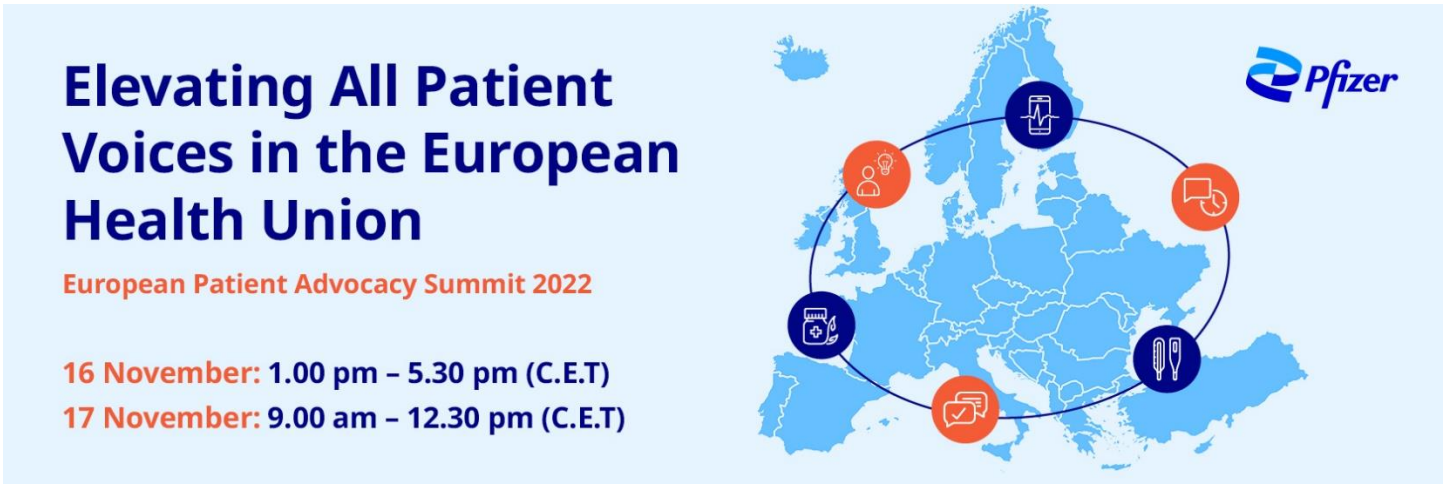


European Patient Advocacy Summit 2022 ‘Elevating All Patient Voices in the European Health Union’

MEETING REPORT
December 2022

PP-UNP-DNK-0309 (Jan-2023)

Contents

1) Executive summary

- Following the success of its last three Patient Advocacy Summits in 2019, 2020 and 2021, Pfizer delivered a further **capability strengthening workshop in 2022** to continue to develop the technical capacity of patient advocacy groups (PAGs).
- The four Summit editions were built on a common observation: **across Europe, national and European patient organizations are not systematically involved in health policymaking,** especially within Health Technology Assessment (HTA). To bridge this gap, the Summits took upon the mission of providing training to members of patient advocacy groups. This was done firstly, through raising awareness of the importance of their voice in health policymaking and secondly through equipping them with the tools and tactics necessary to participate. **Key expected outcomes of the four Summits included the empowerment of patient organizations and their increased involvement in health policymaking**, especially in HTA.
- 2022's summit focused on patient engagement in the healthcare decision-making process, including HTA, and incorporated sessions driven by representatives from three therapy areas: cardiovascular disease (CVD), migraine and obesity.
- Capability building sessions were delivered across four sessions with the following themes: 'How to build an advocacy plan to elevate the patient voice on the EU policy agenda'; 'Building a narrative for impactful disease awareness strategies towards European policymakers'; 'Tools to participate in EU legislative initiatives'; 'Contributing to legislative processes: deep-dive into EU-wide HTA'.
- High-level speakers from organizations representing patients from across Europe participated: the European Brain Council (EBC), the European Patients Forum (EPF), the European Association for the Study of Obesity (EASO), European Coalition for People Living with Obesity (ECPO), the European Federation of Neurological Associations (EFNA), Stroke Alliance for Europe (SAFE), Global Alliance of Mental Illness Advocacy Networks-Europe (GAMIAN-Europe) and the European Migraine and Headache Alliance (EHMA). A representative from EUnetHTA, an organization established to create an effective and sustainable network for HTA across Europe, presented, as well as Stephan Schreck, Stakeholder Relations from the European Commission's Directorate for Health (DG SANTE).

- Opportunities for patient advocacy group (PAG) engagement were present throughout with dedicated Q&A sessions at the end of each presentation, and an enabled *Chat* function within Webex events allowing commentary from participants throughout.

- **91 participants came from the following 14 EU countries: Czech Republic, Denmark, France, Germany, Greece, Ireland, Italy, Netherlands, Poland, Portugal, Romania and Slovakia. PAG representatives also came from countries outside the EU, including the United-Kingdom, Switzerland, Canada and the USA.**

Europe				Other countries
Czech Republic	Greece	Poland	Spain	United Kingdom
Denmark	Ireland	Portugal	Sweden	Switzerland
France	Italy	Romania		Canada
Germany	Netherlands	Slovakia		United States of America

Why is this training program important to participants?

- **The training helped raise awareness of the importance of patient involvement in health policymaking among national and European patient organizations.**
  - As direct beneficiaries of health services, patients have comprehensive knowledge of the impact and effects of a treatment or technology on their condition – a value that EU regulators have recognized. Patient empowerment and involvement are at the core of the European Health Data Space (EHDS), the EU Pharmaceutical Strategy, and the EU's Innovative Medicines Initiative. It will also be a key feature of the upcoming EU-wide HTA, with guidance for stakeholder involvement expected imminently.
    - ✓ *The training specifically highlighted the added value of the patient voice in policymaking through various concrete policy examples and encouraged patient organizations at all levels to take part therein.*
- **The training pinpointed the discrepancies between policymakers' discourse and the reality behind patient engagement opportunities. In principle, the patient voice is an integral part of policymaking. European institutions regularly organize consultations and even recently drafted an initiative on Non-Communicable Diseases through a co-creation process with patient organizations. In reality, opportunities for engagement are complex and allowing only a few patient groups to contribute.**
  - Specific structures for patient involvement in EMA are limited in both scope and impact. Patient engagement is restricted to 35 eligible PAGs, and representatives must be called upon to provide input.
  - Out of the 23 European countries that have an HTA system for the assessment of pharmaceuticals, only 9 indicate involving patients in the HTA at the step of advice and decision-making. The type and level of patient involvement varies widely, which reflects the different rationale, motivation and approach applied in each country. Very few HTA agencies and decision-making bodies currently involve and integrate patients' perspectives in their reports and conduct formal evaluation of the impact of patient involvement in HTA.

- **The training highlighted a link between well-organized and high-profile PAG engagement activities and prioritized disease areas.** Advocacy strategies conducted by CVD patient organizations, including stroke, have proven successful. These diseases are now considered priorities at EU-level. Policymakers are informed of their economic and societal burden and intend to tackle it through the NCD Initiative. The same should be achieved for persons living with obesity and migraine, through rigorous involvement of PAGs in national and EU policy.

  - While obesity rates have reached epidemic proportions in the EU, affecting almost 60% of adults, obesity is not consistently recognized as a chronic disease by policymakers. Policy recommendations focus on lifestyle changes instead of exploring effective treatment options.

  - No government in the EU has put in place a national plan to tackle migraine. It is not a priority despite its high indirect cost (loss of productivity, absenteeism, sick days, years lost to disability).

Key Takeaways

1) **Policymakers, notably at the EU level, are starting to understand the value of patient voices in the healthcare policymaking process, but the patient perspective is not consistently considered or incorporated. There is a lack of transparency on patient involvement opportunities, especially on HTA, and overall little interaction between PAGs and policymakers on a regular basis.**
    - European Commission representative, Stefan Schreck, confirmed that EU institutions value the input of patients in the healthcare policymaking process.
    - The EU-wide HTA Regulation foresees the involvement of patients in the HTA process. However, there is no clear guidance on what type of expertise would be required from them to participate. They will also only be consulted as 'external experts', and not part of the new EU-wide HTA governance. This could threaten the sustainability of their involvement over time.
    - There is also little interaction between European institutions and PAGs, who are only consulted on an ad-hoc basis. So far, they only communicate via an online platform and a portal to share best practices. These forms of engagement still put distance between patients and policymakers.
2) **Patient advocates recognize the value and importance of their voice in healthcare decision-making processes; however, the link between European and national health policymaking is not always clear to PAGs.**
    - While national governments in the EU are responsible for drafting their own national health policies, European institutions still provide them with guidance to help them implement effective health policies. As such, they often seek PAG input to draft policy recommendations and guidance documents. This includes from national groups.
    - This dynamic is not always understood by PAGs which often only advocate at national level. This was mentioned multiple times by EU PAG representatives in the preparation of the event, who commented that there is still progress to be made in helping national PAGs understand why participation at EU-level is beneficial to their advocacy goals, particularly in a post-COVID world.
        - Examples of impactful campaign tactics were presented by representatives from groups such as EASO, ECPO, EBC, EMHA, EFNA and GAMIAN-Europe. Tangible results were also put forward, such as the inclusion of stroke in the EU's NCD Initiative.
    - Representatives from umbrella PAGs commented that they have a significant role to play in supporting national PAGs, which are often smaller or newer, by sharing resources and providing tools. This includes information on how to build advocacy plans and sharing of key messaging

2) Summary of all presentations

Session 1: Wednesday 16 November, 13.00 – 17.30 CET

Speaking time	Panelist
13.00 - 13.10	**Welcome & Introduction** Gary Surmay, Senior Director, Corporate Affairs, Pfizer
13.10 - 13.30	**Inspirational Keynote 1: Patient empowerment is at the core of the European Health Union** Stefan Schreck, Stakeholder Relations, DG SANTE, European Commission
13.30 – 14.15	**How has EASO empowered the obesity patient voice towards EU policymakers?** Jacqueline Bowman- Busato, Head of Policy, European Association for the Study of Obesity (EASO)
14.15 – 14.30	**Coffee Break**
14.30 – 15.10	**Patients Perspectives: The building blocks of a European advocacy plan** Vicki Mooney, Executive Director, European Coalition for People living with Obesity (ECPO) & Andreas Herdt, Chairperson of the German Association of People living with Obesity
15.10 – 15.45	**Advocacy Toolbox Part 1: Your blueprint public affairs plan** Emma Cracknell, Head of Healthcare, Senior Vice President & Director, FleishmanHillard Brussels
15.45 – 16:00	**Coffee Break**
16.00 – 16.35	**Patients Perspectives: Tools and tactics to elevate migraine on the EU health policy agenda** Elena Ruiz de la Torre, European Migraine and Headache Alliance (EHMA)
16.35 – 17.15	**Advocacy Toolbox Part 2: Building an impactful narrative** David Turier, Head of Integrated Communications and Reputation Management, FleishmanHillard Brussels
17.15 – 17.30	**Recapping Day One & Conclusion** Gary Surmay, Senior Director, Corporate Affairs, Pfizer

Gary Surmay, Senior Director, Corporate Affairs, Internal Medicine, Pfizer

Welcome & Introduction

Gary Surmay welcomed participants to Pfizer's fourth European Patient Advocacy Summit, this year focused on strengthening the voice of all patients, especially those representing non-prioritized disease areas, in European health policymaking including HTA. Providing context to its development, Gary highlighted the content of this year's Summit was based on feedback received from participants in previous summits. In 2021, participants specifically indicated they would like to learn more about the communications and campaign skills required to effectively advocate towards EU-level and national policymakers. Key areas of interest being how to build public affairs plans, a narrative and use of social media. Considering the new EU HTA regulation, participants also requested more training and support to prepare for its implementation. To address this need, this year's program consisted of EU and national level expert speakers in health policy, alongside public affairs practitioners, to deliver hybrid sessions across two days that provided practical advice on how to improve participation.

Stefan Schreck, Stakeholder Relations, DG SANTE, European Commission

Inspirational Keynote 1: Patient empowerment is at the core of the European Health Union

Key messages

1) Patient advocacy groups (PAGs) are important in the policy drafting process. They are helpful stakeholders to the European Commission by providing expertise, notably data on the societal impact on their condition.
2) There should be greater level of interaction between patients and the European Commission. Currently, most communications are done via an online policy platform, and a portal to exchange best practices.

Stefan Schreck introduced himself as a representative from the European Commission, working on 'Stakeholder Relations' within the institution. He started his presentation by reminding participants of the importance of patient involvement in drafting European policies. He used a metaphor to convey that European Commission officials are not '*machines*', but people that patients can talk to, notably to influence their thinking. Stefan mentioned three key moments in which patient expertise is needed by the Commission.

First, patients are helpful to identify policy needs. Second, during policy development, their expertise is needed for the policy proposal to be '*appropriate and feasible'*. Stefan described patients as '*the best source of expertise'* in this context. Third, patients are needed upon policy publication to evaluate its implementation at national level. Stefan reminded participants that the Commission regularly consults patients in this respect.

Stefan noted it would be useful for the Commission's unit in charge of health policies to have greater interaction with patients. Today, most communication is done through an online policy platform where PAGs and Commission officials can interact. Another online tool allows them to submit best practices via a portal, so projects can be suggested to national governments for implementation. However, on top of EU-level advocacy, PAGs should not underestimate the influence of national authorities in drafting health policies. Health is a national competence in the EU. PAG advocacy and awareness raising initiatives are particularly important in countries like Italy and Germany, where healthcare policies are fragmented and regional.

Stefan concluded his speech with key advice to patient organizations. He advised them to choose carefully who they are talking to, depending on the legislation's stage of development: '*Before the proposal is adopted, talk to the European Commission. After the proposal is adopted, talk to the European Parliament*'. He also reminded them of the importance of providing data to the Commission to demonstrate societal impact of a condition.

Audience Question and Answer Session
A member of the audience asked Stefan how PAGs could identify who to speak to at national level. Stefan stated that the main interlocutors should be national ministries of health. However, given there are more than 300 regions in Europe, PAGs should also consider engaging with regional stakeholders. Stefan reminded participants that the European health policy landscape is incredibly complex. Often, national health stakeholders are not easily identifiable; in certain cases, this is done intentionally to avoid these stakeholders from being compromised. Stefan also reminded that the level of competencies varies from country to country, complicating the work of PAGs. '*There is no solution in sight in the near future*', he concluded.

A second question from the audience tackled future opportunities for PAG involvement. Stefan advised PAGs to subscribe to the European Commission's newsletter to have the most up-to-date information. There will be a significant amount of patient consultations in the context of the building of the European Health Union, especially on mental health and the upcoming revision of the EU general pharmaceutical legislation.

Jacqueline Bowman- Busato, Head of Policy, European Association for the Study of Obesity (EASO)

How has EASO empowered the obesity patient voice towards EU policymakers?

Key messages

1) Advocacy is a process. PAGs should start by working on their messaging and their sources before building bridges with experts and allies to support their strategy.
2) Words matter, especially in health policy. It is key to ensure that the scientific community and patient representatives are aligned on a common lexicon that is easily understandable to policymakers.

Jacqueline introduced herself as Head of Policy at EASO, holding almost 30 years of advocacy experience. She explained how EASO is the leading voice of obesity science, medicine, and community in Europe, representing scientists, health care professionals, physicians, public health experts and patients. Established in 1986, EASO is a federation of professional membership associations from 36 European countries.

Jacqueline began by explaining how she would center her presentation around four key strategies to successfully elevate third-party voices in policymaking.

First, Jacqueline advised participants to avoid making assumptions when advocating for a cause. Taking the example of her work to classify obesity as a chronic disease, instead of a lifestyle condition, she reminded participants that '*in policy advocacy, every single word we say matters'*. She advised to build a lexicon that can be understood and used by all policymakers, ensuring PAGs and policymakers were all on the same page: speaking the same language, and working towards the same goals.

The second strategy, *building bridges,* is about understanding the external environment that an organization is operating in, and comparing it to the reality of what can be achieved in the future. According to Jacqueline, PAGs should identify their policy issues, their audience, and have a clear goal in mind, before advocating externally. This will ensure that policymakers do not only listen to the loudest PAG voice, but to the most persuasive one.

Jacqueline explained that strategy number three is about developing allies and champions. To achieve this goal, PAGs should develop clear, recognizable materials, including a logo and identifiable colors, that will allow them to convince policymakers to listen. Once PAGs build their competence and confidence in their messaging, Jacqueline's final piece of advice is to start a dialogue. To note, however, is that PAGs representative should never represent their personal selves: they should represent a broader community. The dialogue should be with various stakeholders, multi-disciplinary, outcomes oriented, and evidence based.

To conclude her presentation, Jacqueline shared more about her advocacy experience on behalf of the obesity community. She pointed out some of the difficulties faced, notably the discrepancy between patients' needs and the scientific community. Generally, there is a need to translate scientific knowledge into easy-to-understand messaging for policymakers who, most of the time, have little knowledge of obesity. Jacqueline explained how her organization brought a unique perspective to scientific knowledge: the need for access to treatment, and for the monitoring and evaluation of policies.

She ended her speech with a powerful quote: '*Patient representatives should not be tokens'.* To Jacqueline, patients should be involved in debates because they have a legitimate reason to be. Patient involvement should never be just a box-ticking exercise.

Audience Question and Answer Session

The first question asked where PAGs should focus their efforts if they must prioritize. Jacqueline stated that the hardest part of advocacy is getting a seat at the table with policymakers. To do this, developing clear internal messaging, then identifying the organization's added value within the international community, must be prioritized.

Jacqueline was then asked to provide an example of a specific advocacy challenge she had confronted. She explained writing a speech for a Member of European Parliament which included incorrect financial data. However, the content was still voted upon, and she received a grant for €36 million. Jacqueline's key message is that, in advocacy, there will be uncertainties – what is important is for PAGs to keep fighting for their overall advocacy goals.

Finally, a participant asked how PAGs can ensure their advocacy strategies work. Jacqueline advised use of project management to efficiently organize, but also to '*know the dossier'*. PAGs wanting to influence a specific file should know it very well before commencing advocacy on it.

Vicki Mooney, Executive Director, European Coalition for People living with Obesity (ECPO) & Andreas Herdt, Chairperson of the German Association of People living with Obesity

Patients Perspectives: The building blocks of a European advocacy plan

Key messages

1) Patients can be cautious of participating in advocacy activities. Umbrella PAGs should play an essential role in empowering their members by organizing educational and PA training initiatives.
2) Patient advocacy approaches must be adapted to national policy environments. PAGs must respect members' local challenges and design advocacy campaigns with these factors in mind.

Vicki, Executive Director of the EU-level PAG, the European Coalition for People living with Obesity (ECPO), and Andreas, Chairperson of the national PAG the German Association of People living with Obesity, took part in a fire-side chat about how to build a European advocacy plan.

In her introduction, Vicki emphasized that although she is a professional patient advocate, she first and foremost sees herself as a patient living with obesity. She began by describing that while most of her early career focused on educating the public on obesity, she quickly realized that patients should prioritize policymaker engagement to achieve meaningful change.

Andreas introduced himself as a representative of one of the oldest obesity associations in the world. Upon its founding in 2004, the disease did not receive sufficient acknowledgement and recognition. Furthermore, scientific organizations only allowed a minimal degree of patient involvement. He realized the only way to avoid tokenization of patients was by creating an independent patient group that would exclusively focus on the needs of its members.

Vicki kicked off the discussion by explaining that the word 'advocacy' can seem scary to many patients, preventing them from becoming patient advocates. Looking specifically at obesity, she emphasized that stigmatization is also a significant barrier preventing first steps towards advocacy engagement. Vicki also emphasized that most patients, even those who decide to become advocates, are not public affairs professionals.

Putting forward tips to participants, Vicki encouraged all new PAGs to join larger organizations to benefit from their resources, while reminding them to maintain their unique and independent identity. A point echoed by Andreas who stated that PAGs must develop unique approaches for every country, highlighting that one advocacy template will not be effective due to the diversity in local factors and policy landscapes.

Both Vicki and Andreas emphasized the value of all PAGs collaborating with each other to build advocacy coalitions and align on messages to share with allies. They both referenced promoting a culture of learning within their organizations. According to Vicki, it is this culture of knowledge sharing that can embolden and encourage more members to participate in advocacy initiatives. She specifically recommended PAGs use case studies, translate relevant scientific and policy terminology into layman's terms, organize confidence-building workshops and provide their members with practical toolboxes for advocacy activity.

Andreas encouraged PAGs to embrace change when needed and to evolve with time. For the first couple of years of its existence, his association spent most of its time and resources on providing peer-to-peer support to people with obesity. However, six years ago, the association's focus shifted towards advocacy activities. Like Vicki's experience, Andreas

explained that his organization realized that to achieve meaningful change, their association could no longer afford to abstain from engaging in patient advocacy.

To conclude, Vicki advised PAGs to support their communities and put patients at the center of relevant policy discussions. She emphasized that meaningful change does not happen overnight, and members may leave the journey along the way. Nurturing an organizational culture driven by support and mutual respect, many members will return, and even more new ones will join, allowing your strength as an organization to grow.

Andreas concluded by speaking about the untapped power and potential of the 'silent majority'. This majority consists of people who live with obesity but are unwilling to speak up and advocate for their community. According to Andreas, every PAG can contribute towards activating this 'silent majority' by reaching out to members of peer support groups and by paying attention to patient voices on social media.

Audience Question and Answer Session
The previous panelist, Jacqueline from EASO, agreed with the conversation's key messages, and emphasized the difficulty of advocating for obesity due to the stigma it faces. She acknowledged that patient advocates, especially in the obesity policy sphere, can oftentimes be dehumanized by the media and policymakers.

Emma Cracknell, Head of Healthcare, Senior Vice President & Director, FleishmanHillard Brussels

Advocacy Toolbox Part 1: Your blueprint public affairs plan

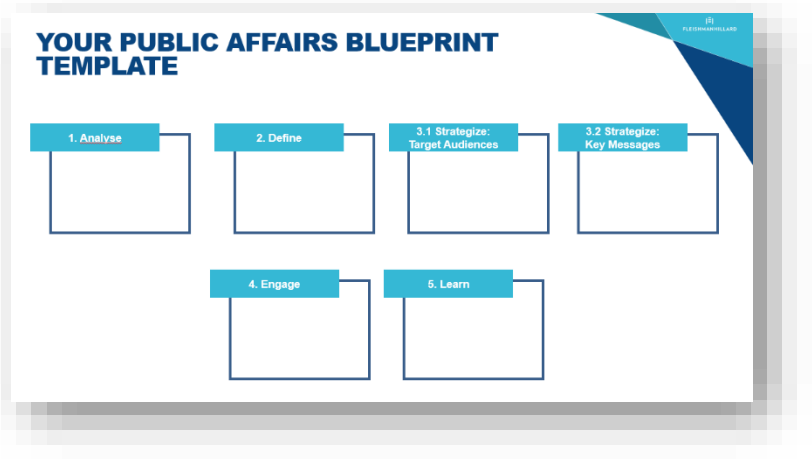
Key messages

1) Building a public affairs strategy takes time. Invest time in researching your policy space, defining your objectives, and understanding what motivates your audience before deploying tactics.
2) Prioritize the issues you would like to focus on. Among all your policy challenges, prioritize which issues you should focus on.
3) Not all tactics are relevant to your organization. Choose those which are aligned with your resources, capacities, and ambition, instead of doing them all at once.

Emma kicked off her presentation by setting the scene as to what public affairs is and why PAGs need it. First, she recapped the definition of public affairs, describing it as communications that seek to influence the opinion and/or actions of policy stakeholders. She explained that public affairs is essential to ensure organizational interests and opinions are best represented in government initiatives and legislation, ultimately supporting PAGs to achieve their organizational goals.

Emma continued by discussing three key reasons why influencing policy change is so challenging and hence why developing an impactful public affairs plan is so important. First, that some disease areas are deprioritized by policymakers leading to a lack of understanding of their impact on individuals and society. Second, that opportunities to participate in healthcare policymaking can be unclear and complex meaning organisations are unsure where to insert influence. Finally, that policymakers are overwhelmed with content and messages from a range of organisations across a variety of issues.

Emma proceeded to highlight the five key steps to building an effective public affairs plan. Emphasizing that in today's presentation, she would focus on steps one, two, three (i) and five.



- Step 1, analyze: conduct research and insights into the policies you would like to change or gaps in the current landscape.
- Step 2, define: based on the analysis, define objectives to reflect desired policy changes, also considering broader organizational objectives. Objectives should be 'SMART' (specific, measurable, achievable, relevant and time bound) in nature, and linked to two to three key policy files or issues that are viewed as having the most impact. Prioritization is important to ensure success.
- Step 3 (i), strategize: first, identify audience by mapping the policymakers responsible for identified policy challenges. Then map the stakeholders who influence them, remembering policymakers are influenced by the environment around them. This includes patients, think tanks, NGOs, healthcare professionals, industry, media and scientists and academics. Then, spend time analyzing what motivates that audience. Complete an exercise which assess what policymakers should think, feel, and do because of your public affairs plan.
- Step 5, learn: it is important to measure the success of a public affairs strategy to optimize it for the future. This can be done by implementing a measurement framework that measures
    - *Exposure* i.e., number of key policymakers reached with messaging (policy papers, information, research shared)
    - *Engagement* with your content i.e., number of relevant policymakers met and/or number of policy makers requesting further information
    - How it has *influenced* policymakers, i.e., are policymakers using your messaging across their own channels
    - What *actions* have policymakers taken because of your activity.

Emma highlighted that step three (ii), developing key messages, and step four, defining tactics, would be covered later in presentations by other members of the FleishmanHillard team.

Audience Question and Answer Session

The first question from the audience focused on how to get buy-in from leadership that public affairs matters. Emma highlighted that a key tactic is to demonstrate to leadership the risk of non-engagement. For example, what is the risk of a particular legislative file and/or policy action on your organization is action is not taken, whether it be financial, license to operate or restriction of access to treatment for patients.

A second question asked about the difference between public relations and public affairs. Emma explained that while the 'public' is at the center of both, the intent is different. Public relations is about influencing purchasing intent, whereas public affairs is about influencing actions of policymakers.

A final question asked about the differences between public being implemented at an EU-level, to a national level. Emma explained how an EU-level plan is about either influencing EU-level policy specifically, and/or providing a blueprint for national public affairs teams to develop plans on their own and looking for cross-country synergies to support this. Ultimately, national plans should always be tailored to markets, due to different motivations, cultures and ultimately, policy landscapes. A member of the audience supplemented this answer by stating that working at an international level will always include prioritization of national markets.

Elena Ruiz de la Torre, European Migraine and Headache Alliance (EMHA)

Patients Perspectives: Tools and tactics to elevate migraine on the EU health policy agenda

Key messages

1) When setting up the EMHA, it was important to work with the broader stakeholder community to help establish a basis and begin to elevate migraine on the EU health policy agenda.
2) Building relationships with policymakers and other stakeholder has been a vital tool to elevate priorities relating to migraine.
3) Elena emphasized the importance of visualizing campaigns to policymakers to increase their impact, with the EMHA using an "impatient chair" to emphasize the time it takes for patients to receive treatment for migraine.

Elena started by introducing the European Migraine and Headache Alliance (EMHA) and how the group was set up. Elena founded EHMA in 2006 to represent the 50 million people in the EU living with migraine and the 138 million with headache disorders.

Elena began by sharing how important she found collaborating with other patients and scientists at the beginning of her journey. Particularly, how they could support in the sharing of different duties and responsibilities. She spoke about the importance of working closely with the European Patient's Forum, the European Academy for Neurology, and the European Brain Council to establish the foundations and begin to elevate migraine on the policy agenda.

Elena spoke about framing migraine, a disease that is not well-understood or recognized, to a policy audience. She identified building relationships with policymakers as one of the best avenues to impactful advocacy. Diving into tactics used, Elena explained the process of hosting her first event in the European Parliament and the importance of the European Parliament Migraine Alliance, created by EMHA, to ensure a footprint in Brussels, with annual events held since. With health being a national competence in the EU, Elena also emphasized the importance of working with national stakeholders and organizing events with national delegates, with individual campaigns launched across Europe to get migraine recognized as a disease, also linking it to discussions over mental health - a disease currently prioritized by European policymakers.

Elena then went on to detail the development of EMHA's campaigns and narratives along with their successes. She discussed the Italian senate recognizing chronic primary headache, including migraine, as a disease with a societal impact. She also discussed the #GetImpatientForMigraine campaign, in which EMHA emphasized the time it takes for migraine patients to see a doctor. The campaign focused on sharing key materials with policymakers in several events across Europe and was accompanied by an "Access to Migraine Care Survey". As part of that, EMHA tried to communicate the human aspect of action on migraine through the picture of an "impatient chair", which visualized the length that patients wait for diagnosis and treatment. Elena emphasized the importance of using every opportunity possible to get information into the hands of policymakers. Other examples of work included "Women and Migraine: Bringing women out of the shadows". Finally, she discussed the importance of patience, with not all campaigns paying off and the need to persevere to ensure that the patient voice is heard.

Audience Question and Answer Session

Elena received a question on the impact of COVID-19 on EMHA advocacy, to which she responded by saying many events were cancelled and that traditional forms of advocacy activity were reduced, forcing a change in focus. For EHMA, this meant contacting KPMG to do surveys and research-based initiatives to ensure important messages were still being conveyed to policymakers in different ways.

David Turier, Head of Integrated Communications and Reputation Management, FleishmanHillard Brussels
Advocacy Toolbox Part 2: Building an impactful narrative

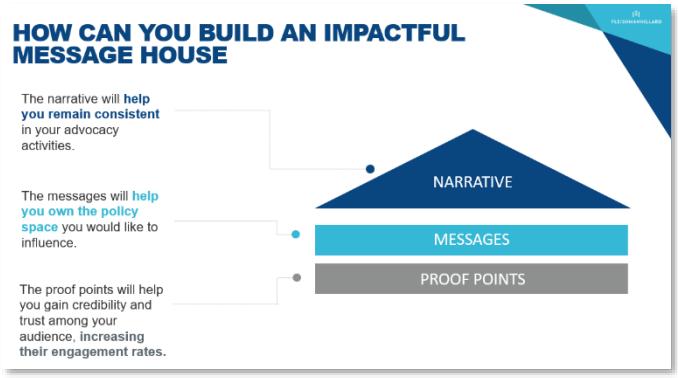
Key messages
1) Communicating can be difficult. Following the structure of the message house can ensure PAGs remain consistent, own a policy space, and increase engagement rates.
2) PAG should choose the type of story they want to tell, by conducting research on where the organization fits in the existing policy debate and identifying the type of persona they would like to adopt.
3) Simplicity coupled with proof points such as facts, data, or testimonials, is essential to effective messaging

Building on Emma Cracknell's presentation on how to build a public affairs plan, David specifically focused on step three (ii) of the advocacy blueprint: *developing key messages*. He opened his presentation with a quote from commentator and theater critic, George Bernard Shaw, '*the single biggest problem with communication is the illusion that it has taken place',* to emphasize the importance of building messaging in advocacy.

David began by reminding participants of the importance of building a cohesive common message on a specific issue. This messaging framework should guide all advocacy activities, following a red thread and providing necessary guidance to an organization. It is also useful in advocacy because it helps policymakers easily understand a given cause. Second, a common message can be carried by PAG members, and external stakeholders, increasing repetition of message and therefore likelihood of policy stakeholder retention.

David proceeded by explaining to participants how to build a message house – a framework regularly used by public affairs specialists to develop an organization's messaging. David highlighted that the message house should support public affairs objectives identified in step two of the previous advocacy blueprint session.

An impactful message house is broken down into three key elements:
1) The 'narrative', a short way of presenting a situation or series of events, that reflects and promotes a particular point of view or set of values. It explains to the policy audience what you want them to do, why it is important and consequences of action.
2) 'Messages' are supporting statements that reinforce the narrative. This is the opportunity to expand on the narrative, highlighting why what you want can add value to policy stakeholders.
3) 'Proof points', to justify the narrative and the messages. This includes data, statistics or testimonials highlighting the impact or scope of a policy challenge.



David noted that the most important phase of message house development, often overlooked, is research. PAGs should take time to assess their policy landscape and find their space in an often-busy external environment:
- How your issue is being discussed in the media?
- Are there other competing narratives/advocates out there?
- What events or existing conversations can our messaging be linked to?

The research phase also includes introspection. David advised PAGs to spend time researching how they want to be perceived by their audience, developing a specific persona. This is a key step: PAGs should know how they would like to present themselves before advocating externally. Examples of personas include thought-leader (wanting to be considered

a leader in a field of expertise), knowledge centre (wanting to be considered an expert in scientific and technical questions) or quick reactor (wanting to provide constructive solutions to policymakers).

David provided participants with concrete advice on how to build an effective message house. In his experience, positive narratives usually gain more attention from policy stakeholders. Furthermore, alignment to their priorities and simplicity make messages more likely to resonate.

To conclude, David agreed while communicating can be a difficult task, development of a messaging house should simplify the process.

David insisted that PAGs choosing the right story to tell, and to make it as simple as possible with relevant data and testimonials.

Audience Question and Answer Session
A member of the audience asked David how health knowledge, which can be technical, can be turned into a simple narrative. David advised PAGs to do the following exercise: '*what newspaper headline would they like to see in five years, relevant to their disease area?'.* The answer to this question will help PAG's prioritize their goals and increase simplicity of message. David emphasized that the technical parts, however, should help build rigorous proof points.

A second question asked what can be done if an incorrect narrative already exists in the external environment. David stated that it is then necessary to put forward research to establish the truth. David presented the example of a rebuttal campaign he created for a client; '*the error may also become part of your story'*, he stated.

A third question asked David for his opinion on where PAGs should spend the most of their time when creating a narrative. David emphasized that research is undoubtedly the most important phase. Getting to know the ecosystem in which a PAG's narrative will evolve is time-consuming, however most rewarding to support the dispersion of messages.

A final question tackled the way that PAGs can represent the patient voice without sounding patronizing. David responded that PAGs should not pretend that they are speaking for others, but rather that they represent a set of beliefs. He emphasized proof points are most important in this context, as they provide authenticity and credibility to PAG claims.

Session 2: Thursday 17 November, 09.00 – 12.30 (CET)

Speaking time	Panelist
09.00 - 09.10	**Welcome & Introduction** Gary Surmay, Senior Director, Corporate Affairs, Pfizer
09.10 – 09.40	**Advocacy Toolbox Part 3: Using social media to achieve advocacy goals** Cloe Roycroft, Vice President, Head of Social and Digital, FleishmanHillard Brussels
09.40 – 10.20	**Fire Side Chat: Tactics to elevate non-prioritized disease areas on the EU health agenda** Orla Galvin, Chief Executive Officer, European Federation of Neurological Associations Fred Destrebecq, Executive Officer, European Brain Council Nigel Olisa, President, GAMIAN-Europe
10.20 – 10.50	**Case-study: Participating in EU legislative processes to elevate stroke patients' voice** Arlene Wilkie, Director General, Stroke Alliance Europe
10.50 – 11.00	**Coffee Break**
11.00 - 11.20	**Inspirational Keynote 2: How can patients meaningfully contribute to HTA?** Maria Dutarte, Executive Director, EUPATI
11.20 – 11.50	**Advocacy Toolbox Part 4: Getting your organization ready for EU-wide HTA** Anne Willemsen, Senior Project Manager, EUnetHTA
11.50 – 12.20	**Patient Perspectives: What should meaningful patient involvement look like in the EU-wide HTA?** Valentina Strammellio, Head of Programmes, European Patients Forum
12.20 – 12.30	**Recapping Day Two & Closing Statement** Gary Surmay, Senior Director, Corporate Affairs, Pfizer

Cloe Roycroft, Vice President, Head of Social and Digital, FleishmanHillard Brussels

Advocacy Toolbox Part 3: Using social media to achieve advocacy goals

Key messages

1) Social media can be a useful tool to add-value to a PAG's public affairs strategy, helping gain visibility to messages and connect with a specific audience.
2) To be as efficient as possible, PAGs should create a social media calendar to publish consistently throughout the year. This will help with organizing and time efficiency.
3) PAGs should take a pro-active approach and use social media to engage with communities on a specific topic, rather than just posting content online.

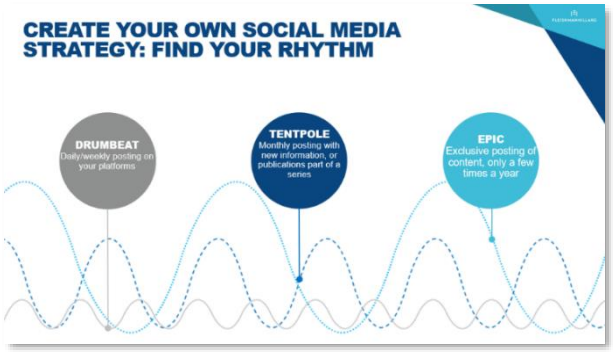
Building on Emma Cracknell's presentation on how to build a public affairs plan, Cloe focused her presentation on step four of the advocacy blueprint: *tactics.* Specifically, the use of social in a public affairs strategy.

Cloe kicked-off by highlighting why social media is an important tool to reach policymakers. She informed participants that 41% of EU policymakers and 61% of Brussels opinions formers use social media to access information. At national level, Cloe provided various examples: French presidential candidates used social media to a huge extent during the elections, Members of the British Parliament post 729 tweets per day on average while disinformation spread on social media influenced voting behaviours in Italy.

Cloe emphasized the need for PAGs to use social media as part of their public affairs activities. It can help increase the visibility of an organization, support engagement with policymakers, and overall raise influence in a policy space.

Cloe provided concrete steps on how to use social media for influence. First, Cloe suggested PAGs choose a social media platform to be active in. Facebook, Twitter, LinkedIn and TikTok all have different purposes, tones and types of language used. As social media strategies can be time-consuming, Cloe advised to choose a maximum of two to focus on.

Timing of content in social media is key. Cloe referred to this as the social media 'rhythm'. Posting on social media should be consistent, with different types of content delivered at different frequencies. Content is known as 'drumbeat', daily/weekly posting on platforms, 'tentpole', monthly posting of new information and 'epic', exclusive content published only a few times a year.



Cloe highlighted that planning was key to a successful strategy. She advised PAGs to build a social media calendar to support regular posting. This is a must to ensure consistency throughout the year. She followed-up with explaining the difference between organic and paid social media. Organic being free content shared including posts, videos, re-share of existing content of organizations/individuals that you follow. Paid being about 'boosting' your content. For PAGs with limited resources, Cloe explained the importance of prioritization and quick-win tactics, for example sharing or commenting on content that you agree with from other channels.

Finally, after providing dos and don'ts to audience members, Cloe concluded by emphasizing the need to evaluate social media strategies. Social media platforms include tools that are great for measurement. Through assessment of what works and what does not, an organization can adapt and use resources more efficiently in the future.

Audience Question and Answer Session
A first question to Cloe targeted disinformation, and how it can be tackled on social media. Cloe advised PAGs to report any disinformation to the platform, and counter it though real facts and data. Cloe reminded participants that is it important, on social, for each PAG to remain true to themselves and their core values.

A second question focused on the evolving situation with Twitter, and whether the platform should be left. Cloe explained that while the situation will develop in the coming months, Twitter remains a useful platform for information gathering. She also reminded participants that through the use of 'targeting', LinkedIn is also a great tool to reach a specific audience (by employer or location) to engage with.

Orla Galvin, Chief Executive Officer, European Federation of Neurological Associations
Fred Destrebecq, Executive Officer, European Brain Council
Nigel Olisa, President, GAMIAN-Europe
Fire Side Chat: Tactics to elevate non-prioritized disease areas on the EU health agenda

Key messages
1) PAGs should be involved at every level of policymaking. They are best informed on their condition.
2) Efficient tactics to engage with policymakers include the presentation of data, collaborations with other PAGs to show alignment, and to ensure that advocacy goals are linked to both EU and national policy context.
3) Highlighting the financial cost of non-treatment is key to help policymakers prioritize a specific disease area.

This fireside chat, moderated by FleishmanHillard' s Emma Cracknell, investigated key tactics to elevate non-prioritized diseases areas on policymakers' agendas. Participants heard from representatives of three European PAGs: the European Federation of Neurological Associations (EFNA), European Brain Council (EBC), and Global Alliance of Mental Illness Advocacy Networks-Europe (GAMIAN- Europe).



To kick-off, all three speakers agreed that patient advocacy is key in policymaking: '*nothing about us, without us'*, mentioned Orla, from EFNA. She kicked-off the conversation by highlighting the high volume of health data gaps and the responsibility of PAGs to inform policymakers thereof. PAGs, as best-informed to provide insights on their condition, have a role to raise awareness of their patients' situation so policymakers draft legislation that is relevant to them.

Nigel, from GAMIAN-Europe, added to Orla's initial point, stating that it should be common practice for patients to be represented at every level. Following a question from Emma on best ways to achieve this goal, Nigel claimed that '*the more voices, the better: the more noise you make*'. He believed in the importance of alignment, internally, through a common principle of uniting all patient voices. Fred, from EBC, added that another tactic to ensure the inclusion of the patient voice is via research and data. According to him, solutions must be offered at the same time as issues are raised. Fred suggested that policymakers are more likely to engage with PAGs if they are presented with the cost of inaction and suggestions on how investment could solve a policy challenge. Orla agreed with this approach, also advising PAGs to consult experts, including researchers and policy officials, to build consensus on a specific issue.

Emma continued the panel debate by asking panelists if each could put forward concrete advice on how to build impactful public affairs strategies. Fred kicked-off by highlighting the need for PAGs to align their advocacy efforts with the agenda of national and/or regional bodies that are seeking to address the same policy challenge. He explained that by making sure actions connect with the agenda of the World Health Organization (WHO) or European institutions, PAGs will have access to a network of likeminded partners across the globe, and thus have their messages resonate. Nigel further emphasized the importance of building networks, stressing that having a 360-degree approach is the key to maintaining traction and ensuring messages are reaching the right stakeholders.

To wrap up the session, Emma asked each panelist to share some key points to take away from the discussions. Orla left the audience with a reminder of just how slow policymaking can be; she encouraged PAGs and individuals to be brave, collaborative, and persistent in their activities. Fred reminded the attendees of the impact that the community can have on the health policy agenda and to '*never underestimate the power of your contribution'*. Nigel concluded the debate with three short and succinct key takeaways; engage with PAGs in your local countries, support collaborative advocacy campaigns, and start discussions early to ensure buy ins from other stakeholders.

Audience Question and Answer Session

An audience member asked panelists to share their experience with policymakers, namely how they have been received when they finally secure a meeting with them. Fred answered that in his experience, policymakers are often hardened to shocking or distressing facts due to the nature of their job, meaning that they are more difficult to convince. Orla added that presenting policymakers with patient and carers' testimonials gives a more human perspective to arguments. She emphasized the importance of linking a disease to its potential socio-economic impact, and to the cost of non-intervention.

An online attendee asked for advice on how best to fight stigma while raising awareness, to which Nigel responded by pointing to the case of the stigma around mental health. He highlighted that mental health is still surrounded by stigma; however, it has been significantly reduced compared to what it once was. Nigel advised taking the same approach with other non-prioritized disease areas, encouraging PAGs to start conversations about their disease areas.

Arlene Wilkie, Director General, Stroke Alliance Europe

Case-study: Participating in EU legislative processes to elevate stroke patients' voice

Key messages

1) The patient voice is vital to strong and effective public policy, and it is vital that patient organizations can communicate their real work expertise to policymakers.
2) Ensuring there is a clear focus on solutions and recommendations is an important way to capture the attention of policymakers, with many of them wanting to hear solutions rather than problems.
3) Perseverance is key and writing reports with recommendations for policymakers with details on data and lived experience can still influence policy years after publication.

Arlene's presentation started off by introducing her organization, the Stroke Alliance for Europe (SAFE), who's members across Europe seek to work towards greatly decreasing the number of strokes. Following this, she emphasized the importance of a strong patient voice in European healthcare policy with the survivor perspective vital to communicating key messages to policymakers. Through this, PAGs are uniquely placed to bring real work expertise to the table, raising awareness of the issues that people are facing in policy fora.

Arlene then went on to discuss the best formulas for success in communicating the patient voice to policymakers, detailing action taken by SAFE. She spoke about how she positioned SAFE reports on the *Burden of Stroke in Europe* and the *Economic Impact of Stroke in Europe* in a catered way to resonate with a European policy audience. One core area identified was the importance of researching the problem from a patient and policymaker perspective and developing clear solutions and recommendations to policymakers, with an emphasis on data and lived experiences.

Arlene then went on to detail the importance of policy recommendations by introducing the Stroke Action Plan for Europe (SAPE). She spoke about the importance of a clear implementable strategy with clear overarching targets and policy recommendations for policymakers. Included in the report were areas important to patients but overlooked by policymakers such as life after stroke, with a societal emphasis on the return on investment of stronger emphasis on stroke. Another area identified as vital is that the strategy was implementable at national level, with SAFE working with the European Stroke Organisation and national coordinators in every nation to develop tailored national plans.

Arlene then introduced a case study, presenting SAFE's contribution to the EU Non-Communicable Diseases (NCD) Initiative, an EU initiative to co-draft key policy measures with subject matter experts and patient organizations to share with European governments in the form of *Best Practices*. Arlene discussed the submission of SAPE as a *Best Practice,* which ultimately led to stroke being referenced throughout the Initiative's guidance document. On this, she spoke about the importance of patience, perseverance and partnerships as core lessons learned.

Audience Question and Answer Session

Arlene was asked a question on the success of the co-drafting process which was used to draft the NCD Initiative. She responded by saying that it was an excellent new way to integrate the patient voice into European policy and hoped it would be further replicated in the future.

Maria Dutarte, Executive Director, EUPATI

Inspirational Keynote 2: How can patients meaningfully contribute to HTA?

Key messages

1) There are still misconceptions about impartiality and independence of patients contributing to HTA, which can be a challenge to increase patient involvement.
2) However, patient training can play a decisive role in increasing patient involvement in HTA, providing them with the tools and confidence to meaningfully contribute to the process.

Maria kicked-off her presentation by introducing the work of her organization, which offers online learning programs for patients wanting to contribute to HTA. The free resources allow them to learn more about the process, without being disease- specific. Her organization's work is based on the principle that patients have invaluable perspectives and experience which could be beneficial to policymakers.

Maria argued that patient training could be a sustainable solution to increase patient involvement in HTA across Europe. She pointed out differences in patient involvement between countries, explaining this is due to structural differences of HTA systems (HTA can be performed at the national or regional levels, depending on the country), and a lack of systematic patient involvement frameworks. The impact of patient training is usually positive, with the percentage of patients advising on HTA having increased from 5 to 12% in the last years. However, there are still obstacles, notably on patients' reputation. There is a general belief, according to Maria, that patients are trained by the industry, thus limiting the possibilities to be invited to contribute. Impartiality and independence are of great importance in HTA.

Maria highlighted a few concrete projects that her organization is undertaking to increase patient involvement in HTA. She is currently building a tool to improve matchmaking between expert patients and researchers, and developing new online modules funded by the European Commission's EU4Health program. She highlighted the role that PAGs could play in HTA and invited them to join the initiative, starting in January 2023.

Audience Question and Answer Session

Maria was asked her opinion on the adoption of the EU-wide HTA Regulation. She responded that she welcomed the text and ensured EUPATI would work alongside other health stakeholders to ensure that patient involvement remains at the center of the process.

Anne Willemsen, Senior Project Manager, EUnetHTA

Advocacy Toolbox Part 4: Getting your organization ready for EU-wide HTA

Key messages

1) The EU-wide HTA Regulation will allow patients to contribute to the process at the EU-level. Patients will provide scientific advice to manufacturers within Joint Scientific Consultations as well as input on the clinical aspect of a medicine within Joint Clinical Assessments.
2) PAG should prepare their patient representatives to contribute to HTA, including ensuring familiarization with guidance documents and registration via stakeholder repositories when available online.

Anne started her presentation by reminding participants that HTA is a process comparing the benefits of a medicine to an already existing treatment option. Ultimately, the process results in a reimbursement decision given by a national HTA body. Anne highlighted the different HTA procedures currently in place in Europe and stated that the EU-wide HTA Regulation should drive alignment.

She explained two new concepts to be implemented under the Regulation, which will change the way HTA is performed in Europe. First, the legislation foresees the establishment of 'Joint Scientific Consultations'. These will allow for the sharing of scientific advice by EMA and HTA bodies to manufacturers on clinical development. They will help manufacturers generate evidence that satisfies the needs of HTA bodies during their assessment. The second concept to be implemented is 'Joint Clinical Assessments', taking the form of joint HTA reports. They will be produced by multiple European Member States, focusing on clinical domains. The joint reports will avoid duplication of work at national level, increase consistency and quality of the assessment and ultimately facilitate patient access.

Anne welcomed the Regulation and indicated that her work is currently focusing on drafting guidelines, to give a proper framework to these new concepts. She highlighted that PAGs will have a role to play, including attending face-to-face meetings and submitting written statements. To this end, she advised PAGs to familiarize themselves with guidance documents and procedures, the input template, declaration of interest forms and the general remit of HTA. She also suggested that PAGs register to databases and stakeholder repositories, when they are made available, to be contacted to contribute. PAGs can also develop their own list of experts that will represent them on the day.

Audience Question and Answer Session
An audience member asked Anne who is usually responsible for selecting patient representatives to contribute to HTA. Anne responded that PAGs can decide who will represent their organization in the process when national HTA bodies contact them for input. She emphasized the importance of PAGs having a list of experts ready for when the day comes.

A second question asked Anne about current opportunities to shape how patient involvement in HTA looks like. She stated that national HTA bodies open consultations for PAGs to input, in which they can share their ideas. In addition, her organization EUnetHTA is always open to hearing feedback from PAGs. Linked to this question, a participant asked about the role of national governments in increasing patient involvement in HTA. Anne responded that national processes for HTA vary from country to country and that, often, PAGs must take the first step and engage with the authority directly.

A further question asked for advice on how to build that relationship with national HTA bodies. Anne suggested interaction with other national PAGs, to build a presence on social media or join an organization offering training on HTA. She also reminded participants that most national HTA bodies have a point of contact for interaction with external stakeholders. An audience member continued the discussion, asking how diverse patient involvement is in HTA. Anne agreed that processes can either be representative of many, with more than 50 contributions to a single file, or only receive comments from one patient representative. She emphasized that more patient involvement means more diversity and representativity of patient needs.

Finally, Anne and the next panelist, Valentina Strammiello from the European Patients Forum, exchanged on overlapping of competencies between different PAGs contributing to HTA. Valentina pointed out that, in many cases, PAG representatives are patients themselves. National HTA bodies should seek for as many different types of input as possible not just patient experts that advise across a wide range of diseases. Anne agreed and concluded that there should be a fine balance to respect in this context.

Valentina Strammiello, Head of Programmes, European Patients Forum (EPF)

Patient Perspectives: What should meaningful patient involvement look like in the EU-wide HTA?

Key messages

1) The patient voice is important in HTA to ensure that the process is democratic and enlightened by experiential knowledge about a specific condition.
2) Although the EU-wide HTA Regulation is a step towards greater patient involvement, the EPF believes that more could be done to ensure patients are fully part of the HTA process.
3) National PAGs have a key role to play in increasing patient involvement in HTA, helping in the prioritization of topics and identifying relevant patient experts.

Valentina kicked-off her presentation by reminding participants of the added-value of the patient voice in HTA. According to EPF, patient involvement in the process allows for the democratization of the decision-making process, for the contribution to robust evidence to support decision-making, and for the delivery of experiential knowledge of living with a chronic or lifelong condition. She highlighted the specific role of PAGs in this process. They should promote trust and the art of diplomacy, the respect of common rules and bring concrete evidence and patients' collective experiential knowledge. On this point, she clarified that PAGs should also support and educate patients to get involved in HTA.

Valentina proceeded by presenting the newly adopted European Regulation on HTA. Her organization believes that the new legislation gives a higher chance for equitable and high-quality care for all patients across Europe and has the potential to strengthen evidence-based decision making at national level. Her organization contributed to the drafting of the legislation by publishing a position statement on the issue in 2018, connecting with Members of the European Parliament, and organizing events to discuss patient involvement. Valentina also highlighted the important role of social media, which greatly helped the EPF to influence debate.

While Valentina welcomed the text as a clear opportunity for patient involvement in different stages of HTA, she believes the concept should be strengthened. So far, patients will 'only' contribute to HTA by providing input. However, they are not expected to be part of the Coordination group, established by the European Commission and overseeing the process, and they have no voting rights in the process. To Valentina, those are 'red flags' which could be tackled via the drafting of relevant guidelines. To inform these guidelines, the EPF launched a survey on patient involvement in HTA in 2022. The purpose of the exercise is to collect feedback on various stakeholders' experiences with patient involvement in HTA. The hope is to highlight key barriers and provide solutions in upcoming guidelines. The results will be published in December 2022.

To conclude, Valentina highlighted some practical advice to PAGs wanting to contribute to HTA. According to her, they should coordinate with peer organizations in other countries to learn about best practices, talk to national level HTA to advocate for topic prioritization, and finally help them identify relevant patient experts.

Audience Question and Answer Session

An audience member asked Valentina why few patients are involved in HTA. She responded that there are two common biases in the field: first, there is a common bias among people that patients contributing are influenced by the pharmaceutical industry. Second, patients themselves are convinced that the process will be too time-consuming. She believes that right now is a critical time to create a framework for involvement, and to have PAGs work towards this goal.

A third question to Valentina focused on financing. Valentina responded that HTA national bodies and the European Commission should consider budgeting for patient involvement. This would ensure qualitative patient involvement in HTA, in a way that is more professional, and sustainable over time.

3) Next steps

Looking specifically at Europe's healthcare policy landscape, we anticipate the following activities in 2023 that may provide opportunities for further patient involvement:

1. **Healthcare will remain a top priority for European and national policymakers, notably with the implementation of the EU NCD Initiative which is set to directly impact the cardiovascular, metabolic and neurological communities.** The text, published by the European Commission in June 2022, provides policy recommendations for EU Member States to prevent and treat NCDs. The text, for instance, recommends the implementation of national stroke action plans and offers EU funding for any Member States that will do so. Migraine is also mentioned in the text, however there is no policy suggestion on the matter. The obesity community, similarly, was upset about the disease being classified as a 'health determinant' and not an NCD per se. PAGs were involved in the drafting of the document and will have a key role to play to liaise with national governments and the European Commission.
2. **Besides a focus on specific diseases, a priority area for European institutions will be implementation of the EU-wide HTA Regulation.** The new EU-wide HTA legislation, which includes provisions on patient involvement, will allow national HTA bodies to take reimbursement decision directly reflecting patients' needs. In 2023, it is expected that the Commission will support national regulatory bodies to carry out and coordinate their scientific and clinical assessments. It will also provide them with specific training to consolidate their knowledge and experience on joint HTA work. It could be foreseen that stakeholder involvement is covered in the training, as it is part of the legislation, however this is not yet confirmed by the Commission.
3. **2023 will also mark two years before the end of the transition period between the adoption of the new EU-wide HTA Regulation and its application at EU-level.** PAGs will have two remaining years to prepare for the EU-wide HTA legislation coming into force. European institutions, as well as EUnetHTA, will jointly work together to publish guidance documents on patient involvement in HTA. It will be important for PAGs wanting to participate to be up to date with latest information. The first EU-wide HTA process for migraine, obesity and stroke medicines will take place in 2030 – the first rounds, starting in 2025, will focus on cancer medicines, Advanced Therapy Medicinal Products and orphan medicines.
4. **European institutions are revising the EU General Pharmaceuticals Legislation.** The text will put forward new responsibilities for the industry to foster innovation, including in areas of unmet medical needs, with the goal of improving access to medicines across the EU. The proposal is foreseen for Q1 2023, and depending on the contents of the text, and its potential impact on access to medicines,
5. **The health policy landscape will be influenced by the preparation of 2024's European elections.** In May and September 2024, the European Parliament will be elected and European Commission re-appointed. They will put forward new priorities. 2023 will be a key year for PAGs working on migraine, obesity and stroke to strategize and put together their policy asks for the new mandates ahead, which will set the direction of policy work until 2029.

4) Conclusion

2022 has been an active year in European health policy. From the publication of a proposal to build a European Health Data Space, to the ongoing revision of the EU General Pharmaceuticals Legislation, to the adoption of the EU-wide HTA Regulation. Each put patient empowerment and/or involvement at their core. The NCD Initiative, as explained by Arlene Wilkie from SAFE, provided a novel opportunity for patient involvement via a consultative process to develop the legislation. Opportunities at national level to support the implementation of this Initiative, supported by EU funding, will also provide further opportunities for PAG influence into 2023 and beyond.

Pfizer's fourth advocacy capability strengthening program aimed to remind participating PAGs of the importance of healthcare policymaking, to ensure current and future policies are representative of their needs. While 2023 will present more opportunities for influence, feedback gathered by both speakers and participants from this year's Summit confirmed that these will remain challenging. Patient involvement in the EU-wide HTA is a key example of this, where there remains no information on the type of expertise nor criteria required for patients to participate. PAGs will be called upon to provide input and unable to provide it proactively.

Feedback from across Pfizer's four Advocacy Summits, from PAG participants, has demonstrated that this capability strengthening program has helped PAGs to better understand how the patient voice is valued in healthcare policy decision-making and HTA, opportunities for patient involvement and next steps.