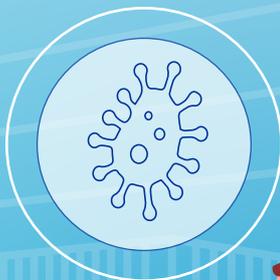
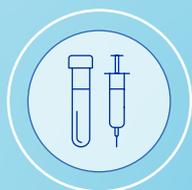




EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

STAKEHOLDER ENGAGEMENT BIENNIAL REPORT 2020-2021

Engaging with patients, consumers,
healthcare professionals and academia



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This report is dedicated to the memory of our friend and colleague Jordi Llinares Garcia for his commitment to improving the lives of patients and citizens in Europe.

I FOREWORD BY EMER COOKE

Collaboration with stakeholders has always been a high priority for EMA. Together a successful model of engagement has been built between regulators, patients, consumers, healthcare professionals and academics.



Despite the challenging time of the pandemic, stakeholder interactions have been maintained across all Agency activities with a focus on key areas such as shortages, big data, clinical trials and product information. Engagement has been strengthened in crisis management, ensuring that the voice of patients and healthcare professionals was listened to and taken into account as we responded to our biggest challenge in recent time.

EMA is continuing to implement the strategic goals of the European medicines' agencies network strategy to 2025 while also taking on a bigger role in crisis preparedness, medical devices and shortages of medicines as part of its extended mandate. The Agency is committed to continue communicating, involving and collaborating with its stakeholders as a priority towards better human and animal health in Europe.

I EXECUTIVE SUMMARY

The COVID-19 pandemic has affected lives globally, not only has there been the devastating impact on health but also long-lasting consequences that have affected everyday activities such as how and where we work to how we interact with each other. On the positive side, citizens gained greater awareness of the the work of regulatory authorities and how medicines, including vaccines, are developed and authorised. Unfortunately, disinformation around vaccines and vaccinations became a bigger issue during the pandemic, and regulatory authorities responded to this by monitoring public concerns on COVID-19 vaccines and producing and disseminating information in lay-language to address them.

EMA and the European Medicines Regulatory Network have played a critical role in the EU's response to the pandemic by accelerating the evaluation of COVID-19 vaccines and therapeutics, making them available to EU citizens in record time. Citizens were reassured that despite faster approvals, the same high regulatory standards were applied and that a robust safety monitoring system, able to rapidly process a high volume of safety information, was in place. This was coupled with an unprecedented level of transparency and communications about the vaccines and the regulatory processes underpinning their evaluation and authorisation.

The involvement of key stakeholders in EMA pandemic related activities was of high priority and patient and healthcare professional representatives were included in EMA's COVID-19 Taskforce (ETF) and participated in more than 85 meetings, respectively. In order to meet unprecedented information needs, key EMA public information on COVID-19 was reviewed by patients and healthcare professionals. Four public stakeholder meetings were held virtually, the first in December 2020 and then in January, March and November 2021. The enhanced use of digital engagement tools ensured that the public was informed along all stages of the development, approval, roll-out and safety monitoring of COVID-19 vaccines and therapeutics. The online events were held in collaboration with the European Commission and ECDC, covering issues of high public interest that went beyond EMA's remit. Active participation from the public enabled us to listen to them first-hand, to better understand and respond to the concerns raised.

Beyond the pandemic, EMA and the EU Network continued to work to maintain regular activities on non-COVID-19 medicines at the highest

level. Patients and healthcare professionals also remained very active in medicine-specific activities, as reflected by the numbers of interactions recorded during the reported period (1111 for patients and 378 for healthcare professionals). In addition, these patients, healthcare professionals and academics were extensively consulted and involved on many other initiatives such as Big Data, electronic product information, clinical trials regulation, ICH activities and support to academia, including fee waivers, etc.

We would like to thank all stakeholders for their continued commitment and expertise ensuring the high-quality of output of the work of EMA and the Regulatory Network and we hope to resume face to face meetings in the near future.

I STAKEHOLDER ENGAGEMENT DURING THE COVID-19 PANDEMIC

The COVID-19 pandemic has emphasised more than ever, the importance of engaging with patients and healthcare professionals.

This section describes their involvement in essential pandemic-related activities and also shows how EMA responded by providing clear information regarding treatment and vaccines for COVID-19 and implementing exceptional transparency measures.

EMA COVID-19 Taskforce (ETF)

In addition to the involvement of civil society in scientific committees, patient and healthcare professional representatives were included in EMA's COVID-19 Taskforce (ETF). The purpose of the ETF is to help EU Member States and the European Commission take rapid, coordinated regulatory action on the development, authorisation and safety monitoring of COVID-19 treatments and vaccines. In addition to members representing EMA committees and key working parties, the ETF includes members and alternates representing patients and healthcare professionals.

These stakeholders participate and witness first-hand how information on therapeutics and vaccines for COVID-19 is analysed across all regulatory phases. In addition to providing relevant input, they play a role in governance and transparency thus building trust in the regulatory decision-making process.

Importantly, they play a critical role in bringing the patient/consumer perspective, clinical expertise and frontline experience in the management of patients. This input is an important complement to all ETF's conclusions.

Patient representatives of EMA's eligible organisations were present at 86 ETF meetings in 2020 and 2021. Healthcare professional representatives contributed to 99 ETF meetings. They also engaged in activities that promoted the value of their role in the ETF (e.g. [scientific publication](#) and e-Poster).

Public stakeholder meetings

Public meetings were held online to inform citizens and stakeholder groups about the development, evaluation, approval, roll-out and safety monitoring of COVID-19 medicines. These meetings allowed active participation from the public and stakeholders who were able to ask questions and express any needs or concerns that arose during the pandemic.



All public meetings were broadcast live and recorded, and presentations published:

- [11 December 2020](#) EU regulatory process for approval of COVID-19 vaccines and EMA's role
- [8 January 2021](#) Basis for the approval and use of first COVID-19 vaccines & safety monitoring
- [26 March 2021](#) Update on COVID-19 vaccines, safety monitoring, and their expected impact at community level
- [25 November 2021](#) Update on COVID-19 vaccines, therapeutics, and an overview of vaccination coverage in the EU

Vaccine Outreach

Considering the uncertainties posed by the pandemic, EMA decided to increase its proactive monitoring of public concerns on vaccines to better understand and address any knowledge gaps. As a medicines Agency in this unique time, it is imperative to listen to and understand public concerns on vaccines and vaccination, and refer them to reliable sources that addresses their needs and concerns.

It is also very important to increase knowledge of and trust in the quality, safety and effectiveness of vaccines, and empower the public and healthcare professionals to make decisions based on evidence.

Therefore, EMA consulted patients, consumers, healthcare professionals and learned societies to user-test [key messages and graphics](#), ensuring that they were fit-for-purpose and requested feedback on the best communication channels and tools to reach EU citizens.

By reaching out to the public and communicating on vaccine science, EMA aimed to address both vaccine hesitancy and misinformation.

Communication and transparency

With diverse sources of information being overwhelmingly available, it becomes even more important for trusted sources, such as regulatory authorities, to communicate clearly, regularly and transparently. It was also important to be able to deal proactively with complex issues and to reach out to different target audiences. EMA's approach was to ensure that new information on development and approval of COVID-19 vaccines was made available quickly, specifically targeting the general public. With EMA and the EU Network in the public eye, the number of requests for information and access to documents increased dramatically.

In addition to the public meetings held for citizens, EMA is holding regular press briefings, media interviews and utilises the broad outreach of

social media to keep the public abreast of key developments. Other means for communicating on the Agency and Regulatory Networks' response to the pandemic, including some of the early learnings were have also been highlighted in scientific publications e.g. [Shaping EU medicines regulation in the post COVID-19 era](#)

Transparency and timely information on COVID-19, including clinical data supporting the various approvals, became more relevant than ever. Making clinical data publicly available supports global research and enables public scrutiny and independent review. Transparency is also key to reinforcing trust in regulatory decisions and in new medicines placed onto the EU market.

EMA took additional measures to provide high levels of transparency for COVID-19 medicines. These included publishing the full product information even before the formal marketing authorisation was granted. In addition, EMA expedited the publication of the full EPAR (European Public Assessment Report) and made the reports available soon after authorisation by the European Commission. EMA also published all clinical data submitted to EMA in applications for COVID-19 medicines, as well as the full risk management plan after assessment by the EMA's scientific committees.



I OVERVIEW OF ACTIVITIES 2020 AND 2021



In mid-November 2020, Emer Cooke took up the post as EMA Executive Director and became the first woman to lead EMA. In March 2021, she addressed the joint meeting of the Patients and Consumers Working Party (PCWP) and the Healthcare Professionals Working Party (HCPWP) for the first time and expressed her support and commitment for continued engagement with these stakeholders. 2020 was also the occasion of the 25th anniversary of the Agency and a [video](#) was created highlighting the key milestones since 1995.



In June 2020, an [early consultation with PCWP and HCPWP](#) was organised to collect views in the context of the revision of the Good Pharmacovigilance Practices (GVP) module addressing risk minimisation measures (GVP module XI). This module aims to clarify and enhance tools for risk minimisation measures (RMM) and strengthen methods for assessing effectiveness of RMM and the possible need for their adjustment in the interest of patient safety. It also includes guidance on the collaboration with patient and healthcare representatives during the related regulatory processes. This early engagement, which occurred prior to formal public consultation, provided additional insight on the feasibility of the proposal for guideline revision.



A workshop on the [revision of the ICH E6\(R3\) good clinical practice \(GCP\)](#) was held in June 2020. This guideline is the reference for conducting clinical trials globally and the purpose of its revision is to acknowledge the diversity of trial designs, data sources, and the different contexts in which clinical trials can be conducted. Engaging with patient representatives and academic clinical researchers is critical to ensure that the revision addresses key concerns expressed by stakeholders involved in clinical trials. Updates were also provided on revisions of ICH E8 and E6 in order to facilitate the development of new medicines, future trial designs and allow use of future data sources.



In September 2020, a joint meeting of the PCWP and HCPWP was organised on [the benefit-risk of medicines used during pregnancy and breastfeeding](#). In Europe, very few medicines are authorised specifically for pregnant or breastfeeding women, due to a limited understanding of the benefits and risks for mother and child. The workshop provided information on ongoing initiatives ([EUROmedicAT](#), [ConcePTION](#), [CONSIGN](#)) that address gaps in structured data collection and post-authorisation evidence generation targeting pregnant and breastfeeding women, which can be built on in the future. The fruitful discussions among participants and panellists will contribute to EMA's strategy for better information on benefits and risks of medicines in pregnancy and breastfeeding.



As of 2018, the General Data Protection Regulation (GDPR) created a new framework for the protection of personal data in the EU. An overview of the application of [GDPR in health and secondary use of data](#) was presented during a joint PCWP/HCPWP meeting in September 2020. At the time valuable insights were also provided into the European Commission's EU Health Data Space, the development of an EU-wide governance framework and code of conduct, and the work of the EMA-HMA joint Big Data Steering Group (BDSG). Input from stakeholders including patient and healthcare professional communities is critical for the progress of these EU initiatives. Their suggestions and concerns will also feed into a Question-and-Answer document EMA is preparing to help stakeholders navigate and understand the GDPR.



The academic sector plays an important role in the development of innovative medicines and a need to put structures in place to better support this group had been previously identified. Therefore, an Academia Liaison position was created in March 2020 based on the [Framework of collaboration between the European Medicines Agency and academia](#). The Academia Liaison coordinates our interactions with the academia network, co-designs events, training and educational opportunities for academia on relevant topics. It also supports the development of regulatory scientific strategies, the involvement in EU-funded projects, and communication with key

European institutions. In addition, the Academia Liaison functions as the contact point for academia to interact with EMA and its network.



Early interactions with EU regulators are important for academia to understand the regulatory requirements and allow the generation of robust evidence needed to establish the medicines' benefits and risks. This helps them to navigate the regulatory process and ultimately translate their discoveries into authorised, patient-focused medicines. Based on feedback received from academia, which indicated that regulatory fees for protocol assistance (scientific advice for orphan medicines) represented a hurdle to engaging with EMA, the Agency decided in June 2020 to [waive all fees for scientific advice for academia](#) developing orphan medicines.



A second multi-stakeholder [workshop](#) on electronic product information (ePI) was organised by EMA in July 2021. Updates were provided on the project deliverables such as the development of a draft EU common standard and a proof-of-concept prototype for ePI. Participants' feedback from the workshop as well as the results from a public consultation informed the final common EU electronic standard and roadmap, which will help to ensure that the project will meet the needs of future users to access, view, and disseminate product information in an electronic format.



In July 2021, a joint meeting was held for the first time between [EMA's Patients and Consumers Working Party \(PCWP\)](#) and [FDA's Patient Engagement Collaborative \(PEC\)](#) to exchange ideas and experiences about their involvement in the work of EMA and FDA respectively. The PEC is a collaborative initiative between the FDA and the Clinical Trials Transformation Initiative (CTTI) and was modelled on EMA's PCWP. The purpose of the PEC is to discuss the engagement of patients in medical product development and regulatory discussions. This first meeting between the transatlantic groups provided the opportunity for members to meet virtually and discuss common topics related to patient engagement and collaboration with and between regulatory agencies around patient involvement. A full meeting report is [available](#). Based on a successful first experience, it was agreed that a joint meeting would take place annually.



During the 2019 [lessons learnt](#) exercise that was undertaken following the identification of nitrosamine impurities in a number of medicines, healthcare professional and patient organisations gave feedback on EMA's public communication. EMA is currently implementing recommendations on communication and has made some changes, including the setting up of a dedicated webpage with information on nitrosamines. EMA will continue working with partners in the EU regulatory network to safeguard the quality of medicines and improve communication about nitrosamine impurities to stakeholders and the public.



An [HMA-EMA joint Big Data Steering Group \(BDSG\)](#) was created, aiming to implement key recommendations on how to increase the use of big data in medicine regulation. Two virtual multi-stakeholder workshops in December [2020](#) and [2021](#) provided updates on the BDSG's patient-focused workplan, its ongoing activities, and its expected deliverables (e.g. [DARWIN EU](#)). Speakers from different stakeholder groups provided feedback on the Big Data recommendations and discussed what they considered benefits, challenges, and areas for collaboration. An active dialogue with key EU stakeholders, including patients and healthcare professionals, remains one of the top priorities for the next two years, with representatives of patient and healthcare professional groups being appointed to the BDSG and the DARWIN EU Advisory Board.



The Clinical Trials Regulation came into force end January 2022 and will change the way clinical trials are conducted in the EU by harmonising the assessment and supervision processes. This will be facilitated via a [Clinical Trials Information System \(CTIS\)](#). The PCWP and HCPWP have been regularly updated on progress and input from patients, healthcare professionals and academia was collected. CTIS is now live and will be maintained by EMA in collaboration with the EU Member States and the European Commission. It will provide a centralised EU portal and database for clinical trials as foreseen by the Regulation. Authorisation and oversight of clinical trials will remain the responsibility of Member States, with EMA managing CTIS and supervising content publication on the public website. Members of the

public will be able to access detailed information on all clinical trials conducted in the EU, in all official EU languages.



The Academia Collaboration Matrix, an Agency-wide infrastructure established in September 2021, aims to coordinate activities in relation to academia in a consistent, systematic and efficient manner. The Academia Collaboration Matrix has developed an [Action Plan](#) that is in line with the EMA [programming document 2022-2024](#), the [Regulatory Science Strategy to 2025](#), and that captures the objectives that the Agency must pursue in order to achieve optimal collaboration with academia. The implementation of the outlined actions requires a cross-Agency approach to ensure that this collaboration is coordinated, builds on knowledge-sharing, and empowers the different EMA departments to progress in their partnership with academia in five strategic domains, namely regulatory science and partnerships, innovation, communication, training and events.



The regulation of medicines must keep up with the changing pace of evolving science and medicine development while maintaining its high regulatory standards and expertise. Regulators should also foster the translation of basic research and innovation into patient-centred access to medicines. To help achieve this, EMA undertook an extensive period of outreach, analysis and consultation with its scientific committees, stakeholders and EU regulatory partners. Shaped by this input, the EMA finalised its [5-year strategy](#), which was published in March 2020. Using analyses from the public consultation and the current knowledge gaps in regulatory science, a core set recommendations were prioritised and compiled into the '[EMA Regulatory Science Research Needs \(RSRN\)](#)' which is an initiative to stimulate researchers and funding organisations to support addressing these needs, and for which both PCWP and HCPWP also provided their contribution.



Stakeholder contribution was also key during the development of the [European medicines agencies network strategy to 2025](#), which sets out how the network will enable the supply of safe and effective medicines in the face of developments in science, medicine, digital technologies, globalisation and emerging health threats, such as the COVID-19 pandemic. The strategy, which was published in December 2020, outlines six priority focus areas in line with the European Commission's roadmap for a

[Pharmaceutical strategy for Europe](#): availability and accessibility of medicines, digital transformation, innovation, antimicrobial resistance and other emerging health threats, supply-chain challenges and sustainability of the network and operational excellence. Development of the strategy took account of early consultative input from patient, consumer and healthcare professional organisations, academia and veterinary stakeholders, as well as stakeholder feedback received through a two-month public consultation on the draft strategy.

Future steps



In the wider context of the EU pharmaceutical strategy, the overarching initiative setting the direction of future EU pharmaceutical policy, EMA's interactions with its stakeholders will continue to be aligned to and support the implementation of EMA's Regulatory Science Strategy to 2025 and the European Medicines Agencies Network strategy to 2025. Activities will focus on the priorities and objectives presented in EMA's Multi-annual programming 2022–2025 and the single programming document 2022–2024.

This will include implementation of activities to extend EMA's mandate to i) ensure a high level of human health protection by strengthening the Union's ability to manage and respond to public

health emergencies, which have an impact on medicinal products and medical devices and ii) contribute to ensuring the smooth functioning of the internal market for such products during public health emergencies.

The specific objectives of the initiative are described in the figure below.

In the coming years, lessons learned from the pandemic will be analysed and discussed with stakeholders and will inform future reviews of EMA's work and strategies as well as future work plans. The specific objectives of the initiative setting the direction of future EU pharmaceutical policy are shown in Figure 1.

Figure 1: Specific objectives of the initiative setting the direction of future EU pharmaceutical policy.

Medicines' shortages



- Establishment of Medicines steering group
- Updated role of EU SPOC network to include the reporting of events
- Single reporting channel
- Publication of list of critical medicines and outcome document

Medical devices' shortages



- Establishment of MDSG
- Establish ISPOCs
- Publication of list of critical devices and outcome documents

Emergency task force



- Update ETF mandate
- Vaccine platform and DARWIN
- Publication and dissemination of outcomes documents

Medical devices' panels



- Setup of permanent secretariat to support expert panels
- Rules of procedures

Patients

Looking ahead, EMA remains committed to ensuring that the patient voice is systematically incorporated throughout medicines' development and evaluation, including during evidence generation and will:

- Implement the updated framework for engaging patients and their organisations in the Agency's activities;
- Continue to explore additional methodologies to gather and use patient data from the wider patient community (e.g. patient preferences, patient reported / relevant outcomes, quality of life measurements, real-world evidence);
- Report on CHMP pilot on early dialogue with patient and consumer organisations in rare diseases;
- Continue to work towards developing global guidance on the collection and use of patient experience data.

Healthcare professionals

EMA is also enhancing interactions with healthcare professionals, including doctors, pharmacists and nurses, to:

- Initiate revision of framework of interaction with healthcare professionals and their organisations;
- Support the Agency in order to access the best possible independent expertise in clinical practice, to incorporate the real-world experience into drug development, benefit/risk evaluation and monitoring;
- Contribute to more efficient and targeted communications to healthcare professionals, which can in turn facilitate information transfer for the patient journey as a means to promote patient safety and optimal use of medicines;
- Better manage and prevent shortages of authorised medicines;

- Continue engaging with healthcare professionals in clinical research and practice on areas such as clinical trial design, personalised medicine, and use of real-world evidence;
- Enhance healthcare professionals' organisations' understanding of the role and activities of the EU medicines Regulatory Network.

Academia

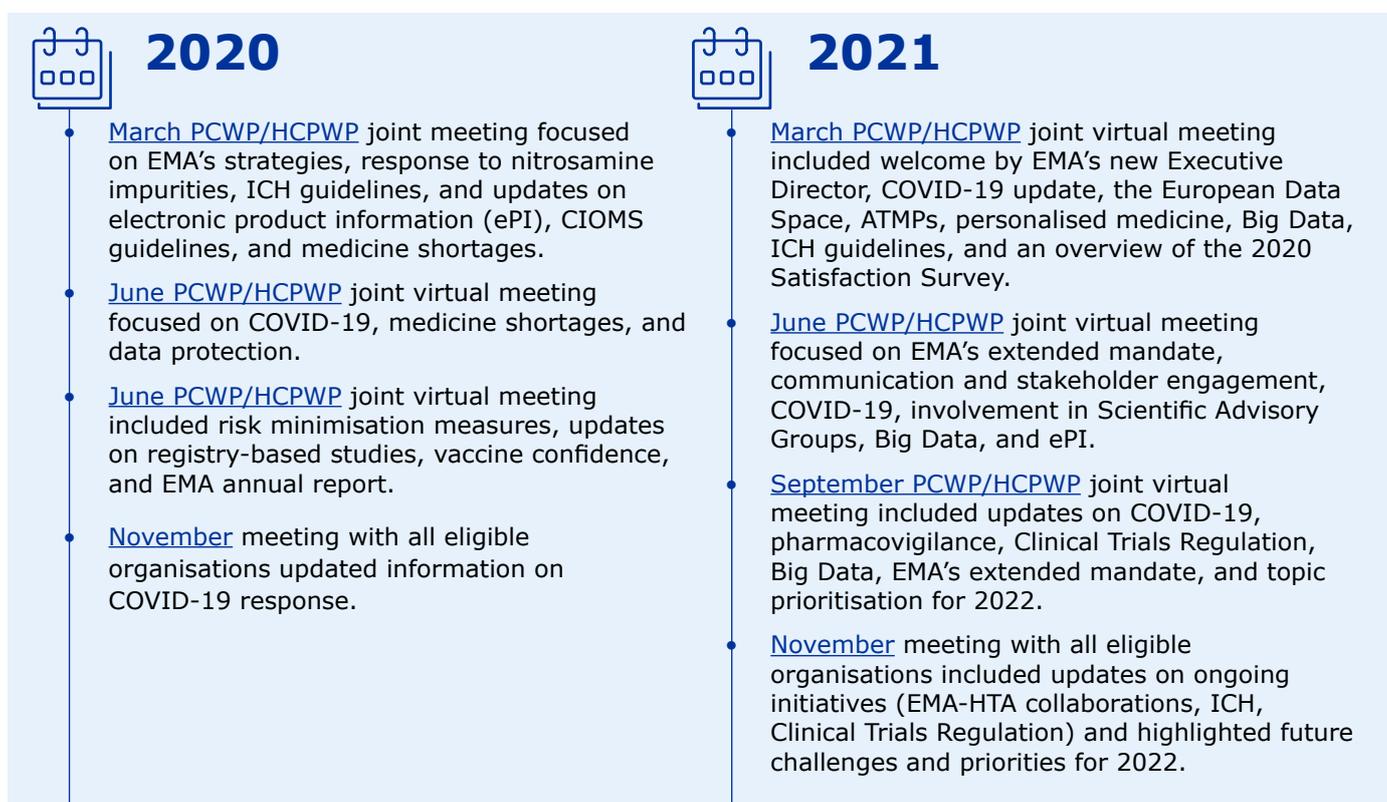
Interactions and engagement with academia and innovators are co-ordinated by the Regulatory Science and Innovation Task Force within EMA and will be reinforced via:

- Interactions with researchers and funding organisations concerning opportunities for research to address regulatory science gaps following the [launch](#) of the [Regulatory Science Research Needs](#) initiative;
- Learning more from academia about their needs and optimising the use of the academia network to better identify and provide support to independent researchers and groups;
- Continued support to develop and provide training to academia, taking into account curricula such as those being developed for ACT EU and prepared by the STARS project in collaboration with national competent authorities to their national academia groups via the EU Innovation Network;
- Continued [collaboration](#) and support to EU-wide research and development platforms and consortia (e.g. funded under Horizon Europe, specifically the Innovative Health Initiative (IHI), considering the [criteria and process for engaging in externally funded regulatory science projects for public and animal health](#));
- Liaising with national academia groups in close collaboration with national competent authorities and the European Innovation Network (EU-IN)

PATIENTS' AND CONSUMERS' (PCWP) & HEALTHCARE PROFESSIONALS' (HCPWP) WORKING PARTIES

Despite the challenges posed by the global pandemic, as seen in Figure 2 the working parties continued to meet and work effectively over the past two years. They adapted well to the virtual environment and continued to collaborate and produce results at a high-level.

Figure 2: The Patients' and Consumers' (PCWP) and Healthcare Professionals' (HCPWP) working parties held the following meetings in 2020 and 2021



Satisfaction survey to all eligible organisations



EMA received feedback from 82 patients and healthcare professionals about their involvement in EMA activities using its biennial satisfaction survey. Over 91% of stakeholders polled said that they were satisfied or very satisfied with their interactions with EMA and over 78% found that their contribution was useful or very useful. Comments provided will inform and facilitate future engagement activities.

In December 2021, EMA's network of:

- Eligible patient and consumers organisations reached a total of 39 organisation
- Eligible healthcare professional organisations reached a total of 39 organisations.

KEY ACTIVITIES: PATIENTS

Patient engagement is critical at all stages of medicines development with early dialogue playing a particularly important role.



Engagement framework: EMA and patients, consumers and their organisations

The framework of EMA interaction with patients' and consumers' organisations was originally adopted by the Management Board in 2005 and revised in December 2014. As engagement has evolved and adapted with increased experience, new legislations, advances in science and crisis situations, the framework has been revised and updated. The framework now titled 'Engagement framework: European Medicines Agency and patients, consumers and their organisations' better reflects EMA's relationship with these stakeholders and continues to allow the Agency to obtain their valuable input and build transparency and trust in EMA and the EU Regulatory System.

[View full engagement framework document](#)



CHMP pilot - early interactions with patients

To enhance the way CHMP currently interacts with patient groups during the assessment of new medicines, a proposal for a pilot was made to reach out to relevant patient/consumer organisations at the start of the evaluation of new Marketing Authorisation Applications (MAAs). This enables patients to share their experiences and concerns about their condition(s) and key aspects that are important to them. The CHMP is able to take these contributions into account in a timely manner during the assessment process.

The pilot was launched in 2021 and has been extended by an additional six months, with an end date of mid-2022. As of December 2021, patients had been involved in early dialogue for 28 orphan medicines in therapeutic fields including haematology, oncology, neurology and endocrinology.

[View full CHMP pilot article](#)



Joint meeting of EMA's PCWP with FDA's PEC

A virtual meeting was organised between members of EMA's PCWP and the US-Food and Drug Administration/Clinical Trials Transformation Initiative (FDA/CTTI) Patient Engagement Collaborative (PEC) for the first time. The purpose of the meeting was to facilitate discussion and share ideas between members with geographical diversity but common interest. Topics included the importance of collaboration between regulatory agencies, patient groups, and communities. There was a particular focus on engaging young people in relevant discussions. Based on the successful experience, this meeting is now planned to take place annually.

[View join meeting of EMA's PCWP with FDA's PEC meeting detail](#)



ICH consultation on patient focused drug development guideline

ICH has developed a reflection paper on Patient Focused Drug Development with the aim of harmonising the approach to include patients' perspectives into medicine development and regulation. This reflection paper identifies a series of questions related to medicine development and regulatory decisions and proposes potential guideline work for ICH to outline methods and standards to be applied when collecting and incorporating patient perspectives to address these questions. A public consultation on this reflection paper took place in March 2021.

[View full ICH consultation guideline](#)

Patient involvement in medicine-related activities

EMA continues to involve patients in scientific meetings such as scientific advice and scientific advisory/ad hoc expert group meetings wherever possible. Information sheets have been created and updated to highlight the process and the added value of patient involvement.

Scientific advice (SA) and protocol assistance (PA)

[The Added Value of Patient Engagement in Early Dialogue at EMA: Scientific Advice as a Case Study](#)

EMA has published an article that reinforces the importance of contributions to the regulatory process and highlights the added value that is brought by people living with conditions as patients, carers, parents or even as patient representatives. The comparison of scientific advice and protocol assistance that EMA received is shown in Figure 3.

[View SA and PA info sheet](#)

Figure 3: Comparison of SA and PA 2020 - 2021

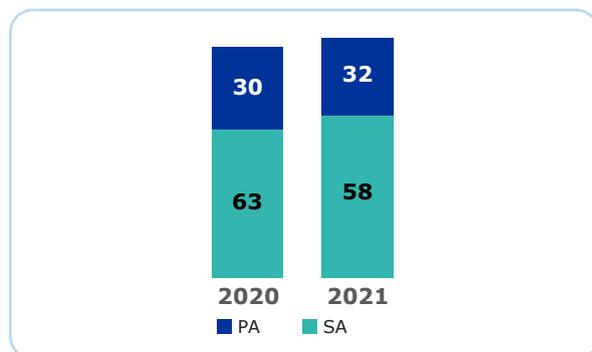
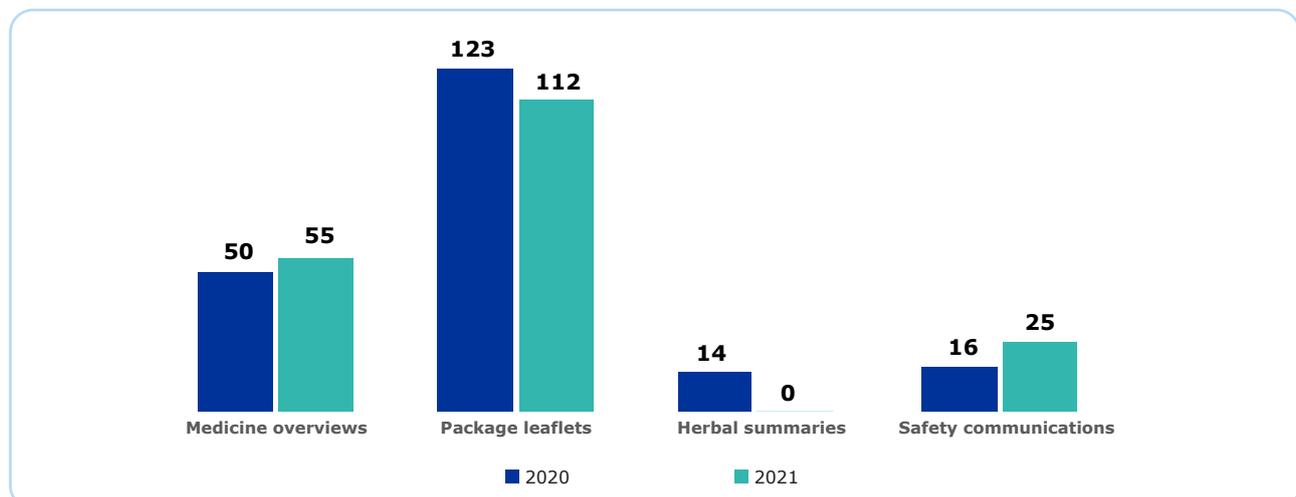


Figure 4: Review of EMA documents



Scientific advisory groups (SAG) and ad hoc expert groups

In 2020, 42 patients and carers participated in 22 SAG/Ad-hoc meetings and in 2021, 25 patients and carers provided input to 14 SAG/ad-hoc meetings. Patients shared their experience in therapeutic fields such as neurology, oncology, haematology, and viral disease. The information sheet for patients participating in scientific advisory groups has been updated.

[View scientific advisory groups and ad hoc expert groups info sheet](#)

Scientific committee consultations

During the review of a medicine, EMA scientific committees may need to reach out to patients with experience of the condition being treated in order to obtain specific information. Several patients were consulted in 2020 and 2021 and invited to provide comments in person (in virtual meetings) or in writing.

The detail of scientific committee consultations can be seen in Table 1.

Review of documents

Documents destined for patients and the general public are reviewed by patients prior to publication. The suggestions and comments made by patients help to ensure that the documents address the targeted audience and use the right language to ensure the message is clear and understandable.

As seen in Figure 4 the review of herbal summaries was on hold in 2021 due to the business continuity planning under which the Agency has been working due to the ongoing COVID-19 pandemic.

Table 1: Scientific committee consultations

Year	Committee	N. consultations*	N. patients consulted
2020	Committee for Orphan Medicinal Products	2	2
	Committee for Advance Therapies	3	3
	Pediatric Committee	3	163
	Committee for Medicinal Products for Human Use	12	25
	Committee on Herbal Medicinal Products	1	7
2021	Committee for Orphan Medicinal Products	5	7
	Committee for Advance Therapies	1	1
	Pediatric Committee	1	8
	Committee on Herbal Medicinal Products	25	28
	Committee for Advance Therapies /Committee on Herbal Medicinal Products*	2	4
	EMA consultations (product related)	6	7

*Consultations were in writing or in person.

KEY ACTIVITIES: HEALTHCARE PROFESSIONALS

The perspectives of practicing clinicians, specialised nurses and pharmacists are critical to discussions around the real-life implications of clinical study design and clinical benefit of candidate medicines.



Survey to HCP eligible organisations on satisfaction and priorities

In early 2021, a survey of healthcare professional organisations was conducted in order to gather information about the added value of interacting with EMA, the benefits of involvement in the HCPWP and how to maximise the interactions. EMA received feedback from 20 healthcare professional organisations in this first of its kind survey. The majority of respondents considered being an EMA eligible organisation to be of high value and important feedback was provided on prioritisation of topics for discussion. This feedback will guide future interactions with healthcare professional organisation and the survey is planned to be repeated in 2023.



Policy officers' group (POG) pilot

The creation of a healthcare professionals policy officers' group (HCP POG) emerged from interactions with EMA eligible healthcare professional organisations over the years. Organisations increased their interactions with EMA through newly appointed policy officers, who also maintained regular contacts with EMA and active contributions and handled requests for experts and consultations. Therefore, a pilot was launched, and six meetings were held in 2021. The HCP POG added value and complemented HCPWP activities. Overall feedback from organisations and EMA on usefulness and benefit of the HCP POG was very positive and the pilot will be extended into 2022.



EMA and Healthcare professional framework: Ten years of cooperation

December 2021 marked ten years of cooperation between EMA and healthcare professionals under a formal framework of interaction. Doctors, nurses, and pharmacists contribute to EMA's mission by offering independent expertise and by facilitating communication with the wider community of healthcare professionals across the EU.

- This report summarises experience including:
- Types of organisations that EMA has been interacting with;
- Steps that led to the framework;
- Key milestones;
- Directions for future interactions.

[View EMA and Healthcare professional framework full document](#)

Healthcare professional involvement in medicine-related activities

Scientific advice (SA) and Scientific advisory groups (SAG) and Ad hoc expert groups

Consultation of practicing clinicians can provide valuable insight into unmet needs, current medicines in use and how they are used as well as a perspective based on real-life of how regulatory decisions can be translated into clinical practice. In 2020 and 2021, healthcare professional individual

experts contributed to scientific advice procedures during the development of medicines on five occasions in 2020 and 2021.



In 2020, 39 healthcare professionals participated in 18 SAG/Ad-hoc meetings and in 2021, 21 experts contributed to 12 SAG/Ad-hoc meetings. Healthcare professionals shared their expertise in therapeutic fields such as psychiatry, neurology, oncology, haematology, immunology, and respiratory diseases.

Scientific committee consultations

During the review of a medicine, EMA scientific committees may need to reach out to various healthcare professionals specialised in different areas to obtain specific information. Several healthcare professionals were consulted in 2020 and 2021 and invited to provide comments in person (in virtual meetings) or in writing.

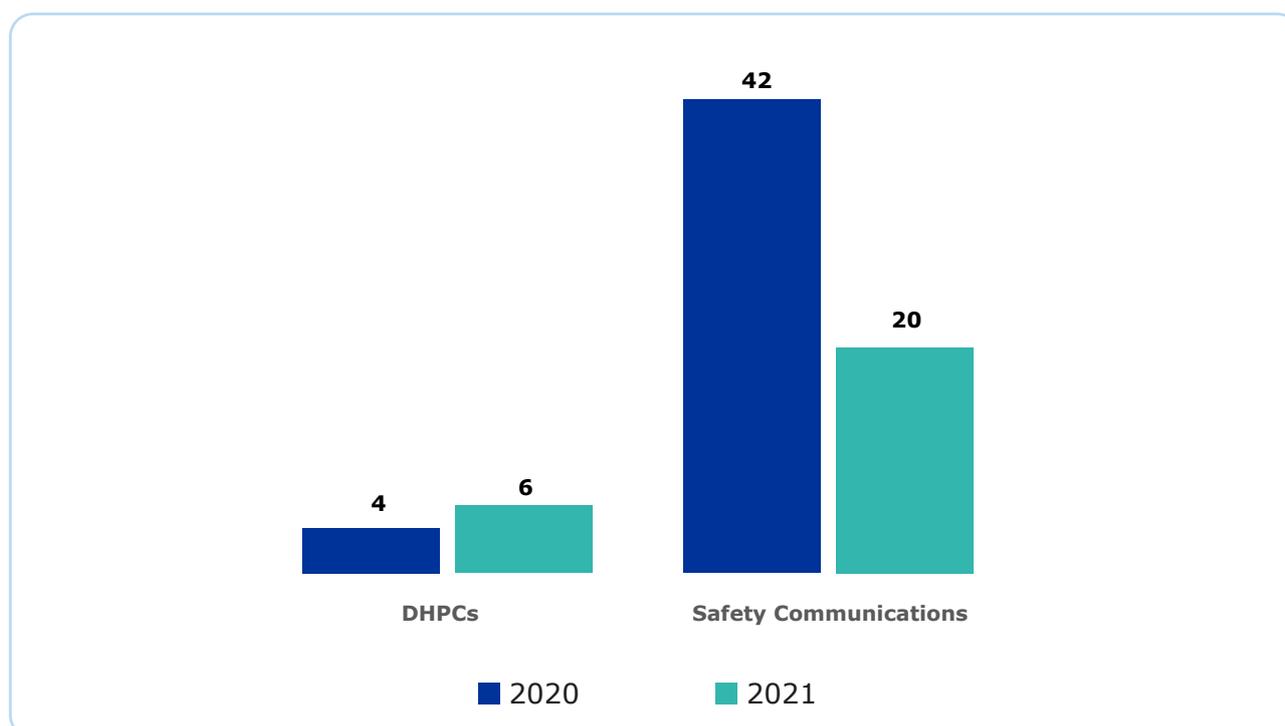
The detail of scientific committee consultations can be seen in Table 2.

Table 2: Scientific committee consultations

Year	Committee	N. consultations*	N. expert consulted
2020	Committee for Advance Therapies	1	1
	Committee on Herbal Medicinal Products	2	2
	EMA consultations	1	1
2021	Committee for Advance Therapies	1	1
	EMA consultations	9	18

*Consultations were in writing or in person.

Figure 5: Review of EMA documents





Review of documents

Safety communications are used to convey important information about the risks of a medicine. The review of these documents by healthcare professionals is beneficial for ensuring that the advice provided is relevant and implementable in practice. Direct healthcare professional communication (DHPC) are sent to healthcare professionals to inform them of important new safety information about a medicine and any actions they should take. The statistic of EMA documents is shown in Figure 5.

KEY ACTIVITIES: ACADEMIA

In December 2021, EMA's network of academia stakeholders reached a total of 78 European organisations.

The Academia Liaison (created 2020) is responsible for managing the academia network, co-designing events, training, supporting the development of regulatory scientific strategies, involvement in EU-funded projects, and communication with key European institutions.

Contact: academia@ema.europa.eu



Action Plan 2021-2023

The Academia Collaboration Matrix has developed an Action Plan that was conceived as a tool to deliver on activities identified in EMA strategic plans while giving due consideration to the environment in which the Agency operates, including resource availability. The actions outlined in the plan aim to maintain a strong engagement with academia, learned societies and research groups and are grouped along five themes: regulatory science and partnership, innovation and support for academia, communication, events strategy, and training. Implementation of the actions began in early 2021

[View action plan full document](#)



EU-funded projects and EMA engagement

The European Medicines Agency participates in externally funded research projects as part of its mission to foster scientific excellence in the evaluation and supervision of medicines, for the benefit of public and animal health. It is important for the Agency to actively support science in relevant areas, as defined in the European Medicines Agencies Network Strategy, the EMA work programme and the Regulatory Science Research Needs. Involvement of EMA must be aligned with its mandate, priorities, and use of resources.

EMA staff may play the following roles in externally funded research projects: i) Consortium partner, ii) Advisory board member or iii) Routine regulatory interactions e.g. ITF.

EMA is involved in research projects that are part of the Innovative Medicines Initiative (IMI). As of today, EMA has contributed to 39 IMI-projects as consortium leader (2), consortium member (8), member of the advisory board (27), steering committee member or associate partner.

IMI projects have generated 1,220 scientific publications. The key areas of engagements include:

- Clinical trial design
- Infectious disease
- Regulatory and HTA process support
- Real-world data and real-world evidence
- Tools to predict and monitor medicine safety

[View EU-funded projects and EMA engagement full document](#)



Regulatory Science Research Needs (RSRN)

Agencies that regulate medicines need to respond to the accelerating pace of change in medicine development, while maintaining the high standard required. Regulators should also foster the translation of innovation into patient-centred access to medicines. Following an extensive period of outreach, analysis and consultation with its scientific committees, stakeholders and EU regulatory partners, EMA has identified several topics where research is needed to address knowledge gaps in regulatory science that are expected to have the greatest impact on improving patient-centred evidence generation. By publishing this list, EMA hopes to stimulate research addressing those needs to support medicine development and evaluation.

[View RSRN full document](#)



Strengthening Training of Academia in Regulatory Science (STARS)

In the context of EMA's commitment to further engage with and train (early career) researchers in regulatory science, EMA co-hosted a STARS multi-stakeholder meeting November 2021 and actively contributed to the development of the STARS strategic document, including core curriculum and comprehensive curriculum.

[View STARS full document](#)

Workshops for academia

A number of workshops for academia were organised during the reporting period.

- Workshops (co)-organised by academia liaison (2020-2021):
- Regulatory training course/workshop for ATMP developers jointly with EATRIS (October 2020)
- DIA session to improve awareness of regulatory tools for academia developers (March 2021)
- Lunch Talk (EIT-health) (Sept 2021)
- CTIS and CTR webinar for academia and SME (Nov 2021)
- Workshops for academia (where academia liaison not being the primary organiser) in 2021:
- CTIS training for academia and SME (Feb 2021)
- EU-PAS register awareness webinar for academia (March 2021)

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Stakeholder Engagement biennial report 2020–2021: Engaging with patients, consumers, healthcare professionals and academia
EMA/562976/2021

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