etc.)
- **Key Persons**
  - Members: https://www.europarl.europa.eu/committees/en/imco/home/members

BUDG (Budget)

- **Initiatives relevant for 2019-2024 Mandate**
  - Responsible for EU Budget (Multiannual Financial Framework – MFF 2021-27)
  - EU4Health Programme (opinion committee)
- **Key Persons**
  - Members: https://www.europarl.europa.eu/committees/en/budg/home/members

BECA (Special Committee on Beating Cancer)

33 members, prospected to exist for 12 months to work on the report on cancer

- **Initiatives**
  - Feedback to Commission Communication on Europe's Beating Cancer Plan (internal document)
  - Report on cancer (prospected in 2021)
- **Key Persons**
  - Members: https://www.europarl.europa.eu/committees/en/beca/home/members
  - Chair, Vice-Chairs, Coordinators, Rapporteur & Shadows: https://www.europarl.europa.eu/cmsdata/213033/BECA_bureau_coordinators_rapporteur_shadows.pdf

MAC (MEPs Against Cancer)

Voluntary interest group, first cancer focused group at the EP set up in 2005. Secretariat and knowledge support provided by ECL.

- **Initiatives**
  - 2020: World Cancer Day & European Week Against Cancer campaigns
  - 2020: Meeting on Paediatric Cancers:
  - https://www.youtube.com/watch?v=2YVUeMe8Ayk&feature=youtu.be
  - 2021 (TBC)
- **Key Persons**
  - Members: https://www.europeancancerleagues.org/meps-against-cancer-mac-events/

Most Influential MEPs in Pharma/Health (cross-committee)

- Peter Liese (EPP, DE)
- Tiemo Wolken (S&D, DE)
- Cristian Silviu Busoi (EPP, RO)
- Véronique Trillet-Lenoir (RE, FR)
- Katerina Konecna (GUE/NGL, CZ)
- Michele Rivasi (Greens, France)

- Alessandra Moretti (S&D, IT)
- Nathalie Colin Oesterlé (EPP, FR)
- Nicolae Stefanuta (RE, RO)
- Joanna Kopcinska (ECR, PL)
- Sara Cerdas (S&D, PT)
- Tilly Metz (Greens, Luxembourg)
- Dolors Montserrat (EPP, SP)
- Cindy Franssen (EPP, BE)
- Ewa Kopacz (EPP, PL)
- Joelle Melin (ID, FR)

**All EP emails have the following format: name.surname@europarl.europa.eu*

How to engage with the Parliament?

I. Request face to face meetings

MEPs are directly elected by citizens and therefore the most open to meeting with external stakeholders. If you are requesting a meeting with an MEP or their assistant, make sure you know which committees and files do they cover to ensure it is relevant for both sides. Make sure your messages are clear. Information provided to MEPs in meetings and via a follow-up email can be used as sources for their speeches in plenaries and committees.

II. Provide amendments to (non)legislative files

When a file is open at the EP, know who are the rapporteur and shadows and provide initial input by sending a position paper and once a draft is circulated table amendments with justification why the draft should be edited. You can find an example of amendments here: https://www.europeancancerleagues.org/wp-content/uploads/ECL-amendments-EU4Health_final.pdf

III. Draft parliamentary questions

MEPs ask questions to European Commission as a part of the Commission's oversight. These questions usually explain different past and planned EU initiatives. You can draft questions you have and send them to MEPs who can submit them in written or oral form. Questions can also pressure the Commission to act. See examples of parliamentary questions here:
https://www.europarl.europa.eu/plenary/en/parliamentary-questions.html

IV. Use MEPs as ambassadors of your cause

MEPs often get involved to promote multiple causes that are close to their heart. Be sure to engage with MEPs who are interested in your cause and involve them in your activities. This can increase visibility of your public campaigns.

V. Engage with MEPs in public events

Invite MEPs to your events and contribute to conversation in events of other organisations which are hosted by MEPs.

When to engage with the Parliament?

1. Pre-/(Non-)Legislative Phase

1.1 Setting an agenda – by creating ambassadors and building coalitions, largest window of opportunity is before European elections when parties create their manifestos;

1.2 Exchange of views – stakeholders can be invited in EP working group meetings (see Health Working Group's agenda above), meetings and informal exchanges can be organised by external organisations; as EP's agenda is largely influenced by the Commission agenda it is important to check how will they be reacting to different initiatives and talk to MEPs about upcoming EU files;

1.3 Reports (INIs/MfRs) and Opinions – once announced, contact rapporteur, shadows and opinion rapporteurs and provide input throughout the drafting period (usually concluded within 2-3 months).

2. Legislative Process – step by step

2.1 Conference of Presidents allocates the Commission's proposal
2.2 Political Group's coordinators appoint the rapporteur and shadow rapporteurs – political advisers of the rapporteur's party play a key role
2.3 Appointed MEPs start working on draft reports and opinions
2.4 Discussions in Committees, submitting amendments
2.5 Compromise amendments (on files when too many amendments submitted, e.g., shortages ca 1,000 amendments submitted)
2.6 Votes in Committees – influence curve starts to go down, most amendments already submitted and MEPs in the Committee know their priorities
2.7 Vote in Plenary on EP amendments – Trilogue – vote in Plenary again to adopt the final legislative text – political groups can still submit amendments before the plenary vote

EP: KEY TAKEAWAYS

1. **Which Committee gets assign to hold the report** (and which committee only provide opinions) have significant impact on the tone of the amendments to legislation (e.g., ENVI closer to ECL's views than ITRE)
2. **Know which out of 705 MEPs are influential and relevant for your** cause and what is their mandate before taking a meeting; Understand where MEPs come from and what is their political party, nationality, policy sector (committee) and personal attachment to the topic.

3. **Start drafting amendments as soon as a file is published**, to be sure they are implemented early – make them as clear as possible so assistants can copy paste them as drafted and understand why they should defend them;
4. **Meet with Rapporteur and Shadow Rapporteurs, their APAs and group policy advisors** as soon as possible to plant your messages in the report.

COUNCIL OF THE EUROPEAN UNION

Role: Negotiates and adopts EU legislation, coordinates Member State's policies, concludes international agreements, adopts EU budget. Gives the European Commission mandate to draft legislation.

Council levels and configurations

Working Parties

More than 150 WPs and committees, comprised of MS officials, prepare the work of ministers in the different Council configurations. Agenda of WP coordinated by Council Presidency. Line-by-line scrutiny of the texts in WPs, can take a lot of sittings (e.g., HTA proposal for over 2 yrs)

Permanent Representatives Committee (COREPER)

Agreements can be reached in WPs and only formally forwarded to COREPER. Sometimes when WPs do not reach agreement the COREPER can try to negotiate a settlement itself, refer the proposal back to the WP with suggestions for a compromise or pass the matter up to the Council. Most proposals feature on the agenda of COREPER several times, as they try to resolve differences that the working party has not overcome.

Council configuration

Around two-thirds of the items on a Council agenda will be for adoption (already negotiated by WPs/COREPER). Council further negotiates where no agreement was reached in COREPER/WP or items that are too politically sensitive to be settled at a lower level. The Council is a single legal entity, any of its 10 configurations can adopt an act that falls under the remit of another configuration. The Council takes decisions by a simple majority, qualified majority or unanimous vote, depending on the issue.

Relevant configurations

- **Employment, Social Policy, Health and Consumer Affairs Council configuration (EPSCO)** works to increase employment levels and improve living and working conditions, ensuring a high level of human health and consumer protection in the EU;

- The **Competitiveness Council (COMPET)** works to enhance competitiveness and increase growth in the EU. It deals with four major policy areas: internal market, industry, research and innovation and space;
- **Environment Council configuration (ENVI)** is responsible for EU environment policy, including environmental protection, prudent use of resources and the protection of human health. It also deals with international environmental issues, especially in the area of climate change;
- **General Affairs Council configuration (GAC)** coordinates preparations for European Council meetings. It is also responsible for a number of cross-cutting policy areas, including MFF, cohesion policy, institutional setup etc.
- Presidency representative (chair of WG or COREPER) and the secretariat represent the Council in the trilogue

Influence on Council decision-making

Pre-legislative phase – Council Conclusions

The Dutch Council Conclusions of 2016 laid the work of the EU in pharmaceutical policy for the next decade to come.

Legislative phase

Working Parties is where key discussions between Brussels and the Capitals take place. Attachés negotiate by mandate given by the ministries. Ultimately ministers decide on Council positions, therefore, **key is to feed the influence in the capital to achieve success in the Council.** When files move to COREPER/Council formation, the level of possible influence is very slim. Need to influence in the WP stage of negotiations.

Key Council representatives in Brussels

Each MS has a permanent representation to the EU with attachés representing different ministries. Non-EU/EEA countries have Missions to the EU structured in a similar way.

You can find an ECL-managed list of Health Attachés here.

COUNCIL: KEY TAKEAWAYS

1. **Lobby in the capital (Member State) to achieve real influence with a supporting relationship- building with attachés in Brussels;**
2. **Time your engagement based on the agenda of the Working Parties for technical advice and Council configurations for political statements.**

EUROPEAN MEDICINES AGENCY (EMA)

Role: The EMA is and EU agency which facilitates the development and access to medicinal products in the EU. EMA committees evaluate applications for marketing authorisation,

including the use of different schemes (accelerated approvals, orphan designation, PIP etc). EMA monitors the safety of medicines throughout their life cycle. See interactive timeline for more info: https://www.ema.europa.eu/en/from-lab-to-patient-timeline

Key committees, groups and persons

Committees, composed of European experts made available by national competent authorities of the EU and EEA Member States, are involved in evaluation of products, providing scientific advice, developing guidelines etc.:

- Committee for Medicinal Products for Human Use (CHMP)
- Pharmacovigilance Risk Assessment Committee (PRAC)
- Committee for Medicinal Products for Veterinary Use (CVMP)
- Committee for Orphan Medicinal Products (COMP) – responsible for orphan designation
- Committee on Herbal Medicinal Products (HMPC)
- Committee for Advanced Therapies (CAT)
- Paediatric Committee (PDCO) – responsible for PIP waivers

Stakeholders engagement in the work of the Agency:

- Patients and consumers (ECL = eligible organisation, PCWP observer)
- Healthcare Professionals
- Academia
- Industry

Expert networks:

- Heads of Medicine Agencies (HMA)/EMA Taskforce on Availability of Authorised Medicines (shortages management)
- HMA/EMA joint Big Data Steering Group
- HMA Timely Access Subgroup

Key EMA contacts (organisational chart)

- Executive Director Guido Rasi (to be replaced by Emer Cooke in November 2020) is responsible for all operational matters of the Agency guido.rasi@ema.europa.eu
- EMA Management Board oversees the Agency's activities and strategy
- Head of Human Medicines Alexis Nolte alexis.nolte@ema.europa.eu
- Head of Data Analytics and Methods Peter Arlett
- Head of Regulatory Science and Innovation Anthony Humphreys RegulatoryScience2025@ema.europa.eu
- Head of Research and Innovation Jordi Llinares Garcia jordi.llinares@ema.europa.eu
- Head of Clinical Studies and Manufacturing Fergus Sweeney Fergus.Sweeney@ema.europa.eu
- Head of Clinical Trials Pieter Vankeerberghen

- Head of Stakeholders and Communication Melanie Carr melanie.carr@ema.europa.eu
- Head of Public Engagement Juan Garcia Burgos public-engagement@ema.europa.eu
- Head of Document Access and Publication Anne-Sophie Henry-Eude

Key activities and ECL's input

- Regulatory Science Strategy 2025
  - ECL's input: https://www.europeancancerleagues.org/wp-content/uploads/EMA-Regulatory-Science-2025-ECL-submission.pdf
- European medicines agencies network strategy
  - ECL's input: https://www.europeancancerleagues.org/wp-content/uploads/EMA-HMA-Strategy-2025-consultation_ECL-response-27082020.pdf
- Transparency
  - Ombudsman inquiry input: https://www.europeancancerleagues.org/wp-content/uploads/ECL-Comments-European-Ombudsman-EMA-inquiry-Dec-2018.pdf
  - Publishing of marketing authorisation data: https://www.europeancancerleagues.org/wp-content/uploads/ECL-EORTC-statement_22012020-EMA-transparency-clinical-study-reports.pdf

Influencing work of the EMA

1. Taking part in meetings of the Patient and Consumer Working Party (PCWP)
2. Providing feedback requested ad hoc by EMA via email to eligible organisations
3. Providing feedback to public consultations
4. Including EMA representatives in the work of the Task Force – event speakers and attendees, meetings, sending reports, etc.

ii. International Organisations

While European Institutions are the primary target of the ECL Task Force and are more influential in decision-making regarding patient access to treatments, the role of international bodies should not be underestimated.

WORLD HEALTH ORGANIZATION (WHO)

Role: WHO strives to secure universal health coverage. Key functions are: i) coordinating international health work; ii) assisting governments in strengthening health services; iii) collecting statistical and epidemiological data; iv) facilitating research cooperation among scientists and experts; v) providing political leadership by proposing conventions, agreements and regulations and making recommendations. The World Health Assembly, composed of representatives from all 194 member states, serves as the agency's decision-making body.

Key activities in medicines policy

- WHO Model List of Essential Medicines (updated every 2 years)
- **WHO Essential Medicines and Health Products (EMP) Department** works with countries to promote affordable access to quality, safe and effective medicines, vaccines, diagnostics and other medical devices.
    - Key resources: https://www.who.int/medicines/access_use/en/
    - Key Publications:
        - Improving affordability and effectiveness of cancer medicines (Technical Report, 2018) https://www.who.int/publications/i/item/9789241515115
        - WHO guideline on country pharmaceutical pricing policies (2015) https://www.who.int/publications/i/item/9789241549035
- **Two Technical Working Groups on Fair Pricing**
    - Group 1: Exploring pricing approaches sensitive to health systems' ability to pay and to the need for achieving universal coverage of pharmaceutical products
    - Group 2: Aligning incentives for research and development for pharmaceuticals
    - Contact: fairpricing@who.int
- Biennial **Fair Pricing Forum** (2017, 2019, 2021)
- **WHA Transparency Resolution** 2019
    - Final text: https://apps.who.int/gb/ebwha/pdf_files/WHA72/A72_ACONF2Rev1-en.pdf
    - ECL's reflection: https://www.europeancancerleagues.org/wp-content/uploads/Transparency-resolution-A2M-TF-Position-paper-2019.pdf

Key contacts

- Hans Kluge, Regional Director WHO/Europe, klugeh@who.int
- Natasha Azzopardi-Muscat, Director of the Division of Country Health Polices and Systems at WHO Regional Office for Europe, natasha.azzopardi-muscat@um.edu.mt
- Sarah Garner, Co-ordinator Innovation, Access and Use, garners@who.int
- Allison Colbert, Technical Officer, Essential Medicines and Health Products, colberta@who.int
- Marilys Corbex, Technical Officer, Cancer, corbexm@who.int

Influencing work of the WHO

1. Taking part in Fair Pricing Forums
    - 2021 FPF will likely take place online and will be hosted by Brazil, all TF members are encouraged to participate in the forum
2. Providing feedback to public consultations
    - E.g., in 2019 ECL sent input to WHO consultation on a fair price
3. Taking part in the work of the WHO where possible

- providing input to reports and initiatives
- Engaging with two technical working groups
- Taking part in the Oslo Initiative

4. Including WHO representatives in the work of the Task Force – event speakers and attendees, meetings, sending reports, etc.

EUROPEAN OBSERVATORY ON HEALTH SYSTEMS AND POLICIES

Role: The Observatory supports and promotes evidence-based health policy-making through comprehensive and rigorous analysis of the dynamics of health care systems in Europe.

Key publications in medicines policy

Studies of the observatory can be used as sources for the work of the Task Force.

- Ensuring access to medicines: How to redesign pricing, reimbursement and procurement? (2018)
- Ensuring access to medicines: How to stimulate innovation to meet patients' needs? (2018)
- How can voluntary cross-border collaboration in public procurement improve access to health technologies in Europe? (2016)

Key contacts

- Josep Figueras, Director, figuerasj@obs.who.int
- Matthias Wismar, Senior Health Policy Analyst, wismarm@obs.who.int

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT (OECD)

Role: OECD work on establishing evidence-based international standards and finding solutions to a range of social, economic and environmental challenges. OECD provides a forum and a knowledge hub for data and analysis, exchange of experiences, best-practice sharing, and advice on public policies and international standard-setting

Key publications in medicines policy

Studies of the OECD can be used as sources for the work of the Task Force.

- Addressing Challenges in Access to Oncology Medicines (2020)
- Performance-based managed entry agreements for new medicines in OECD countries and EU member states (2019)
- Pharmaceutical Innovation and Access to Medicines (2018)
- Value in Pharmaceutical Pricing (2013)

Key contacts

- Valerie Paris, Senior Health Policy Analyst, Valerie.PARIS@oecd.org
- Suzannah Chapman, Junior Health Policy Analyst, Suzannah.CHAPMAN@oecd.org
- Eliana Barrenho, Labour Market Economist, eliana.barrenho@oecd.org
- Guillaume Dedet, Health Economist and Policy Analyst, guillaume.dedet@oecd.org
- Martin Wenzl, Health Policy Analyst, martin.wenzl@oecd.org

iii. Stakeholder Coalitions

To amplify our action, impact and cover the largest possible ground, ECL Task Force engages in different coalitions and stakeholder groups.

EUROPEAN PUBLIC HEALTH ALLIANCE (EPHA)

EPHA organises quarterly meetings of its members about access to medicine where members update each other on their activities. They further organise an annual forum dedicated to hot topics in access policy. The ECL Secretariat attends the WG and contributes to joint policy recommendations.

- More information on EPHA A2M activities: https://epha.org/universal-access-and-affordable-medicines/
- Key contact: Yannis Natsis, Policy Manager, yannis@epha.org
- Joint EPHA-ECL policy recommendations on medicine shortages: https://www.europeancancerleagues.org/wp-content/uploads/EPHA-Medicine-Shortages-Position-2020.pdf

FAIR PRICING COALITION

International Association of Mutual Benefit Societies (AIM) organises regular meetings of Brussels-based organisations involved in fair pricing of medicines. The ECL Secretariat attends meetings of the Coalition.

- More about AIM's policy priorities: https://www.aim-mutual.org/position-papers/
- Key contacts: Thomas Kanga-Tona, Project Manager, thomas.kanga-tona@aim-mutual.org; Anne Hendrickx, Solidaris (Belgian Mutual Fund), Member of the International Association of Mutual Benefit Societies (AIM)'s Pharmaceutical Working Group, anne.hendrickx@solidaris.be
- Joint AIM-ECL statements:
    - Fair Pricing: https://www.europeancancerleagues.org/wp-content/uploads/AIM-Fair-Pricing-Principles_July2020.pdf
    - Vaccine Strategy and Procurement: https://www.aim-mutual.org/wp-content/uploads/2020/09/Joint-statement-Transparency-is-needed-to-reap-the-full-benefits-of-the-EU-vaccines-strategy.pdf

EFPIA ONCOLOGY STAKEHOLDER PLATFORM

The European Federation of Pharmaceutical Industries and Associations (EFPIA) hosts regular meetings of stakeholders in oncology to discuss issues including oncology data, clinical trials and access. The Chair of the Task Force and the Secretariat attends meetings of the stakeholder platform.

- More on EFPIA's work on oncology medicines: https://www.efpia.eu/about-medicines/use-of-medicines/disease-specific-groups/fighting-cancer/

- Key contacts:
  - Nathalie Moll, Director General, nathalie.moll@efpia.eu
  - François Bouvy, Executive Director, Economic and Social Affairs, francois.bouvy@efpia.eu
  - Edith Frénoy, Director Market Access, HTA Policy lead, edith.frenoy@efpia.eu
  - Mihai Rotaru, Manager Market Access, Coordinator of Oncoligy Platform, mihai.rotaru@efpia.eu
  - Kristine Peers, General Counsel, kristine.peers@efpia.eu
  - Elizabeth Kuiper, Executive Director, Public Affairs, elizabeth.kuiper@efpia.eu
  - Tobias Helmstorf, Head Global Oncology Policy, Bayer, member of EFPIA Oncology Platform, tobias.helmstorf@bayer.com
  - Ivana Cattaneo, Vice-Chair of the EFPIA Oncology Platform, Public Affairs Director Oncology Europe, Novartis, ivana.cattaneo@novartis.com
  - Alexander Roediger, Executive Director Oncology Policy, MSD, Chair of EFPIA Oncology Platform, alexander_roediger@merck.com
  - Minxian Congé, Government Affairs Lead of Oncology at AbbVie, Vice-Chair of EFPIA Oncology Platform, minxian.conge@abbvie.com
- ECL's Participation in launch of EFPIA's report on access to medicines: https://www.youtube.com/watch?v=2yYOBM7c0Xg&feature=youtu.be

9. MONITORING & EVALUATION

The effectiveness of the A2M TF strategy is subject to regular evaluation based on the below outlined sub-objectives, expected outcomes and indicators. The indicators relate to communications and visibility of A2M TF. In addition, indicators related to influence (uptake of political messages in political files) should be monitored and accounted. To enable accurate evaluation, Members shall annually report to the Secretariat re their activities related to the dissemination of the information/outputs related to the Task Force.

OBJECTIVES	SUB-OBJECTIVES	RESPON-SIBLE	ACTIONS	OUTCOMES	INDICATORS
Ensure that the A2M TF is sufficiently known among those concerned with cancer, medicines and health issues to attract partners, collaborators and supporters. Target groups: Global, European and national decision-makers, industry, media, other NGOs (HCPs, patients, consumers, public health, etc.)	Promote general awareness about the A2M TF	ECL	Promote the inclusion of A2M TF work in wider ECL communication	Widespread coverage of A2M TF in ECL communication activities	Number of publications, events, website pages providing information on the A2M TF
		ECL	Promote inclusion of promote the inclusion of A2M TF work in other NGOs/associations comms	Widespread coverage of A2M TF in third party's comms activities	Number of third parties contacted Number of mentions on third party events, newsletters, social media, press releases, etc. providing information on the work of the A2M TF
		ECL & TF Members	Provide information to relevant stakeholders (seminars, networking, presentations etc.)	More stakeholders better informed about A2M TF	Number of stakeholders sensitised
	Inform about A2M TF outputs	ECL & TF Members	Publish outputs on websites and social media	Online access to outputs/publications	Number of links clicks, likes and shares
		ECL & TF Members	Highlight A2M TF in newsletters	Awareness among newsletter subscribers	Number of subscribers and clicks
		ECL & TF Members	Refer to publications in meetings with stakeholders	Awareness among specific target groups	Number of presentations made & size of audience
		ECL & TF Members	Press releases of publications/events	Awareness of A2M TF outputs	Media coverage of the press release
		ECL & TF Members	Keep the A2M TF section of the ECL's website up to date	Access to information on A2M TF outputs	Number of visitors to the A2M TF webpages on ECL
		TF Members	Include info about the A2M TF in own organisation's websites/webpages	Access to information on A2M TF outputs	Number of visitors to the A2M TF webpages on TF Members websites

	Provide information and advice directly to stakeholders	ECL	Give feedback through consultations, (joint) statements, position papers Make presentations (e.g., to EU stakeholder groups) Organise events & meetings online/f2f (Brussels/EU level)	Stakeholders are better informed about A2M TF asks and its recommendations	Number of events, consultations filled, statements and position papers published
		TF Members	Give feedback through consultations using ECL's response as a base Make presentations (e.g., to national stakeholder groups & national decision makers) Organise events & meetings (nat/reg level)	More target audiences and more sectors more aware	Number of presentations, events, webinars and meetings organised
Increase the use/uptake of the A2M TF outputs and activities to those stakeholders who could make use of them. Target groups: EU and national decision-makers, industry, media, other NGOs	Facilitate access to information on completed A2M TF publications /outputs	ECL	Publish and distribute the A2M TF papers and reports	Raise awareness of publications focusing on specific themes	Number of brochures distributed/downloaded
		ECL	Highlight policy recommendations on social media	Increased awareness of policy recommendations	Number of posts' impressions
		ECL & TF Members	Participate in thematic meetings	Increased exchanges between stakeholders	Number of meetings & participants
		ECL	Promote networking (by organising/participating in seminars, workshops, events…)	More stakeholders more aware of ongoing/completed projects	Number of relevant contacts approached
		TF Members	Promote national/regional networking	More stakeholders more aware of ongoing/completed projects	Number of relevant contacts approached
	Proactively disseminate the outputs of ECL A2M TF to specific target groups	ECL	Make presentations, man stands and/or distribute publications at key conferences/ seminars/ meetings	Increased awareness of relevant A2M TF outputs amongst stakeholders	No of events attended, number of participants number of publications distributed
		ECL	Organise launch events for key outputs	Dissemination of outputs results/ recommendations to stakeholders	Number of stakeholders in attendance
		ECL	Produce and implement dissemination and outreach plans for each output	Plan produced and implemented for all outputs	Plans implemented

	Promote the outputs of the A2M TF among policy makers	TF Members	Promote awareness of A2M TF among national and regional institutions and decision-makers	Awareness among policy-makers and implementers	Number of promotional activities undertaken
		ECL	Regular contacts with relevant EC policy units, Agencies, MEPs, Attachés and other org reps	Awareness of the outputs among relevant policy officers and decision-makers	Number of personnel met/contacted
Enable members to communicate outputs to raise awareness of national stakeholders and general public and on contribution of the EU in this field. Target groups: Nat. decision-makers, general public	Provide general information on A2M TF and its outputs	ECL	Maintain and develop the A2M TF webpages and social media accounts	Increased awareness of A2M TF and EU policy related to cancer and its treatment	Number of visitors/ followers
		TF Members	Organise presentations to national and regional stakeholders	Increased awareness of A2M TF and EU policy related to cancer and its treatment	Numbers of participants
		TF Members	Contact national and regional media	Increased awareness of A2M TF and EU policy related to cancer and its treatment	Number of articles, numbers of readers/ watchers/ listeners
		TF Members	Disseminate publications	Increased awareness of A2M TF and EU policy related to cancer and its treatment	Number of outputs distributed/ downloaded
		A2M TF Members	Members websites	Increased awareness of A2M TF and EU policy related to cancer and its treatment	Number of visitors to relevant website pages