EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

2019-2022 working party mandate highlights

PCWP/HCPWP joint meeting, 3 March 2022

Presented by Maria Mavris
Public and Stakeholders Engagement Department, EMA

An agency of the European Union

Final meeting of the 2019-2022 mandate

The working parties….

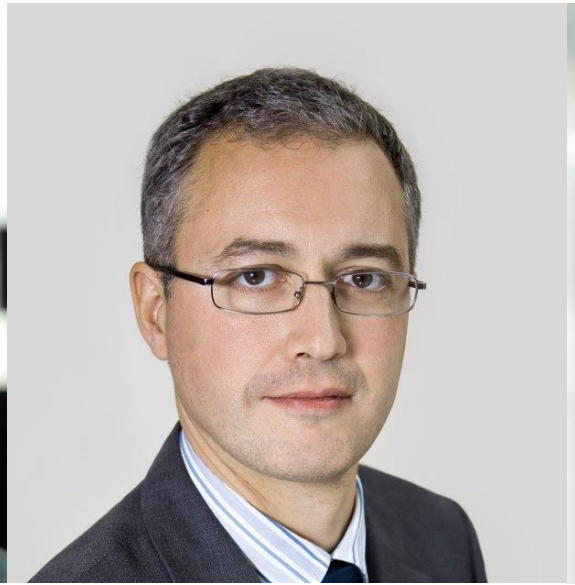
PCWP

HCPWP

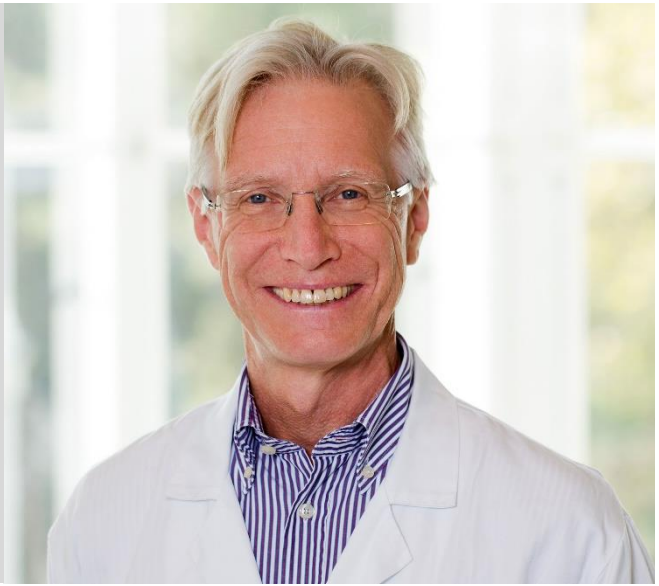
with the Co-chairs:

Kaisa Immonen, PCWP Co-Chair

Juan Garcia Burgos, EMA



Ulrich Jäger, HCPWP Co-Chair



and support from:

PCWP secretariat

Maria Mavris

Nathalie Bere

Nora Lazaro

HCPWP secretariat

Ivana Silva

Zhenya Shtereva

and Public and Stakeholder Engagement Department:

A mandate that began like any other….

2019

Workshops

General practitioners

Family physicians

RSS 2025

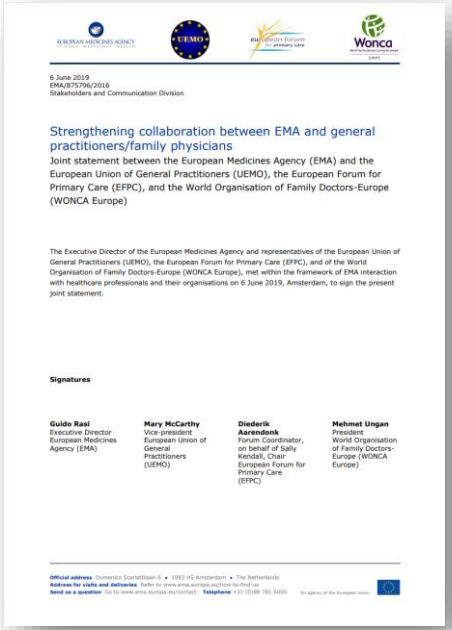
EVIP

Vaccination portal

Public consultations

Survey on antibiotic use and resistance

Strengthening collaboration between EMA and general practitioners / family physicians



6 June 2019
EMA/875796/2016
Stakeholders and Communication Division

Strengthening collaboration between EMA and general practitioners/family physicians

Joint statement between the European Medicines Agency (EMA) and the European Union of General Practitioners (UEMO), the European Forum for Primary Care (EFPC), and the World Organisation of Family Doctors-Europe (WONCA Europe)

The Executive Director of the European Medicines Agency and representatives of the European Union of General Practitioners (UEMO), the European Forum for Primary Care (EFPC), and of the World Organisation of Family Doctors-Europe (WONCA Europe), met within the framework of EMA interaction with healthcare professionals and their organisations on 6 June 2019, Amsterdam, to sign the present joint statement.

Signatures

Guido Rasi
Executive Director European Medicines Agency (EMA)

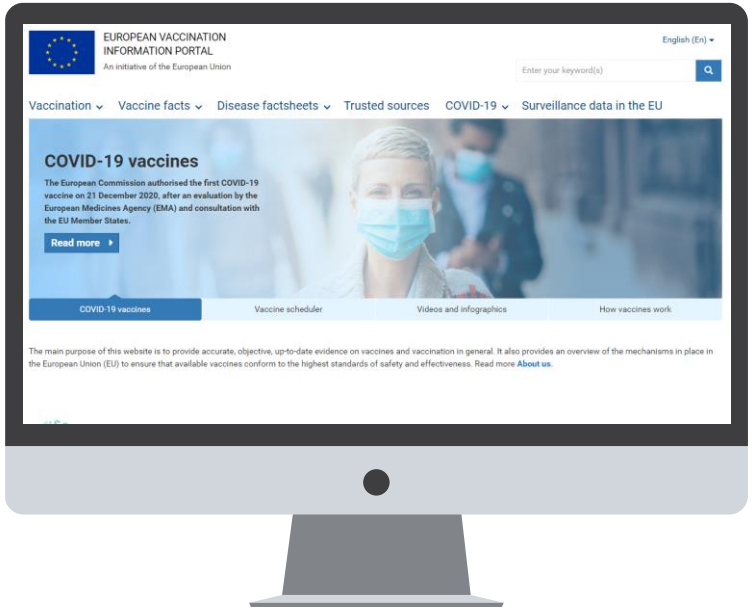
Mary McCarthy
Vice-president European Union of General Practitioners (UEMO)

Diederik Aarendonk
Forum Coordinator, on behalf of Sally Kendall, Chair European Forum for Primary Care (EFPC)

Mehmet Ungan
President World Organisation of Family Doctors-Europe (WONCA Europe)

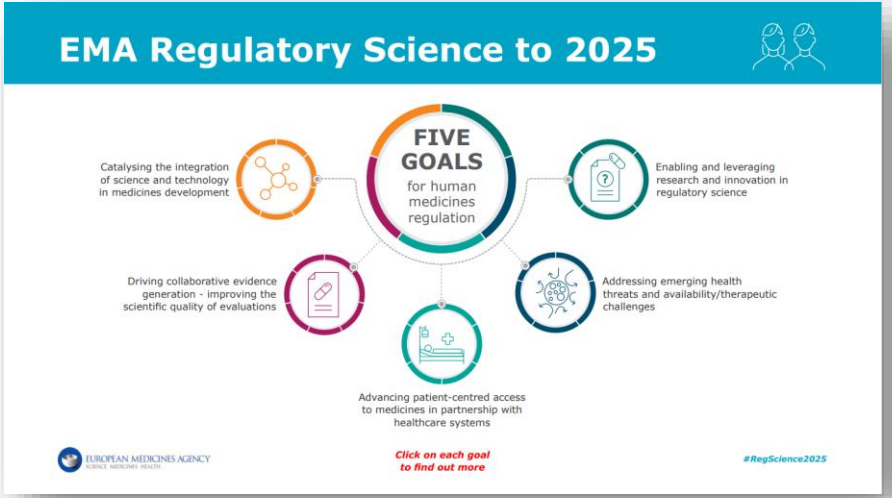
European Vaccination Information Portal (EVIP)

WPs involved in user-testing of the public portal

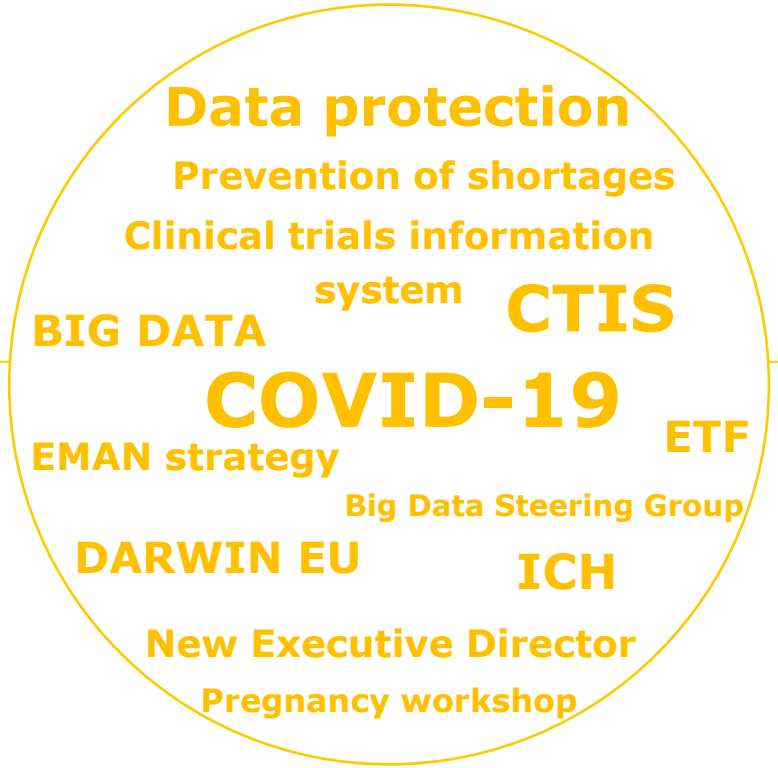


ECDC survey with healthcare professionals on antibiotic use and resistance

EMA Regulatory Science to 2025, multi-stakeholder workshop



2020



HMA EMA Joint Big Data Steering Group

Jelena Malinina (BEUC)

Ioanna Agache (EAACI)

Topic Group on data protection

Stacey Grealis (EULAR PARE)

Marilena Vrana (EHN)

Kieran Breen (EPDA and CAT member)

Laure Gossec (EULAR)

Tjalling van der Schors (EAHP)

DARWIN EU Advisory Board

Elizabeth Vroom (UPPMD)

Aldo Maggioni (ESC)

Clinical Trials Information System (CTIS)

WPs involved in testing of the public portal

CTIS HIGHLIGHTS Issue 1 June 2020 Page 4

Stakeholder Engagement

The involvement of stakeholders (EU Member States; sponsors – industry; sponsors – academia; EU Institutions and groups; Non EU governance bodies; EU national governance bodies; international healthcare and standardization bodies; EMA committees and management; public, patients and healthcare professionals) in the elaboration of CTIS was ensured at very early stage. It was done via the stakeholders consultations EMA held on the draft functional specifications in 2014 and on implementing the transparency rules in 2015.The feedback received was thoroughly analysed and used when appropriate as an input for further system advancement. A training was organised in 2014 and a series of workshops aiming to seek users input in the course of 2017 and 2018. The collaboration with stakeholders continues through the regular meetings held with the CTIS Members States' Group, CTIS Expert Group and CTIS Stakeholders' Group in order to inform attendees about the progress in the delivery of CTIS , the future actions planned, as well as to provide feedback from the past governance groups meetings. Currently the stakeholders as well as general public are kept informed about the CTIS state of play via the respective sections on the corporate website and User community Confluence website.

Product Owners nominated from the Member States and the sponsor associations are directly involved in all phases of the CTIS delivery. They provide direct input to the IT developer, regarding the existing and expected system functionality and are the main source of business requirements. The Product Owners are involved in multiple activities like assessing the Audit and Go-live readiness of the system, establishing the delivery priorities to prepare the system for audit, describing to the IT developer how the system should behave to comply with the Regulation and with the user needs, and verifying that the system is being delivered in alignment with their expectations and in compliance with the Regulation.

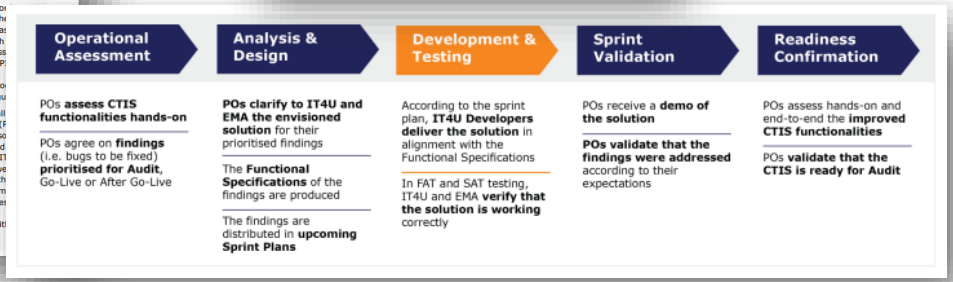
The governance structure of CTIS consists of EMA's Management Board (EMA MB), EU CTR Coordination Group, CTIS Expert Group, CTIS Members States' Group and CTIS Stakeholders' Group. The EMA MB is the EMA's integral governance body and has a decision-making role. It has the oversight of the CTIS governance. The EU CTR Coordination Group, supported by the Monitoring Subgroup, has also a decision-making role at strategic level, monitoring the implementation activities in relation to the Regulation and coordinating the activities of the various working parties. The CTIS Expert Group participates in the decision-making from a tactical level, contributing with expertise to the definition and development of the system. The CTIS Members States' Group and the CTIS Stakeholders' Group do not possess decision-making roles.

Delivery Model of CTIS

The current delivery model of CTIS was implemented in 2019 and is based on agile design and development principles that entail an iterative methodology with short cycles (sprints – lasting 4 weeks and releases – consisting of 3 sprints and lasting 12 weeks) to promote better planning of design, development, end user testing and validation, as well as better engagement with the stakeholders. It consists of different phases: release planning, analysis and design, sprint planning and development and testing. (Image 6).

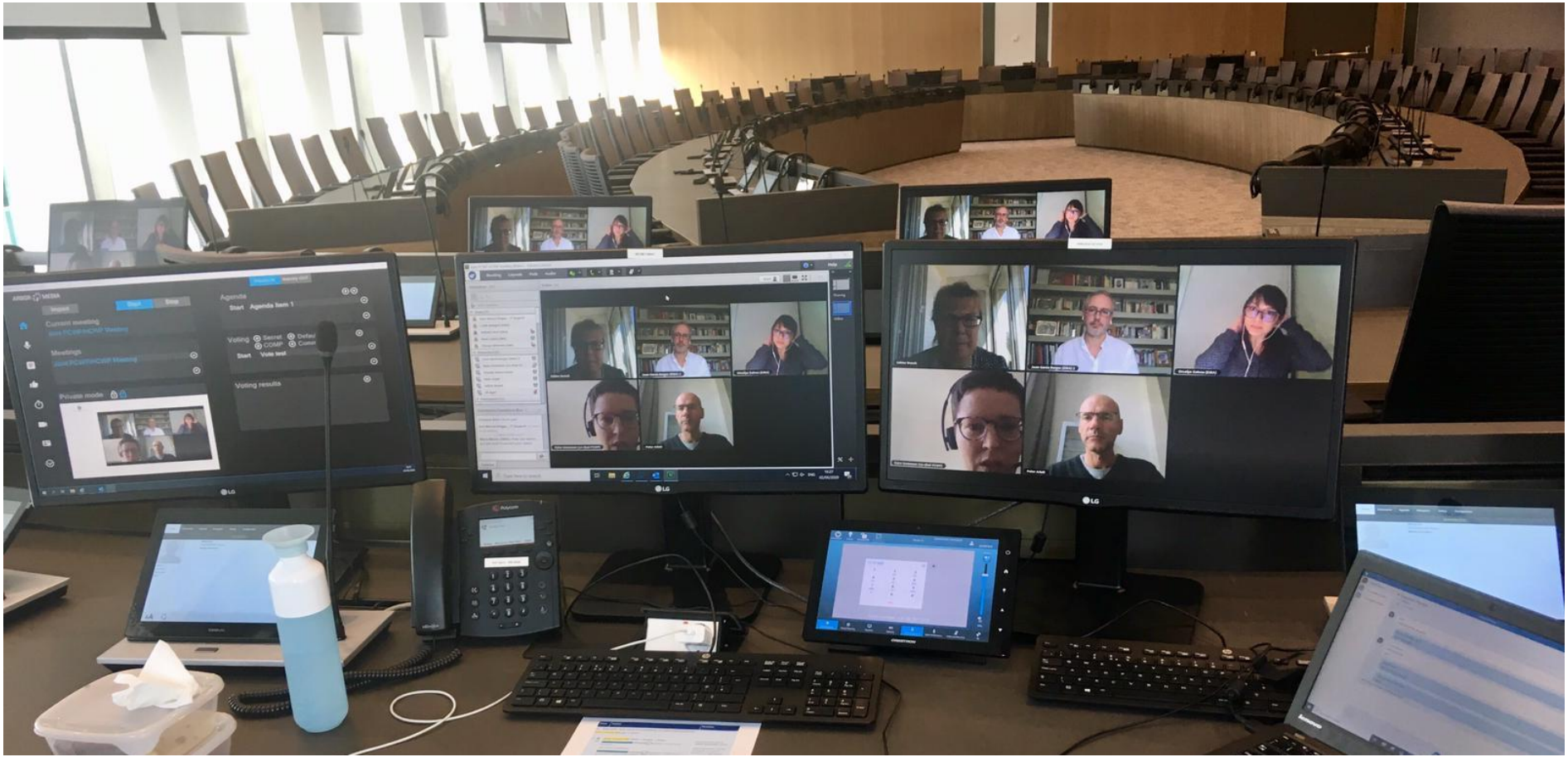
The requirements established for the system by the legislation are set out in the Functional Specifications. These are detailed in the design and supplemented with issues arising from user assessments and testing. Items and areas for development are prioritised from this collective set of requirements to feed in the analyses and design process in accor with the development Milestones and th Release and Sprint planning. The Releas plan describes the specific goals of each release, the functionalities to be address and the Key Performance Indicators (KP The Sprint plan gathers the relevant requirements and items from the backlo organises them in different sprints (regu

With the current delivery model, a small number of nominated Product Owners (F representing Member States and Sponso take ownership of the CTIS delivery and continuously in direct contact with the IT developer. The close collaboration betwe Product Owners and IT developer and th adoption of a plan of shorter and thus m predictable development cycles, releases consisting of sprints, results in regular collection of feedback and alignment wit users' expectations.



A mandate that began like any other….

…..then changed



European Medicines Agencies Network strategy to 2025

WPs involved in early engagement and public consultation

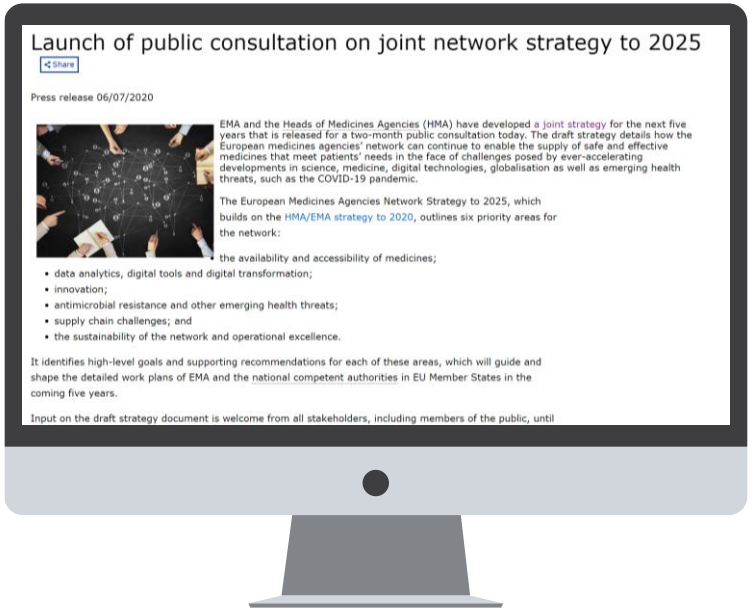
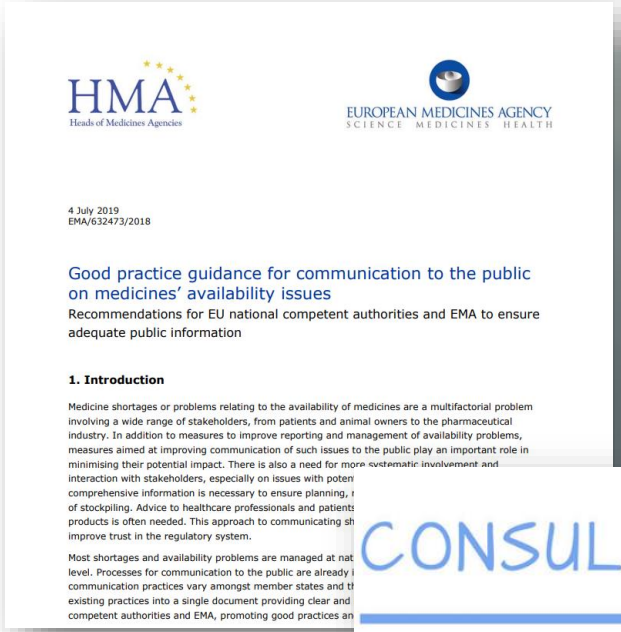


Figure 7. Top key words from feedback for Accessibility and availability of medicines

Good practice guidance for patients and HCP on the prevention of shortages



HMA
Heads of Medicines Agencies

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

4 July 2019
EMA/632473/2018

Good practice guidance for communication to the public on medicines' availability issues

Recommendations for EU national competent authorities and EMA to ensure adequate public information

1. Introduction

Medicine shortages or problems relating to the availability of medicines are a multifactorial problem involving a wide range of stakeholders, from patients and animal owners to the pharmaceutical industry. In addition to measures to improve reporting and management of availability problems, measures aimed at improving communication of such issues to the public play an important role in minimising their potential impact. There is also a need for more systematic involvement and interaction with stakeholders, especially on issues with poten
comprehensive information is necessary to ensure planning,
of stockpiling. Advice to healthcare professionals and patients
products is often needed. This approach to communicating sh
improve trust in the regulatory system.

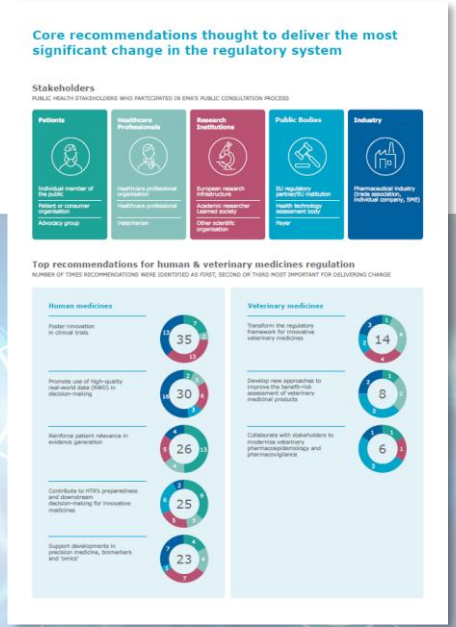
Most shortages and availability problems are managed at nat
level. Processes for communication to the public are already
communication practices vary amongst member states and th
existing practices into a single document providing clear and
competent authorities and EMA, promoting good practices an

Meeting: Discuss concept paper on prevention of shortages

Emer Cooke: new Executive Director

EMA recommendations from RSS 2025

Discussion on implications for patients and HCPs



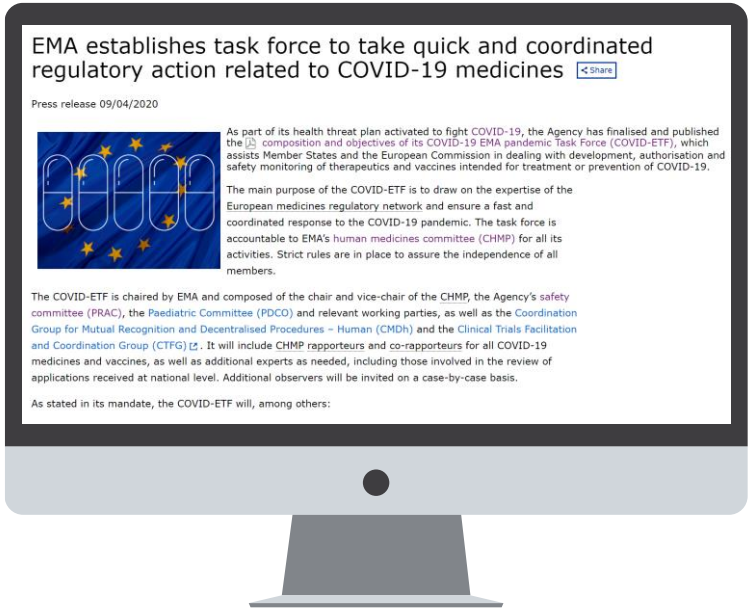
EMA's COVID-19 taskforce (ETF)

Kaisa Immonen (EPF)

Leire Solis/
Jose Drabwell (IPOPI)

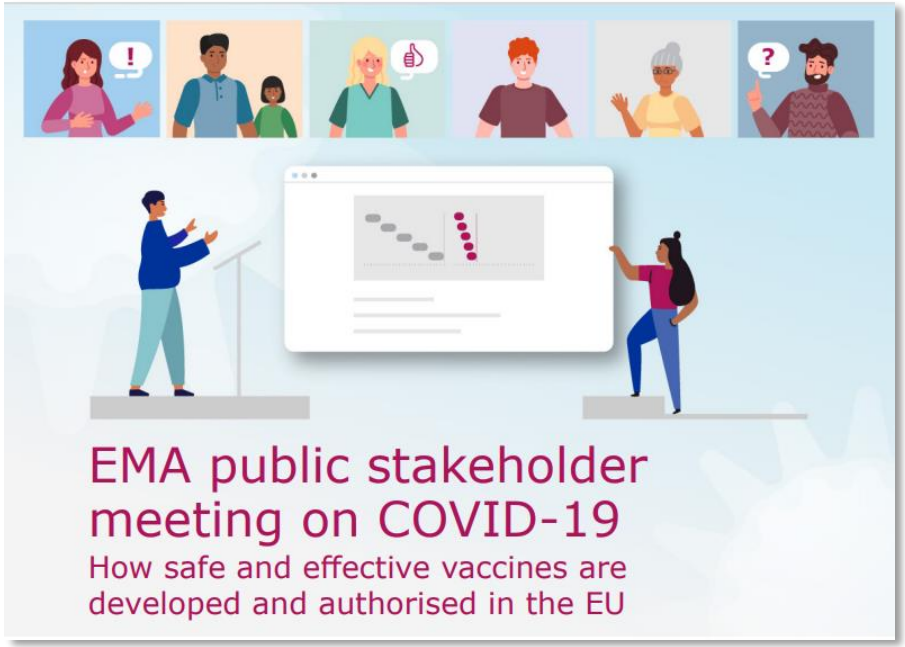
Anita Simonds (ERS)

Tiago Villanueva (UEMO)



First COVID-19 public stakeholder meeting

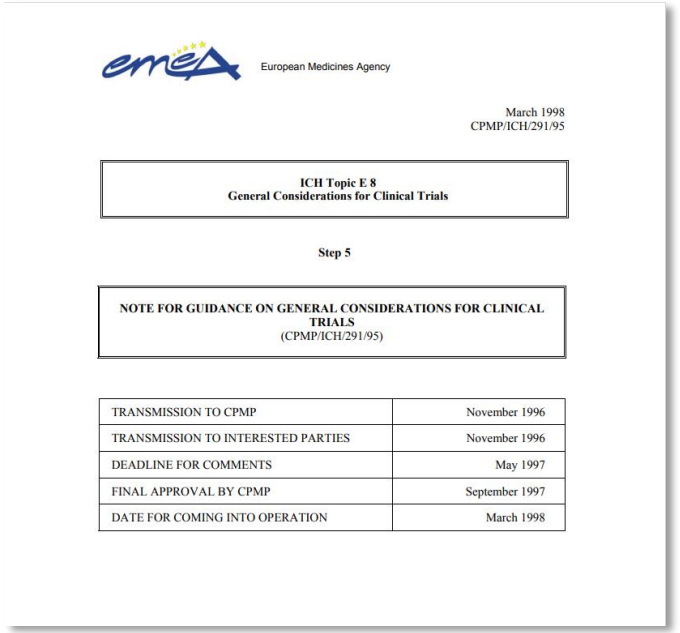
11 December 2020



ICH guidelines: General considerations for clinical trials and GCP

Review by patients and HCP

ICH
harmonisation for better health



European Medicines Agency

March 1998
CPMP/ICH/291/95

ICH Topic E 8
General Considerations for Clinical Trials

Step 5

NOTE FOR GUIDANCE ON GENERAL CONSIDERATIONS FOR CLINICAL TRIALS
(CPMP/ICH/291/95)

TRANSMISSION TO CPMP	November 1996
TRANSMISSION TO INTERESTED PARTIES	November 1996
DEADLINE FOR COMMENTS	May 1997
FINAL APPROVAL BY CPMP	September 1997
DATE FOR COMING INTO OPERATION	March 1998

Workshop: GDPR and Secondary Use of Health Data for Medicines

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

2 December 2020
EMA/532436/2020

GDPR and the secondary use of health data

Report from EMA workshop held with the EMA Patients' and Consumers' Working Party (PCWP) and Healthcare Professionals' Working Party (HCPWP) on 23 September 2020

Introduction

The introduction of the General Data Protection Regulation (GDPR) in 2018 has created a new framework for the protection of personal data in the European Union. It is particularly relevant to healthcare, where technological advances and the increasing availability of data from a range of sources offer many opportunities for the further processing (or secondary use) of data in scientific research, medicine development and policy making. However, with these opportunities come legal, technological and digital skills challenges.

This workshop was set up to discuss these challenges and opportunities with patients, consumers, and healthcare professionals and to present the development of an EU-wide governance framework and a future code of conduct on processing personal data in the health sector. These and other initiatives such as EMA's Questions and Answers (Q&A) on the GDPR in secondary use of health data will ensure the full potential of big data in the health arena can be harnessed in a way that benefits EU citizens, while at the same time protecting their privacy. This report offers a high-level summary of the output from the workshop.

'Healthcare professionals have long been advocating the use of big data in the interest of our patients', Ulrich Jaeger, Co-Chair of HCPWP

Workshop: Benefit-risk of medicines used during pregnancy and breastfeeding

GVP module XVI risk minimisation measures

Early engagement of patients and HCP in revision

HMA
Heads of Medicines Agencies

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 March 2017
EMA/204715/2012 Rev 2*

Guideline on good pharmacovigilance practices (GVP)

Module XVI – Risk minimisation measures: selection of tools and effectiveness indicators (Rev 2)

Date for coming into effect of first version	1 March 2014
Date for coming into effect of Revision 1	28 April 2014
Draft Revision 2* finalised by the Agency in collaboration with Member States	6 March 2017
Draft agreed by the EU Network Pharmacovigilance Oversight Group (EU-POG)	23 March 2017
Draft adopted by Executive Director as final	28 March 2017
Date for coming into effect of Revision 2*	31 March 2017

*Note: Revision 2 includes the following:

- Changes to XVI.A. to delete the description of routine risk minimisation tools as they are detailed in GVP Module V and describe only additional risk minimisation tools in GVP Module XVI; therefore Modules V and XVI have to be read together for a full understanding of the selection of risk minimisation tools;

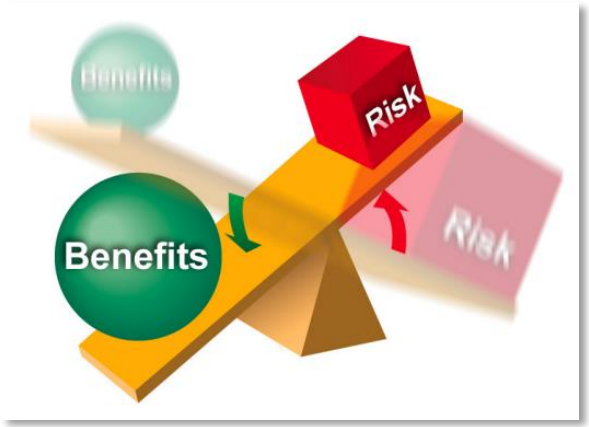
- Changes to XVI.C. to add a paragraph to emphasise the role of Member States in the implementation of risk minimisation measures;

- Changes to XVI.C.1. and XVI.C.2. to add text clarifying the responsibility of the marketing authorisation holder to implement all conditions or restrictions with regard to the safe use of the product in a particular territory;

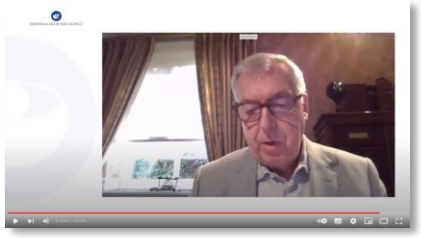
- Changes to XVI.C.1.1.3. to clarify that patient alert cards included in the package are part of the product information;

Editorial amendments throughout the Module to increase the clarity of the guidance and the consistency of its presentation with other GVP Modules.

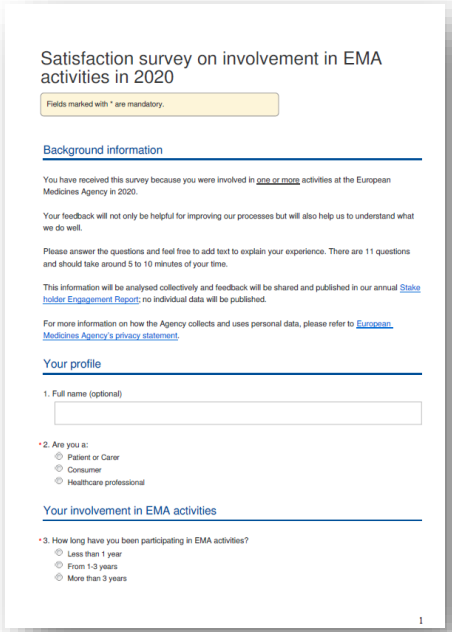
This revision of the Module was not subject to public consultation because it concerns amendments with the specific objective to align its content with the changes in or adding text from GVP Module V Revision 2, which was subject to public consultation.



Workshop: 25 years of EMA



Satisfaction survey to all eligible organisations



Satisfaction survey on involvement in EMA activities in 2020

Fields marked with * are mandatory.

Background information

You have received this survey because you were involved in one or more activities at the European Medicines Agency in 2020.

Your feedback will not only be helpful for improving our processes but will also help us to understand what we do well.

Please answer the questions and feel free to add text to explain your experience. There are 11 questions and should take around 5 to 10 minutes of your time.

This information will be analysed collectively and feedback will be shared and published in our annual Stake holder Engagement Report; no individual data will be published.

For more information on how the Agency collects and uses personal data, please refer to European Medicines Agency's privacy statement.

Your profile

1. Full name (optional)

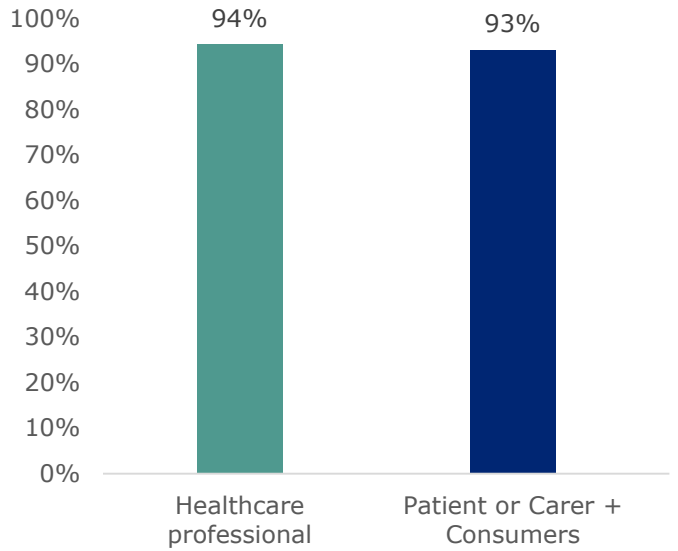
*2. Are you a:
- Patient or Carer
- Consumer
- Healthcare professional

Your involvement in EMA activities

*3. How long have you been participating in EMA activities?
- Less than 1 year
- From 1-3 years
- More than 3 years

1

Overall satisfaction with interactions with EMA



2021

CHMP pilot

PCWP-PEC joint meeting

Public COVID meetings

ICH guidance - patient engagement

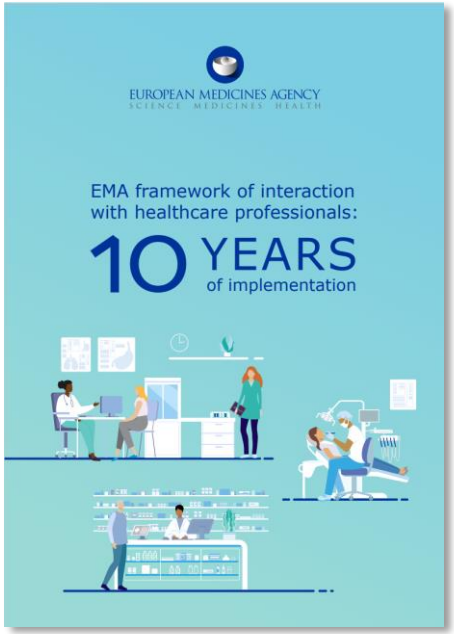
User testing of COVID materials

10 years of HCP framework

RSRN

Academia action plan

10 years: Framework of interaction with healthcare professionals



CHMP pilot: Early dialogue with patient organisations

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

January 2021
EMA/97615/20212021
Stakeholders & Communication Division

Pilot phase for CHMP early contact with patient / consumer organisations

Background and rationale

Patients and their representatives are involved in many activities at EMA and the added value of including their perspectives within committee evaluations has been well demonstrated.

They are currently involved at various timepoints during the medicines' lifecycle, including CHMP evaluations. However, requests for patient input generally come at a later stage of the evaluation, often once major objections have been identified (e.g. expert meeting, oral explanation). Experience shows that late input may lead to missed opportunities to properly incorporate patient perspectives into the assessment process. Therefore in order to make current engagement practices more efficient and enhance timely participation, it is proposed to establish contact with relevant patient / consumer organisations at the start of new medicines assessment. This will enable patients to share aspects such as quality of life, treatment options and unmet medical needs so that the CHMP is well-aware of all aspects from the beginning. This is also expected to facilitate further interactions with patients as the procedure progresses.

This proposed action and process improvement is in line with both the CHMP work plan objective to: 'Incorporate additional and regular processes to capture and include patients' views and preferences in the benefit/risk evaluations', and EMA's Regulatory Science Strategy recommendations which highlight the need to enhance methods to systematically incorporate patient data in regulatory decision-making.

ICH guidance on patient engagement

ICH harmonisation for better health

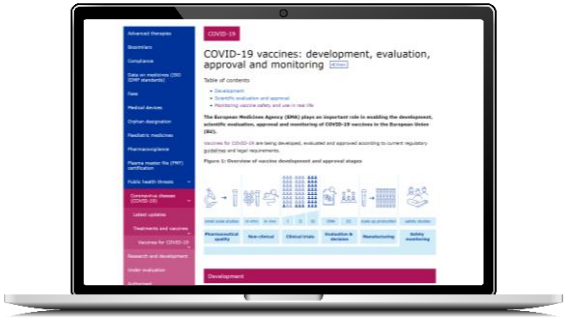
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

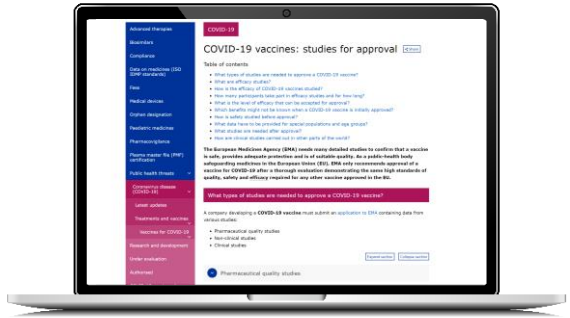
24 June 2021
EMA/CHMP/ICH/338534/2021
Committee for Medicinal Products for Human Use

ICH reflection paper - proposed ICH guideline work to advance Patient Focused Drug Development (PFDD)

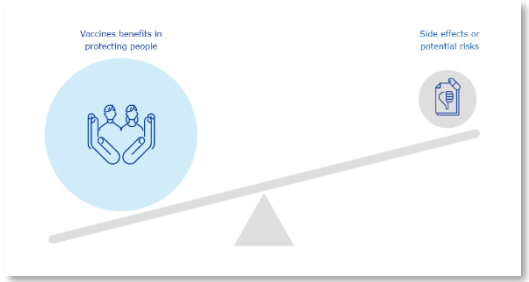
Release for information	24 June 2021

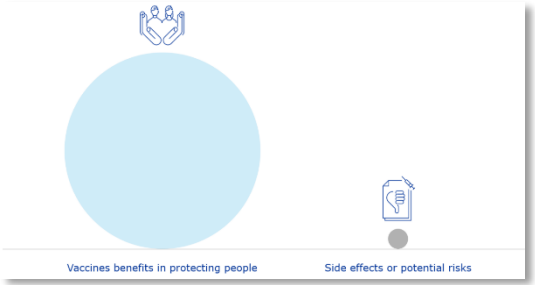
User-testing COVID-19 communication materials





Do you think these figures are clear and easy to understand? Which of the figures do you prefer?





EMA public stakeholder meetings on COVID-19

#EMAPublicMeeting2

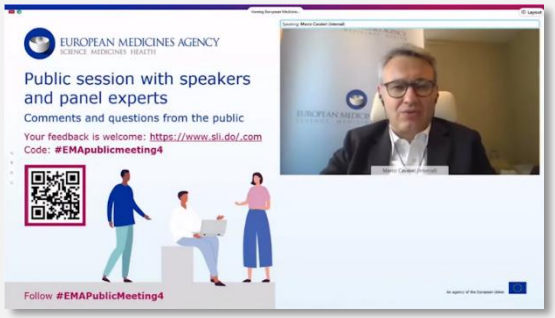
8 January 2021

Basis for the approval and use of first COVID-19 vaccines & safety monitoring.

#EMAPublicMeeting3

26 March 2021

Update on COVID-19 vaccines, and their expected impact at community level.



#EMAPublicMeeting4

25 November 2021

Update on COVID-19 vaccines and an overview of vaccination coverage in the EU.

Academia Action Plan 2021-2023

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

28 April 2021
EMA/159144/2021
Research and Innovation (TRS-RNI)

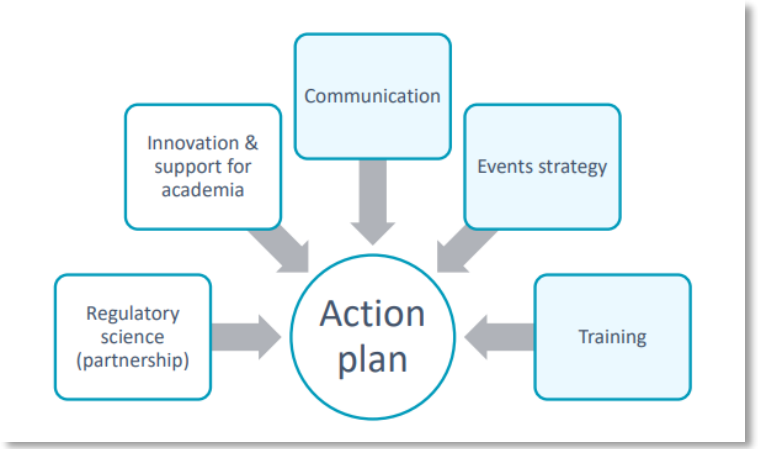
Academia Collaboration Matrix action plan
(2021 – 2023)

Introduction

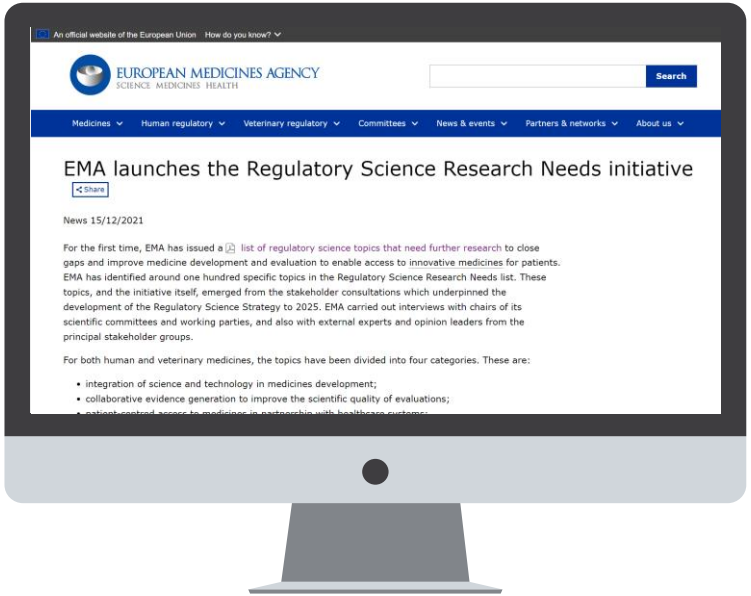
The European Medicines Agency (EMA) is committed to maintaining a strong working relationship with European academics and researchers. Collaboration with academia is necessary for the Agency to be prepared for future challenges as well as opportunities offered by advances in science and technology. The Agency has targeted engagement with academia, learned societies and research groups in a range of areas.

This Academia Collaboration Matrix action plan 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 resources availability.

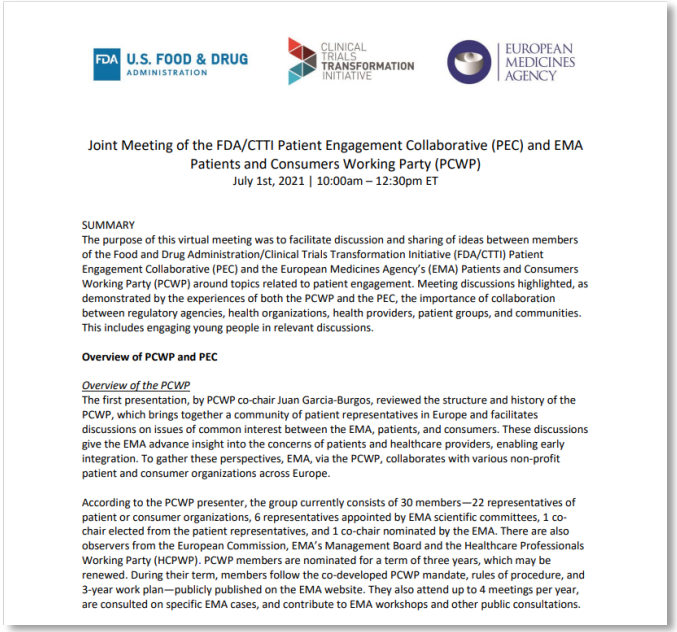
The EMA programming document 2021-2023 states as an objective for the Regulatory Science and Innovation (TRS) Task Force to "Leverage collaborations between academia and network scientists to prepare for engagement with Horizon Europe and Innovative Health Initiative (IHI), define EMA's regulatory science research agenda and enable exchange of knowledge and expertise." Specifically the programming document refers to "an Agency-wide plan for interaction with academia is being developed, which aims (1) to support governance and oversight of interactions with externally funded research and networks; (2) identify academic disciplines/research topics; (3) support the establishment of staff-exchange programmes and placements; (4) create academia-targeted materials to promote existing regulatory tools; (5) set up a communication strategy."



Regulatory Science Research Needs



EMA and FDA patient engagement: PCWP/PEC joint meeting



FDA U.S. FOOD & DRUG ADMINISTRATION | CLINICAL TRIALS TRANSFORMATION INITIATIVE | EUROPEAN MEDICINES AGENCY

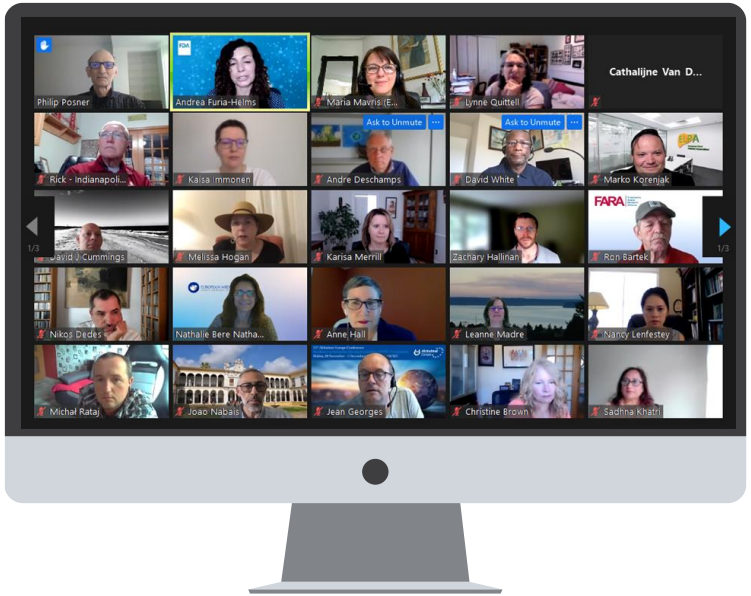
Joint Meeting of the FDA/CTTI Patient Engagement Collaborative (PEC) and EMA Patients and Consumers Working Party (PCWP)
July 1st, 2021 | 10:00am – 12:30pm ET

SUMMARY
The purpose of this virtual meeting was to facilitate discussion and sharing of ideas between members of the Food and Drug Administration/Clinical Trials Transformation Initiative (FDA/CTTI) Patient Engagement Collaborative (PEC) and the European Medicines Agency's (EMA) Patients and Consumers Working Party (PCWP) around topics related to patient engagement. Meeting discussions highlighted, as demonstrated by the experiences of both the PCWP and the PEC, the importance of collaboration between regulatory agencies, health organizations, health providers, patient groups, and communities. This includes engaging young people in relevant discussions.

Overview of PCWP and PEC

Overview of the PCWP
The first presentation, by PCWP co-chair Juan Garcia-Burgos, reviewed the structure and history of the PCWP, which brings together a community of patient representatives in Europe and facilitates discussions on issues of common interest between the EMA, patients, and consumers. These discussions give the EMA advance insight into the concerns of patients and healthcare providers, enabling early integration. To gather these perspectives, EMA, via the PCWP, collaborates with various non-profit patient and consumer organizations across Europe.

According to the PCWP presenter, the group currently consists of 30 members—22 representatives of patient or consumer organizations, 6 representatives appointed by EMA scientific committees, 1 co-chair elected from the patient representatives, and 1 co-chair nominated by the EMA. There are also observers from the European Commission, EMA's Management Board and the Healthcare Professionals Working Party (HCPWP). PCWP members are nominated for a term of three years, which may be renewed. During their term, members follow the co-developed PCWP mandate, rules of procedure, and 3-year work plan—publicly published on the EMA website. They also attend up to 4 meetings per year, are consulted on specific EMA cases, and contribute to EMA workshops and other public consultations.



2022

Mandates

Working parties' workplan

EMA's extended mandate

Patient framework update

Analysis of self assessment process

Update: Framework engagement with patients' and consumers' organisations

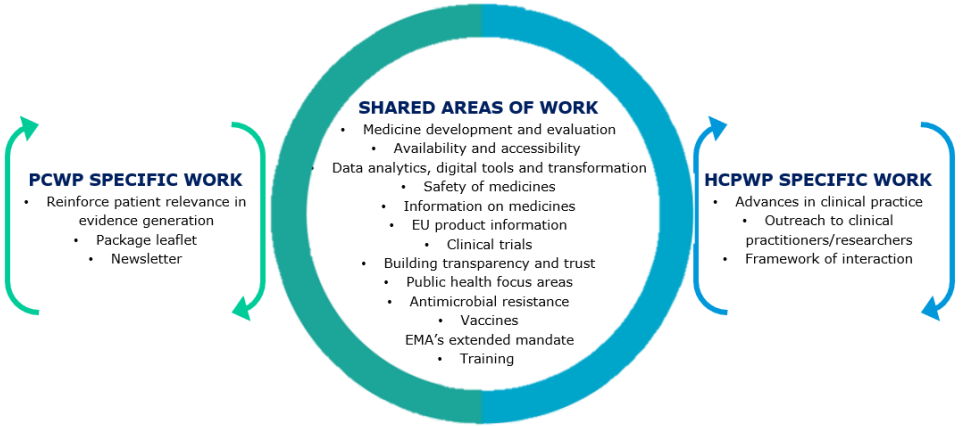
Revision of working parties' work plan

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 January 2022
EMA/22769/2022
Stakeholders and Communication

2022-2025 Work plan for the Patients' and Consumers' Working Party (PCWP) and the Healthcare Professionals' Working Party (HCPWP)

Chairpersons	Status
EMA: Juan Garcia Burgos HCPWP: PCWP:	Endorsed by PCWP and HCPWP on xx July/August 2022 Adopted by CAT, CHMP, COMP, HMPC, PDCO and PRAC on xx September 2022



EMA's extended mandate

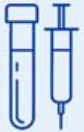
Medicines' shortages

- 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

Emergency Task Force

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

Medical devices' shortages



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

Medical devices panels

- Set up of permanent secretariat to support expert panels
- Rules of procedures

Analysis: New self-assessment process by eligible organisations

Thank you!

For your continued time and effort…

May the next 3 years be equally fruitful!