EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

PCWP/HCWP: 2016 - 2019

Highlights of involvement in EMA activities

Patients' and Consumers' Working Party (PCWP)

Healthcare Professionals' Working Party (HCPWP)

Co-chairs

PCWP

Kaisa Immonen

HCPWP

Gonzalo Calvo

Isabelle Moulon

Juan García Burgos

PCWP/HCPWP secretariat

PCWP


Maria Mavris


Nathalie Bere


Nora Lazaro

HCPWP


Monica Ensini


Ivana Silva


Nicola Martin

Thank you also to…


Activities
Topics
Initiatives
Concepts
Collaborations

2016

Webpages

Measuring impact

Framework of interaction

WEBRADR **BIG DATA**

Eligibility criteria

Public hearing preparations

Patient database

Clinical data publication

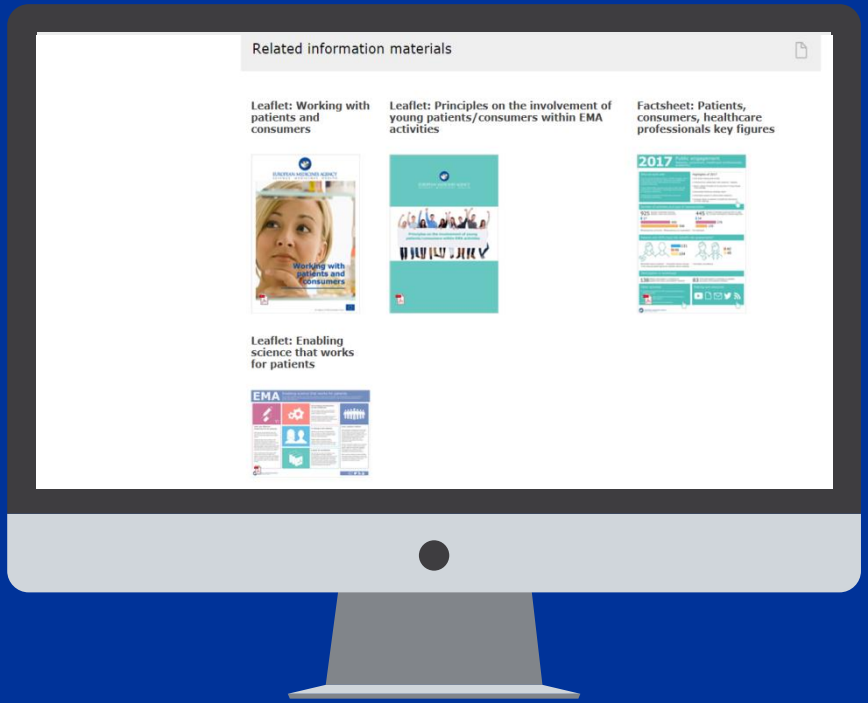
PCWP 10th anniversary

EMA/FDA exchange

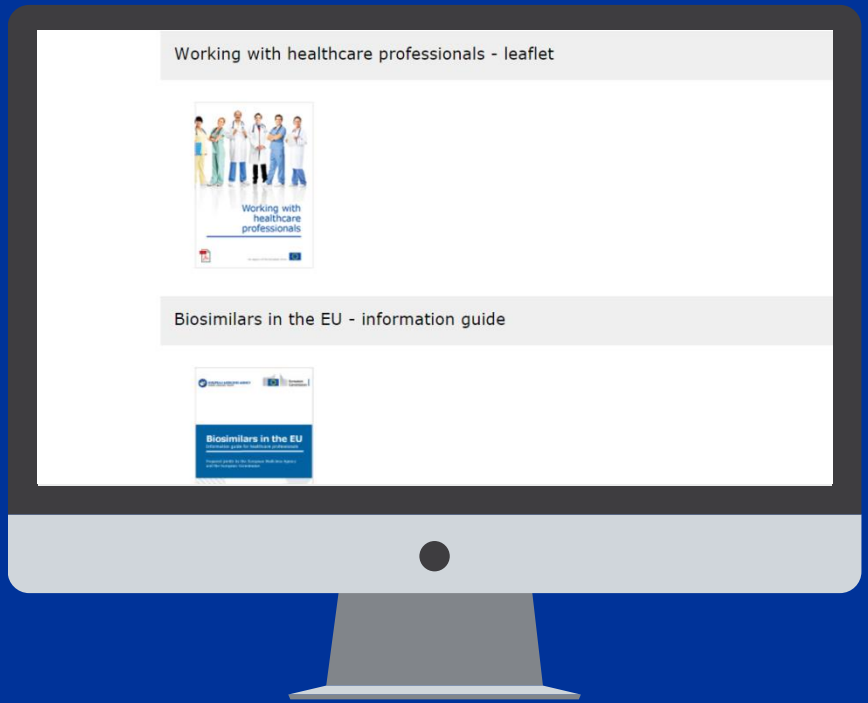
2016

Updated webpages for…

Patients and consumers



Healthcare professionals



2016

Impact of Pharmacovigilance activities; survey; workshop

Healthcare professionals framework: revision

Social media workshop

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

24 October 2016
EMA/625077/2016
Stakeholders and Communication Division

Sharing health information in the digital age: potential and challenges of social media

Report from a workshop on the impact of social media on patients, healthcare professionals and regulators

Introduction

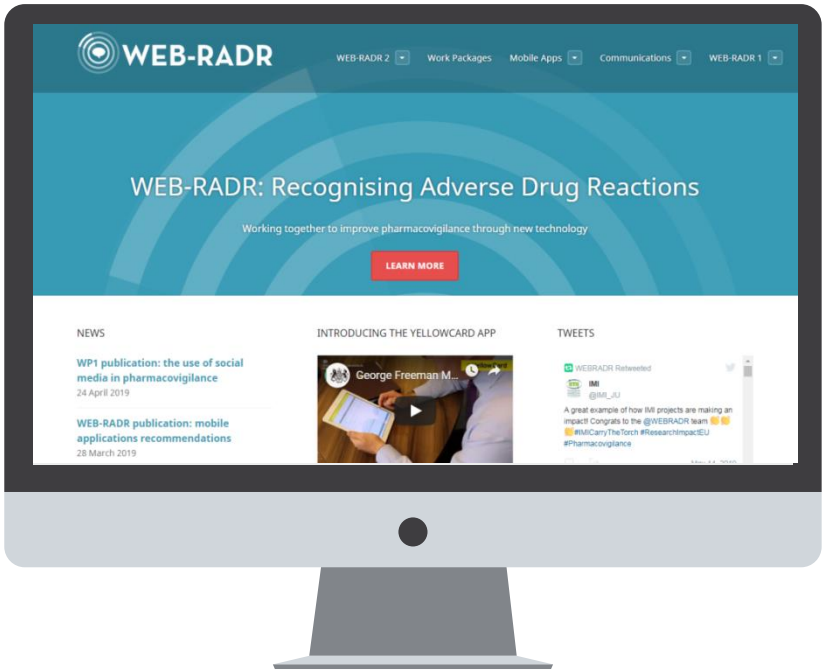
Social media[1] is a group of electronic communication tools that allow users to view, create and share information, ideas, and other forms of expression via virtual communities and networks. In the health setting, social media has the potential to change how healthcare professionals, researchers, patients and consumers manage and share health-related data, and may impact on how information on medicines and their use is generated, shared and discussed.

EMA's Patients' and Consumers' Organisations Working Party (PCWP) and Healthcare Professionals' Organisations Working Party (HCPWP) discussed challenges and practical applications of social media and their impact on regulators, patients and healthcare professionals during a workshop held on 19 September 2016.

This workshop was the first in a series of meetings that will cover linked topics related to advances in digital health including social media, 'big data' analysis and IMI (Innovative Medicines Initiatives) projects such as WEB-RADR[2], where EMA will provide a platform for discussion and an opportunity for mutual learning.

2016

WEB-RADR



WEB-RADR

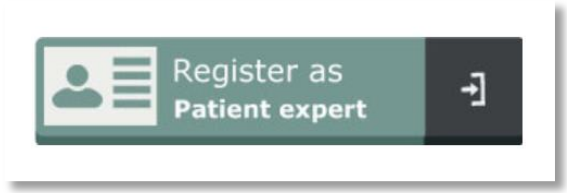
innovative medicines initiative

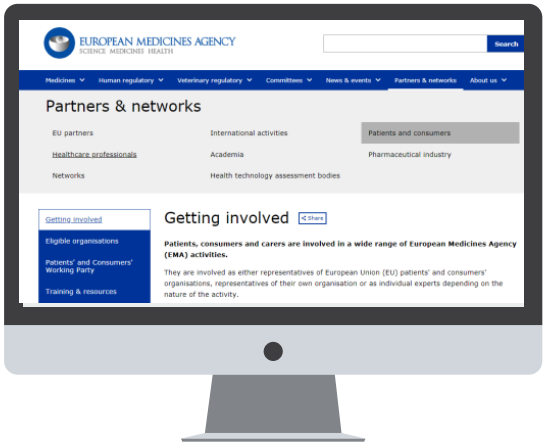
efpia

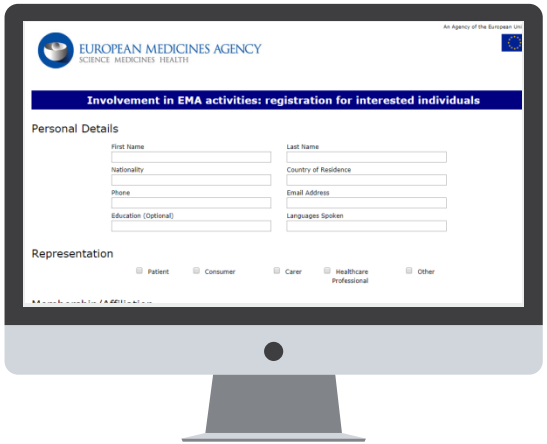
WEBRADR: https://web-radr.eu/

2016

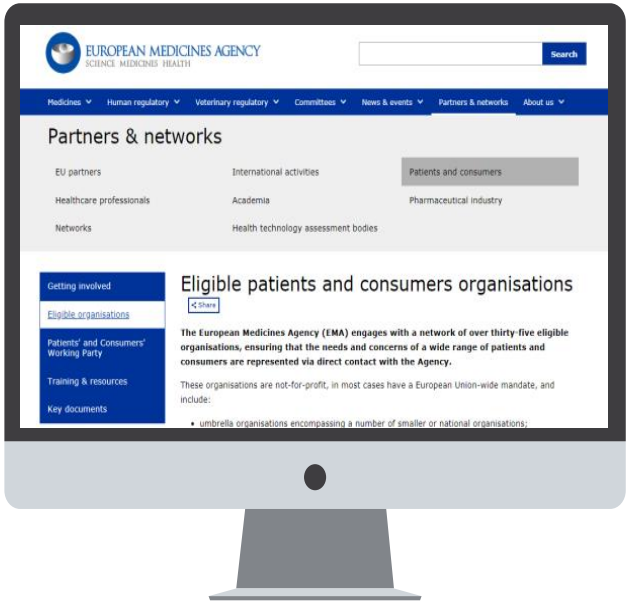
Individual patient database launch

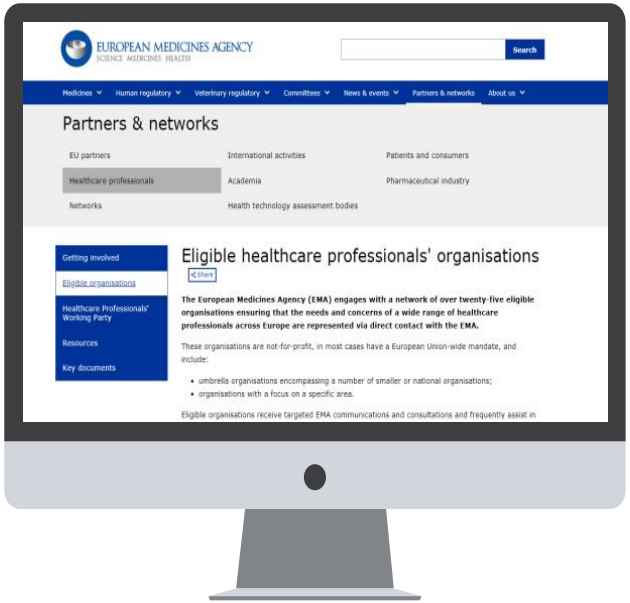




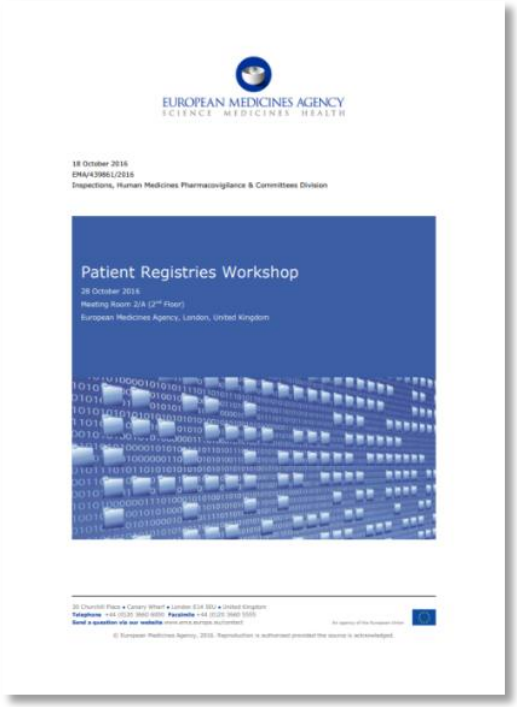


Organisation eligibility criteria: revised



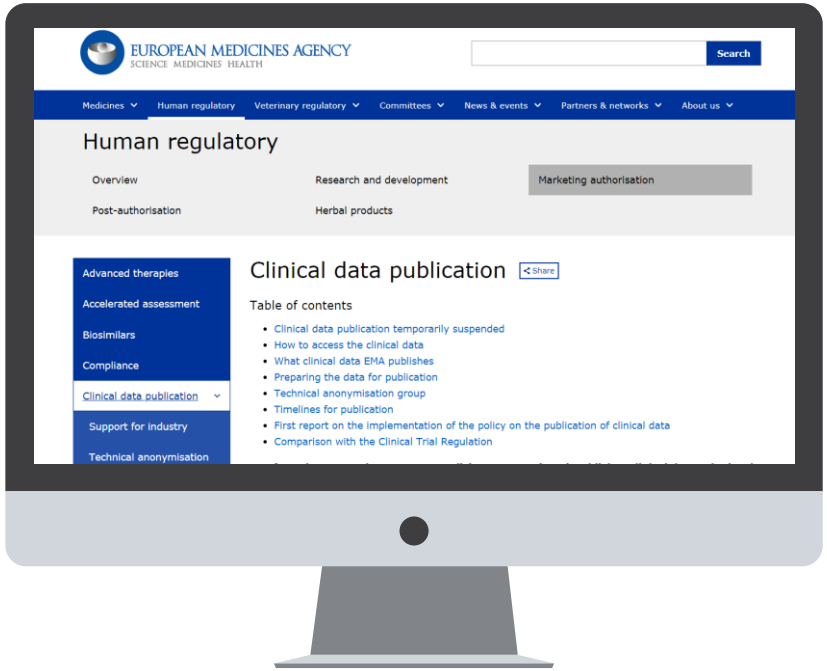


Patient registries workshop

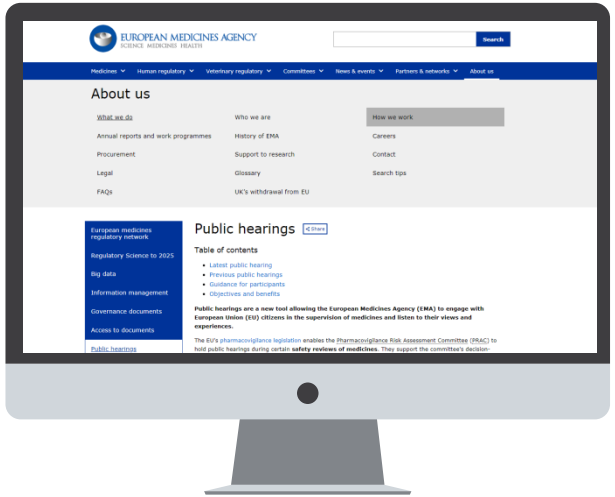


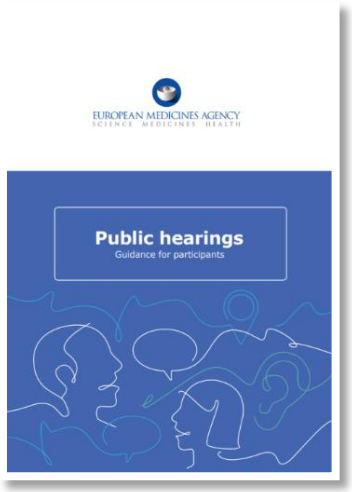
2016

Clinical data publication; user testing

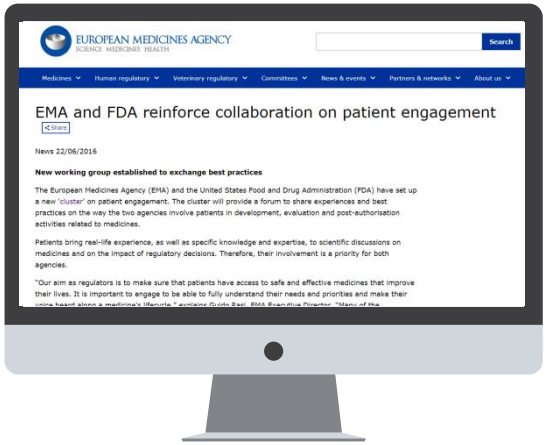


Public hearing preparations





EMA and FDA: patient engagement



FDA: https://www.fda.gov/patients/learn-about-fda-patient-engagement/fda-and-european-medicines-agency-patient-engagement-cluster

Big data (workshop in medicines development)

PCWP 10th anniversary

PCWP 10

2017

Public hearing

Personalised medicine

Antimicrobial resistance

Biosimilars **Academia**

Involving young people

Perception survey

Patients in CHMP meetings

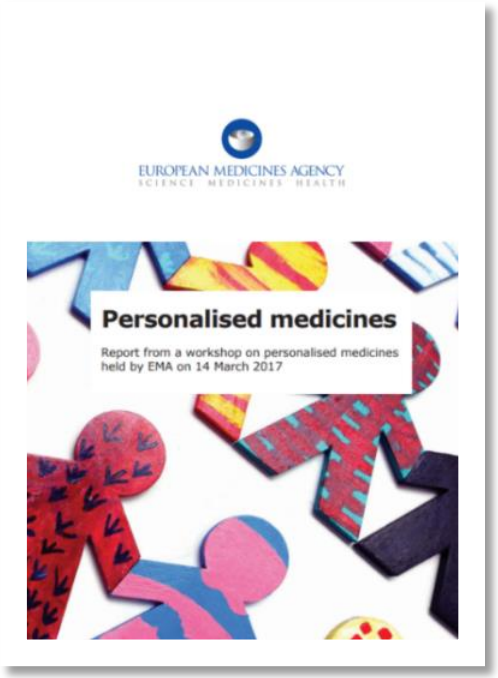
Additional monitoring

Availability of medicines

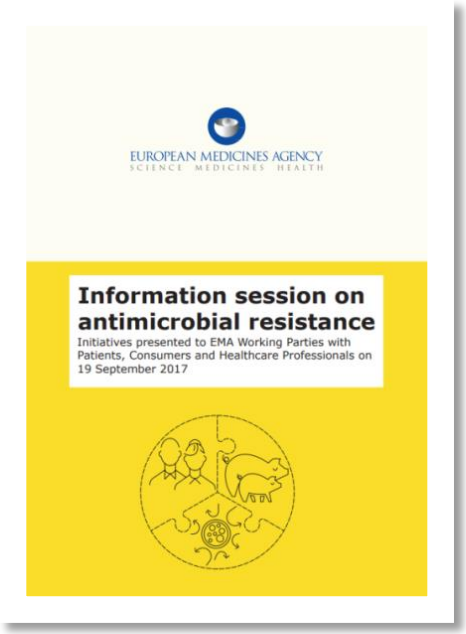
10th training day

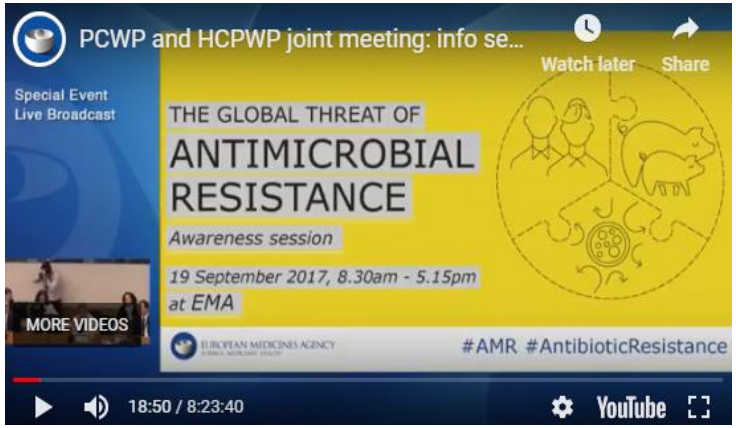
EMA action plan

Personalised medicines workshop

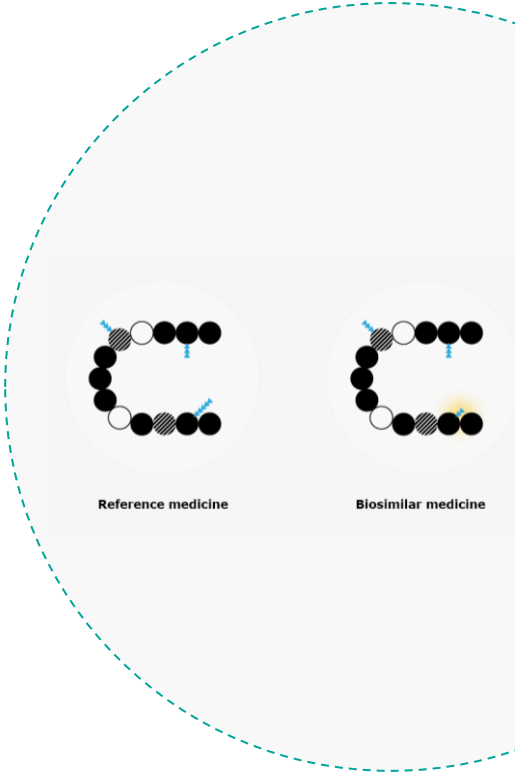


Antimicrobial resistance (AMR): information session





Biosimilar medicines



EMA communication: perception survey

Organisation eligibility assessment: streamlining process

ELIGIBILITY

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 March 2018
EMA/24913/2005 - rev. 3
Stakeholders and Communication Division

Criteria to be fulfilled by patient, consumer and healthcare professional organisations involved in European Medicines Agency (EMA) activities

1. Introduction

This paper defines the criteria that patient, consumer and healthcare professional organisations should fulfil in order to be considered 'EMA eligible organisations'

Organisations meeting the criteria defined herein become part of the Agency's network of European organisations listed on its website, and are the first point of contact for involvement in EMA activities, as and when appropriate. The initial assessment performed to confirm compliance with these criteria, as well as subsequent annual reviews, follows the steps detailed in the document "Assessment of patient, consumer and healthcare professional organisations compliance with EMA eligibility criteria" (EMA/566453/2012 – rev. 1)".

2. Definition of patient/consumer and healthcare professional organisations

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

15 March 2018
EMA/698917/2017
Stakeholders and Communication Division

Assessment of patient, consumer and healthcare professional organisations' compliance with EMA eligibility criteria

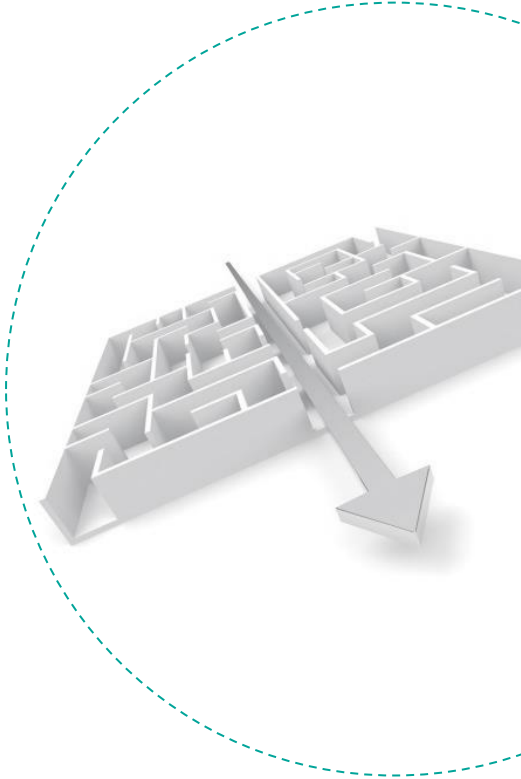
1. Introduction and purpose

As defined within the frameworks for interaction, the Agency endeavours to establish and maintain a network of European patient, consumer and healthcare professional organisations to foster consistent and targeted interactions with a broad range of organisations across Europe with diverse expertise and interests.

'Eligibility criteria' for selection of organisations (*link to be added*) have been established to ensure that the Agency works with the most appropriate organisations.

Organisations may submit an application for eligibility at any time and, provided the criteria defined herein are met, they become part of the Agency's network of European organisations listed on the Agency website, and are the first point of contact for involvement in EMA activities, as and when appropriate.

The purpose of this document is to explain how information obtained from each organisation during the Agency's assessment of 'eligibility', is assessed to conclude whether that organisation is eligible.



EMA/EUnetHTA work plan 2017-2020

EunetHTA: https://www.eunethta.eu/about-eunethta/history-of-eunethta/

eunethta

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

13 November 2017
EMA/661613/2017
Human Medicines Research and Development Support Division

EMA-EUnetHTA three-year work plan
2017–2020

Introduction

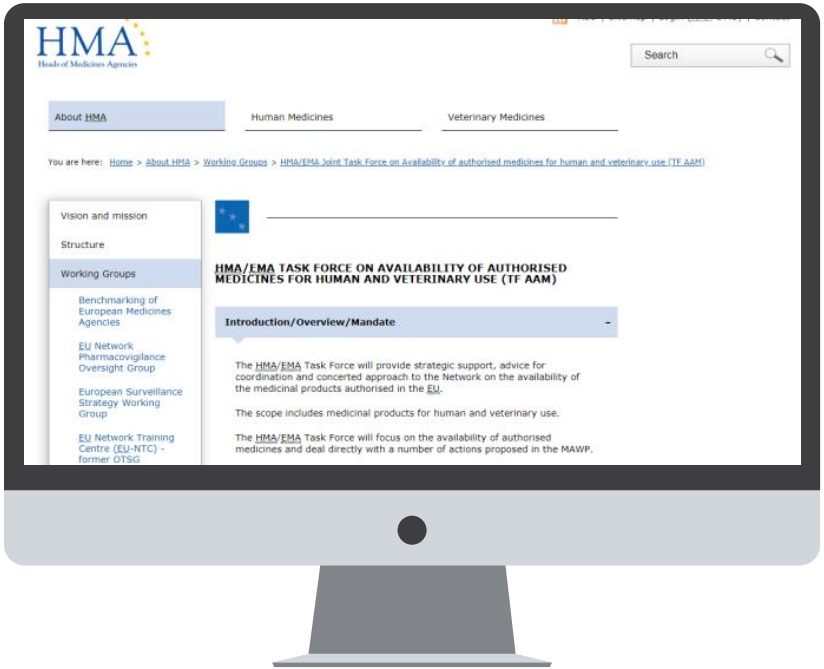
The EMA-EUnetHTA collaboration, which began in 2010 based on recommendations from the High-level Pharmaceutical Forum[1], aims to harness synergies between regulatory evaluation and health technology assessment (HTA) along the lifecycle of a medicine. Following initial work to improve the way data published by EU regulators as part of their benefit-risk assessment can contribute to relative effectiveness assessments by HTA organisations, additional topics of mutual interest were identified.

A first EMA-EUnetHTA work plan had been established for the years 2012-2015; a report on the outcomes of this joint work plan has been published in April 2016. Following up on the achievements and developments, a new joint work plan for the years 2017-2020 has been agreed. The overall goal of the collaboration is to improve efficiency and quality of processes, whilst respecting their respective remits and ensure mutual understanding and dialogue on evidence needs, to facilitate access to medicines for patients in the European Union.

Areas for the EMA-EUnetHTA collaboration

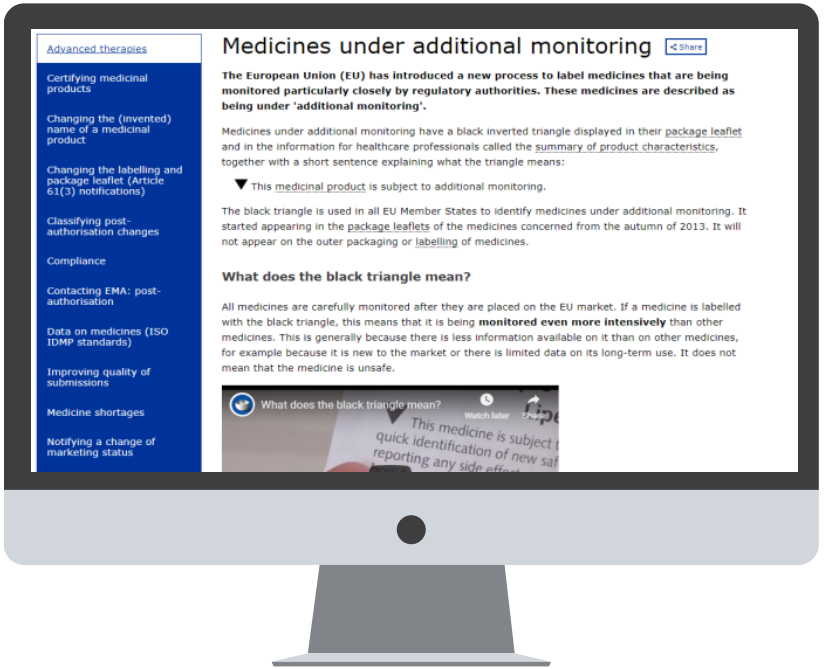
eunethta

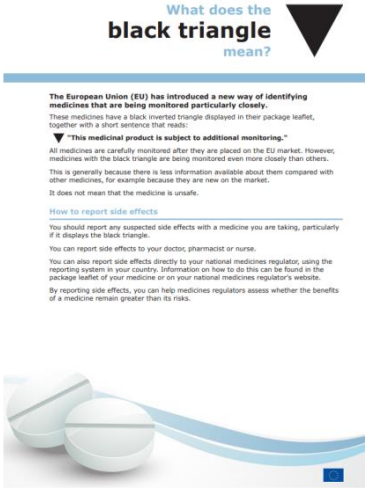
Availability of medicines: HMA/EMA Taskforce



HMA: https://www.hma.eu/522.html

Additional monitoring: impact survey





Patients in CHMP meetings

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

3 March 2017
EMA/191955/2017
Stakeholders & Communication Division

Outcome Report on Pilot to involve patients in benefit/risk discussions at CHMP meetings

1. Background/Rationale

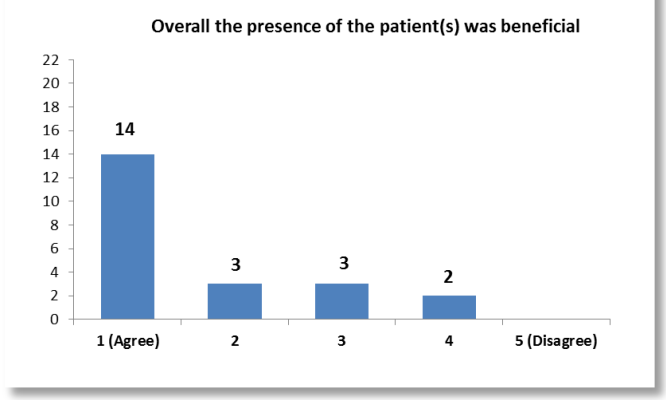
A range of mechanisms have been put in place throughout the medicine lifecycle to acquire patients' perspectives within EMA benefit/risk (B/R) considerations and the added value has been demonstrated many times. It was felt however that one area which could be further expanded was within the Committee for Medicinal Products for Human Use (CHMP) meetings to allow additional opportunities to hear and take account of patients' views during the assessment of B/R. This is in line with the CHMP work programme which recommends further integrating patients' values in the B/R assessment and reflects the Agency's emphasis on stakeholder involvement.

2. Involvement in benefit/risk discussions

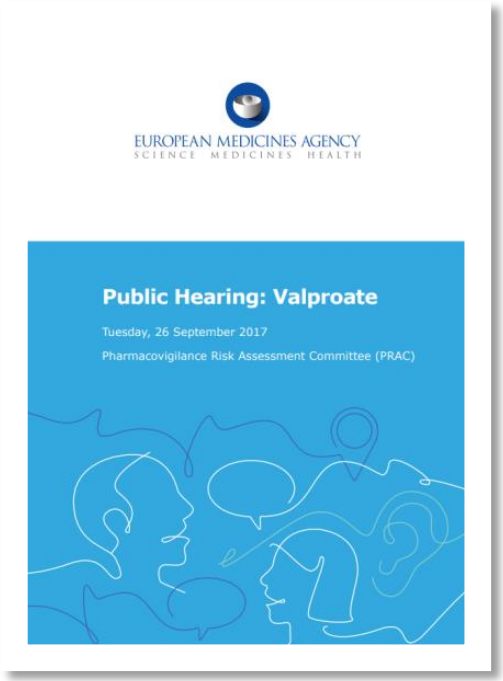
Patients are involved in B/R evaluations through participation in SAG/ad-hoc expert group meetings, scientific advice procedures and also written consultations. Building on this, it was proposed to invite patients to participate in specific B/R discussions during CHMP meetings, where they would be able to contribute to the CHMP discussions at the time of an oral explanation. It was decided to trial a pilot phase for a period of at least one year to fully assess the feasibility of the proposal and explore how this could occur to maximal effect.

3. Pilot phase

Methodology

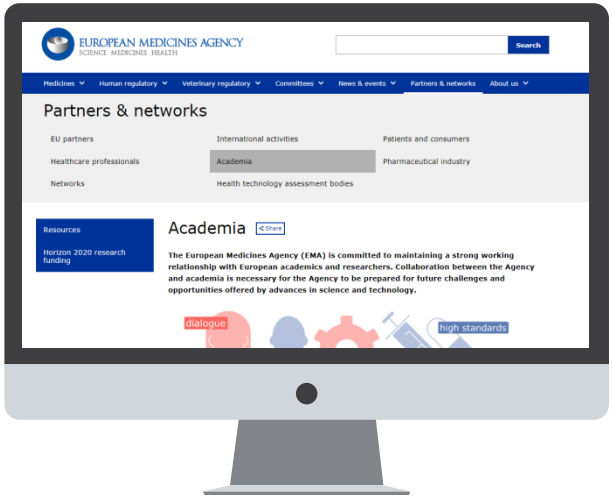


1st public hearing: Valproate medicines

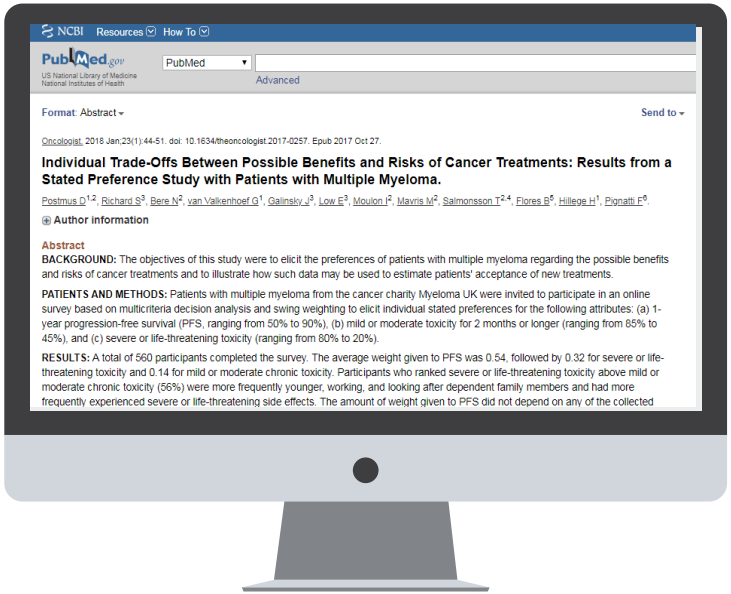


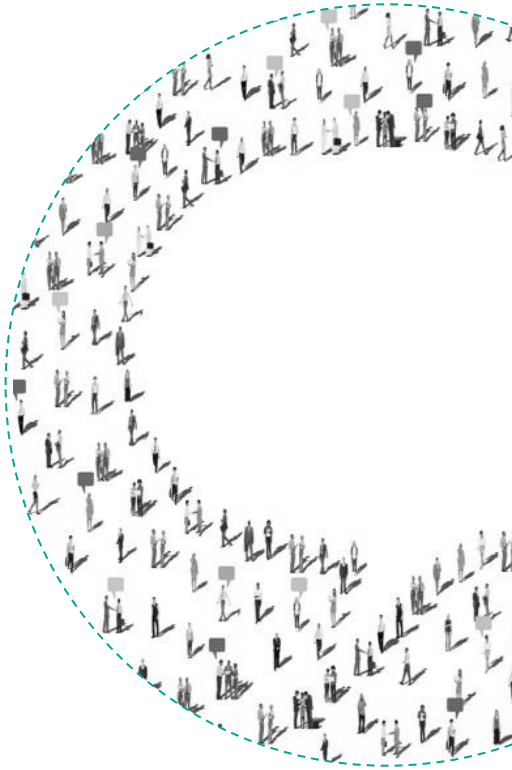
Involving young people: principles adopted

Academia framework: adopted



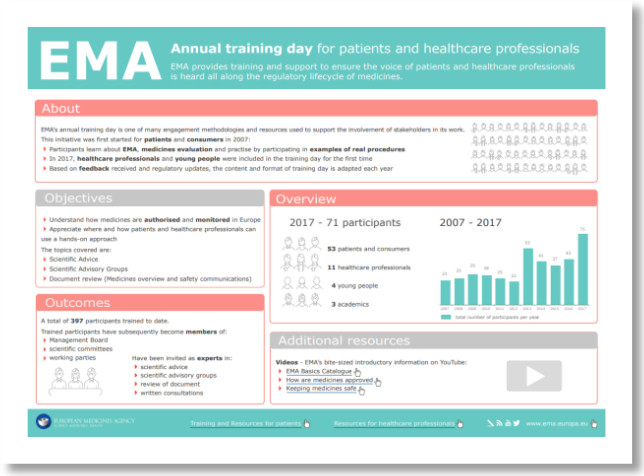
Patient preference study in multiple myeloma

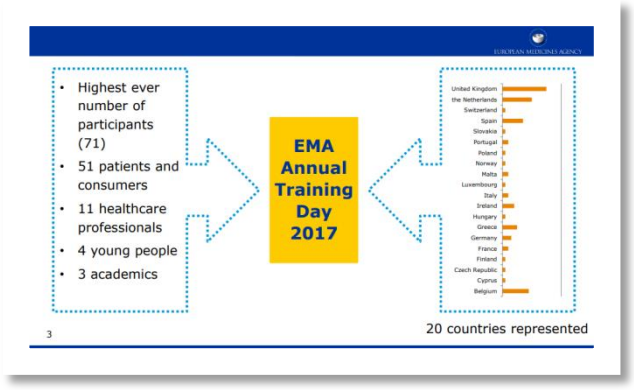




PubMed: https://www.ncbi.nlm.nih.gov/pubmed/29079638

10th annual training day





Medicine information: EMA action plan

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

14 November 2017
EMA/680018/2017
Stakeholders and Communication Division

EMA action plan related to the European Commission's recommendations on product information[1]

The European Medicines Agency (EMA) recognises the importance of the European Commission report[2] and its recommendations to improve the EU product information. This represents a unique opportunity to improve the information EU patients receive on their medicines, within the boundaries of the current legislation.

In order to meet high public expectations that the report has generated, it is important that any action is properly planned and executed, relevant stakeholders are involved and due consideration is given to the required expertise, timing and resources.

The following is an analysis of the timelines, technicalities which will be needed to implement the necessary actions to meet the objectives set in the report.

This analysis has not taken into account the impact of Brexit. However it needs to be noted that prioritisation, timelines and resource allocation will depend on how activities will be affected during the Agency's relocation and business continuity plan (BCP).

The different actions are broken down by each of the Commission's recommendations:

1. Room for improvement of package leaflet (PL) rather than summary of product characteristics (SmPC)

2018

Topic Groups

Joint Work Plan

Real World Evidence

2nd Public hearing

European Immunisation Week

Additional monitoring

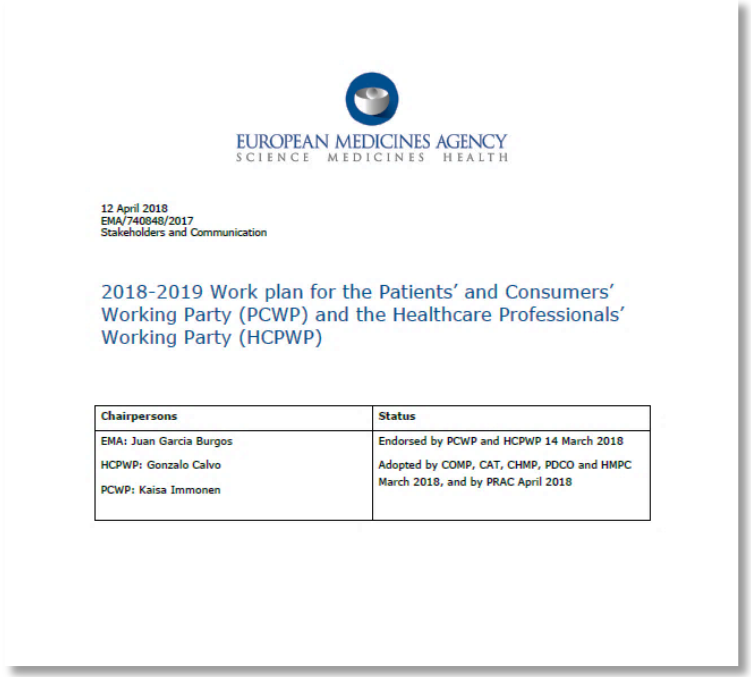
EMA Regulatory Science 2025

Patient registries

Availability of medicines

ePI

Joint WP work plan agreed



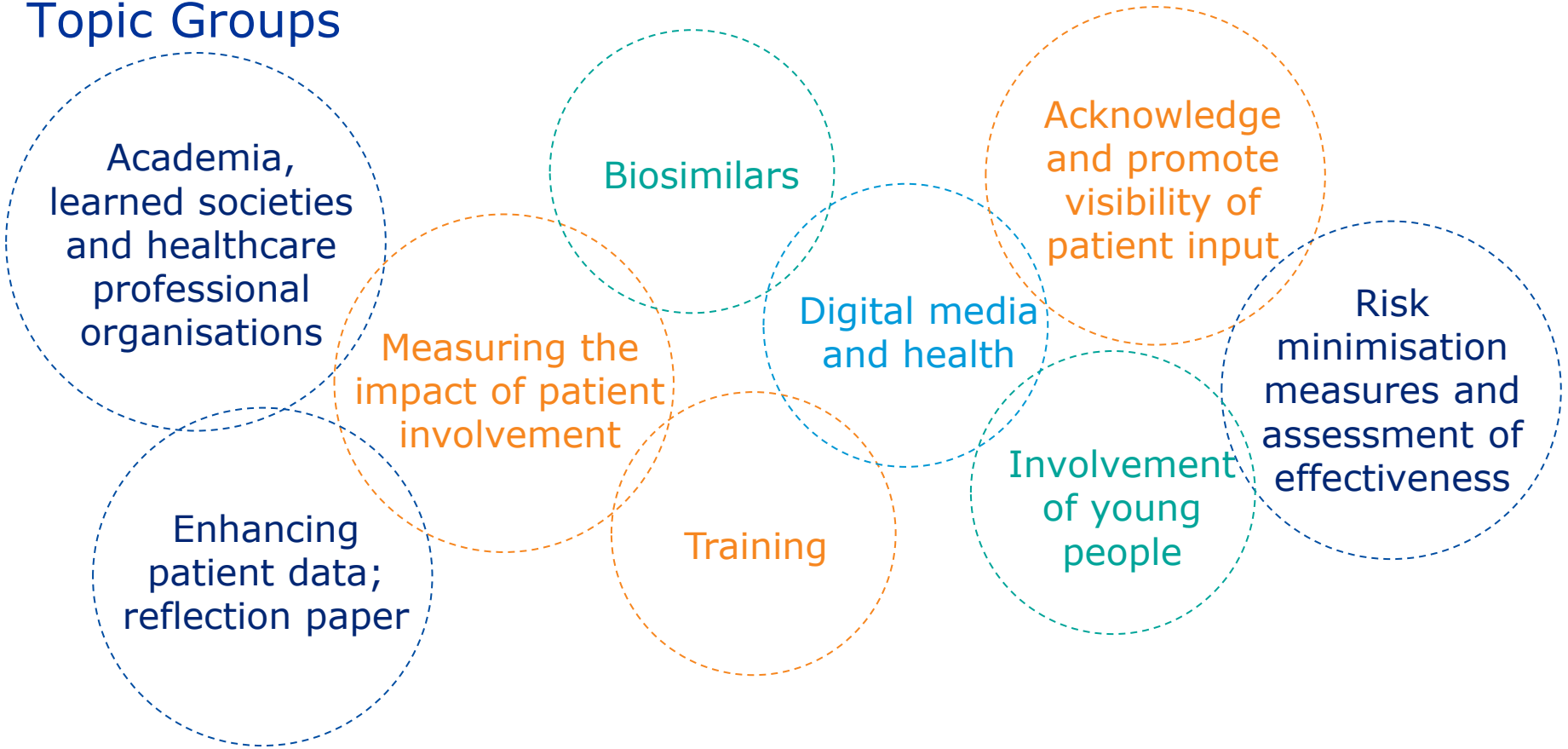
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

12 April 2018
EMA/740848/2017
Stakeholders and Communication

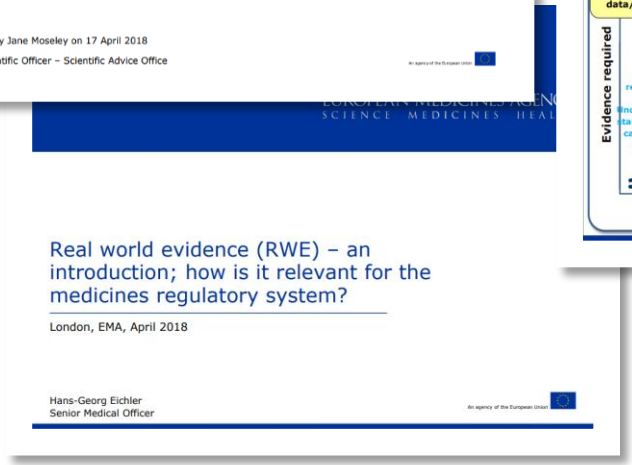
2018-2019 Work plan for the Patients' and Consumers' Working Party (PCWP) and the Healthcare Professionals' Working Party (HCPWP)

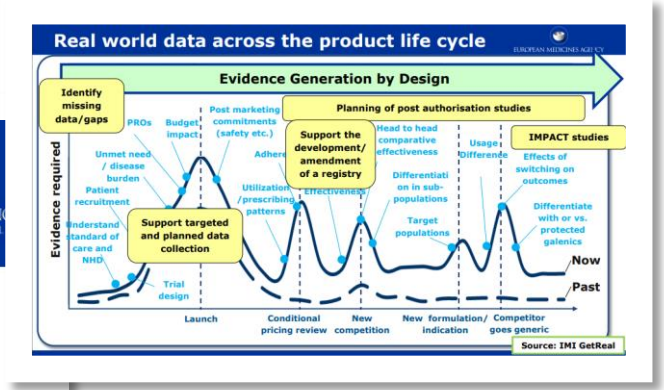
Chairpersons	Status
EMA: Juan Garcia Burgos HCPWP: Gonzalo Calvo PCWP: Kaisa Immonen	Endorsed by PCWP and HCPWP 14 March 2018 Adopted by COMP, CAT, CHMP, PDCO and HMPC March 2018, and by PRAC April 2018

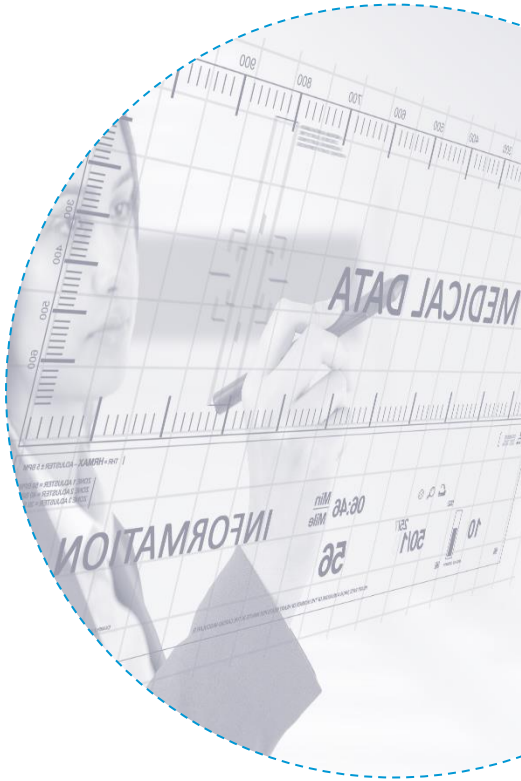
Topic Groups



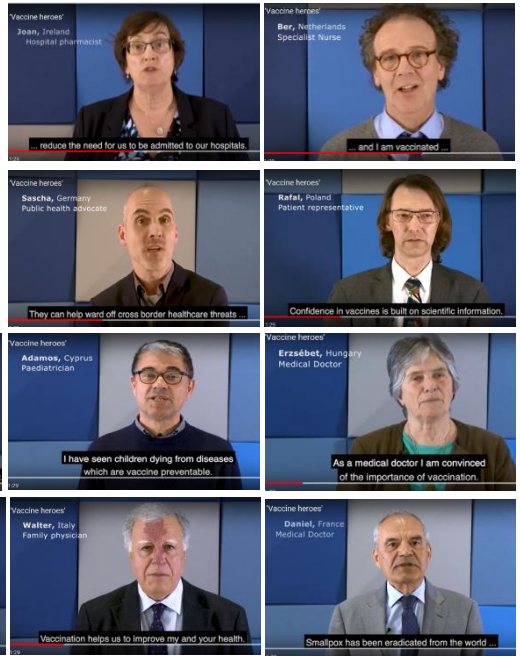
Real World Evidence in medicine development

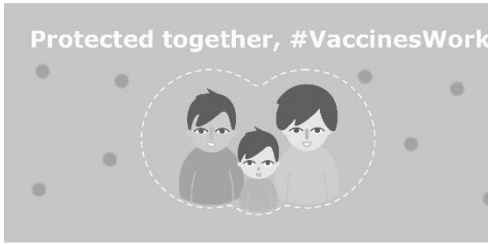




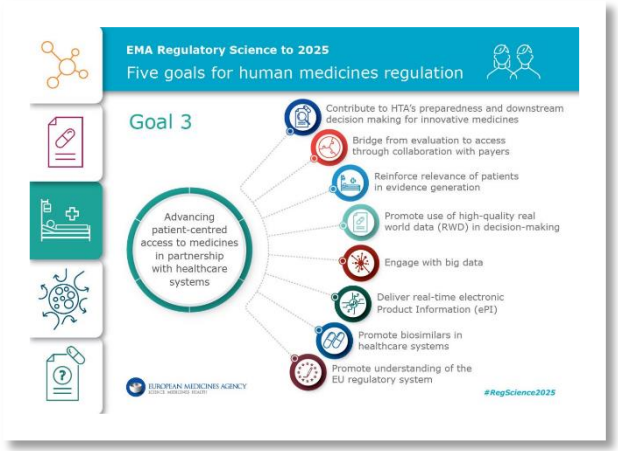


European Immunisation Week



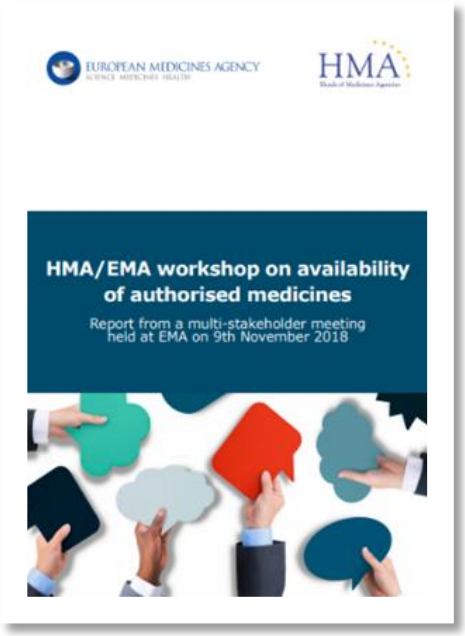


EMA Regulatory Science to 2025

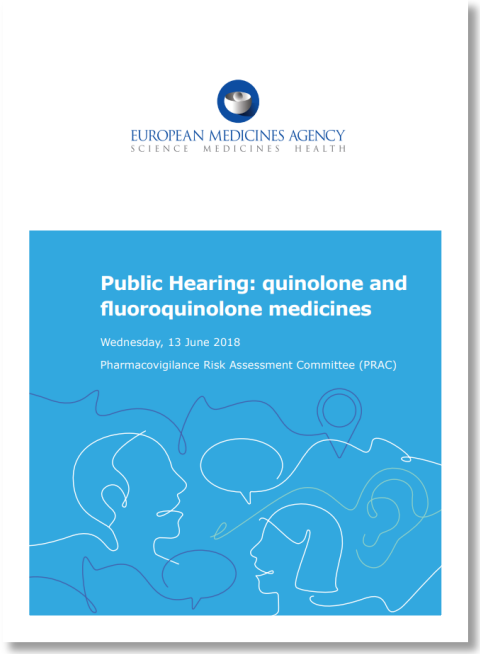


Additional monitoring: awareness survey

Availability of medicines: HMA/EMA workshop



2nd public hearing: Quinolone and Fluoroquinolone medicines

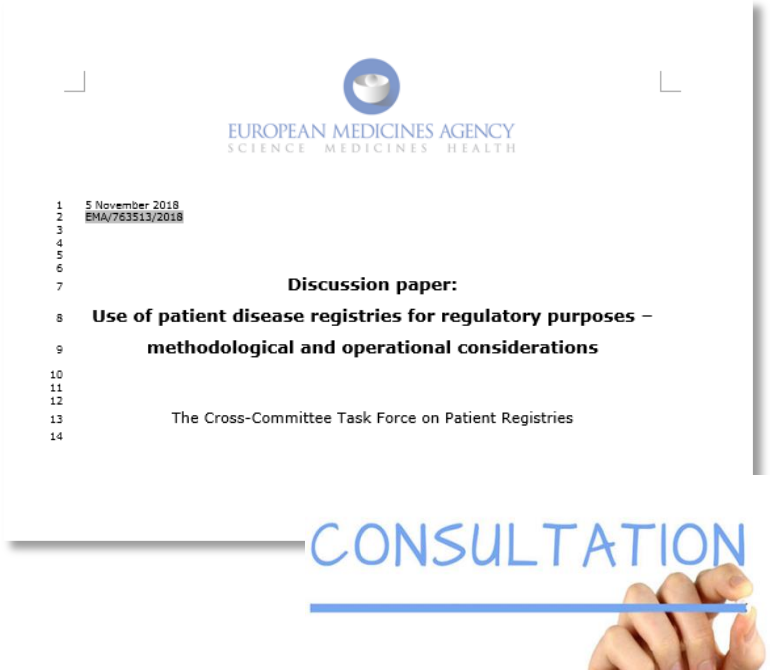


Good Pharmacovigilance Practices (GVP)

Population- or Product-Specific Considerations:

PI Vaccines
PII Biologicals
PIII Pregnancy & breastfeeding Public consultation 2018/9
PIV Paediatrics Final October 2018
PV Geriatrics Development to be continued after October 2019

Patient registries: initiative update



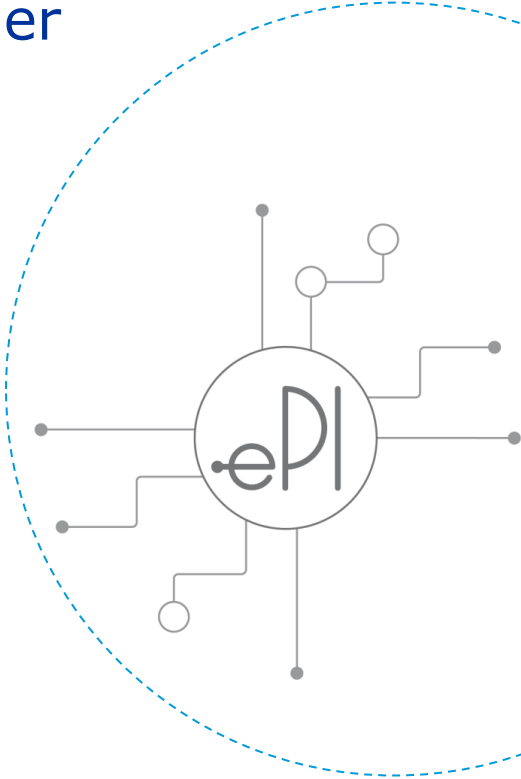
Cystic Fibrosis Registries Workshop: 14th June 2017

Multiple-Sclerosis Registries Workshop: 7th July 2017

CAR T-Cell therapies Registries Workshop: 9th February 2018

Haemophilia Registries Workshop: 8th June 2018

Electronic product information: Multi-stakeholder workshop



2019

Mandates

Rules of procedure

Medicines safety

Info cards

Members voice

Committee feedback to working parties

EMA relocation

Revised WP mandates and Rules of Procedure

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

4 February 2019
EMA/109591/2018
Stakeholders and Communication Division

Rules of procedure for the Patients and Consumers Working Party (PCWP) and the Healthcare Professionals Working Party (HCPWP)

1. Roles and responsibilities

Membership of the PCWP and HCPWP implies a commitment from its members, through their **appointed representatives**, to participate actively in the work of the working party, which includes:

- Identify relevant topics for information, discussion and reflection.
- Exchange views and positions from organisations, scientific committees and EMA on topics addressed by the working party.
- Participate in meetings and written consultations of non-confidential nature.
- Propose recommendations to EMA, scientific committees and organisations on topics addressed by the working party.
- Inform their organisations and scientific committees about the activities of the working party.
- Agree on the mandate, work plan and any governance-related documents of the working party.

The working party shall have two **Chairpersons** (referred to as Co-Chairs, hereafter). One Co-Chair (also referred to as the EMA Co-Chair) will be a representative of the EMA secretariat and will be nominated by a Decision of the Executive Director. The other co-chair (also referred to as the HCPWP/PCWP Co-Chair) will be elected amongst working party members, following the procedure described in point 4. The Co-chairs shall in particular:

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Mandate, objectives and composition of the Patients and Consumers Working Party (PCWP)

1. General considerations

The Regulation (EC) No. 726/2004 of the European Parliament and of the Council, in particular Article 78 (1), gives additional responsibility to the European Medicines Agency (EMA), its Management Board and its committees to develop contacts with patients and consumers.

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Stakeholders and Communication Division

Mandate, objectives and composition of the Healthcare Professionals Working Party (HCPWP)

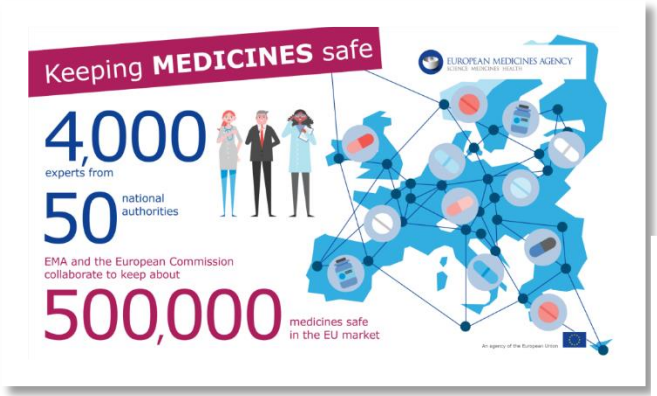
1. General considerations

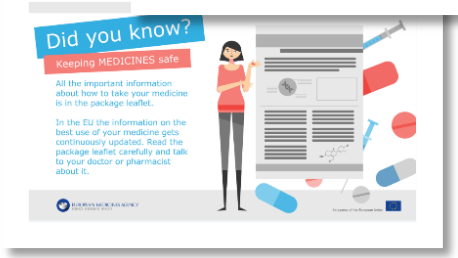
The Regulation (EC) No. 726/2004 of the European Parliament and of the Council, in particular Article 78 (1), gives responsibility to the European Medicines Agency (EMA), its Management Board and its committees to develop contacts with healthcare professionals.

During its 15 December 2011 meeting, the EMA Management Board endorsed in a *"Framework of interaction between the EMA and healthcare professionals"* (EMA/688885/2010) foreseeing the creation of a forum of exchange with healthcare professionals' organisations within the Agency, with links to EMA Human Scientific Committees (CAT, CHMP, COMP, HMPC, PDCO and PRAC).

To meet this requirement, the Healthcare Professionals Working Party (HCPWP) was formally established as the EMA Human Scientific Committees' Working Party with Healthcare Professionals' Organisations (HCPWP) in 2013 and re-confirmed in the revised framework for interaction, adopted on 16 December 2016 (EMA/89918/2016).

Medicines safety: information cards





Members voice: sharing practices

Health literacy initiative for young patients

Patient Access Partnership (PACT)

State of Health in the EU: the Community Pharmacy Contribution

Patient registries

Guidance documents

EU network of patient contact point for pharmacovigilance

Online training for MS nurses project, MS Nurse Professional

Challenges and Constraints of Insulin Source & Supply

Guideline on biosimilar for nurses

Twitter use training

We are here for our fellow patients

Members presenting how they include regulatory sciences in fellowships and training of young researchers

Committee members on the working parties


COMP



CAT



CAT



CHMP

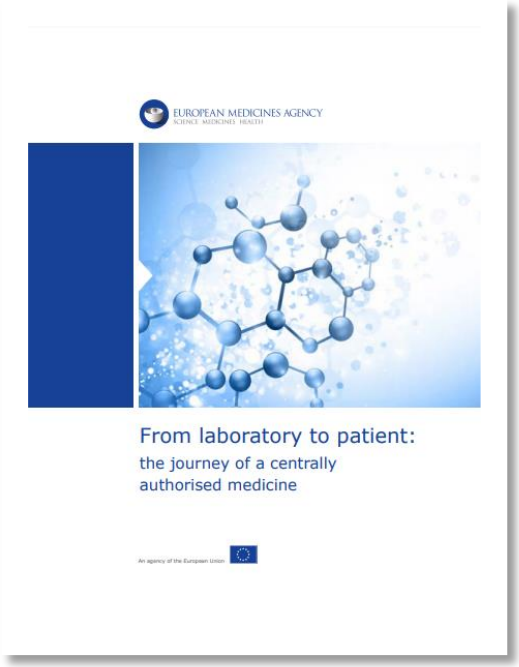


PRAC



HMPC

EMA initiative to explain evaluation procedures



Thank you!

For your continued time and effort…

May the next 3 years be equally fruitful!