



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



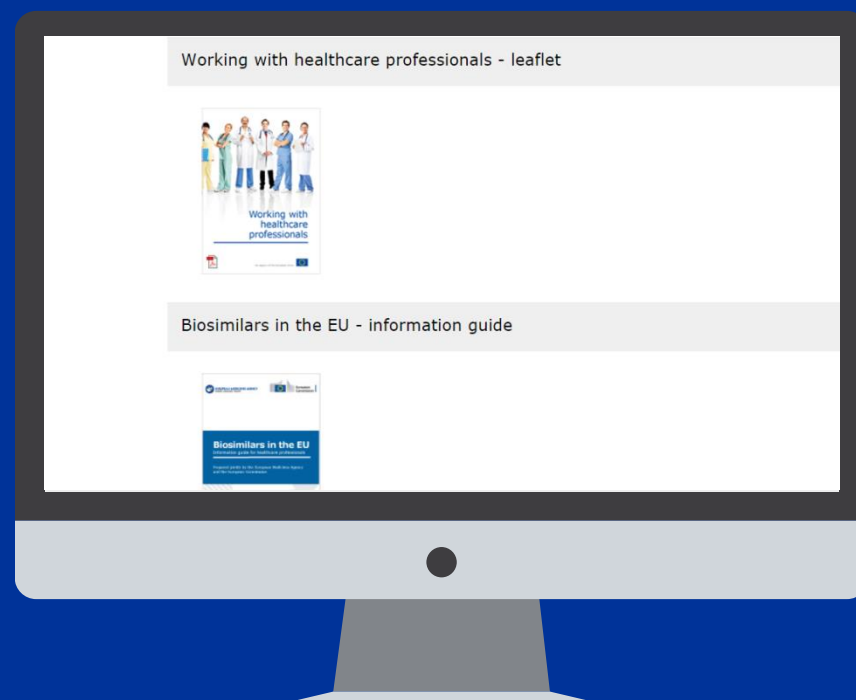
2016

Updated webpages for...

Patients and consumers



Healthcare professionals





2016

Impact of Pharmacovigilance activities; survey; workshop





2016

Healthcare professionals framework: revision





2016

Social media workshop



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 media¹ 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-RADR², where EMA will provide a platform for discussion and an opportunity for mutual learning.



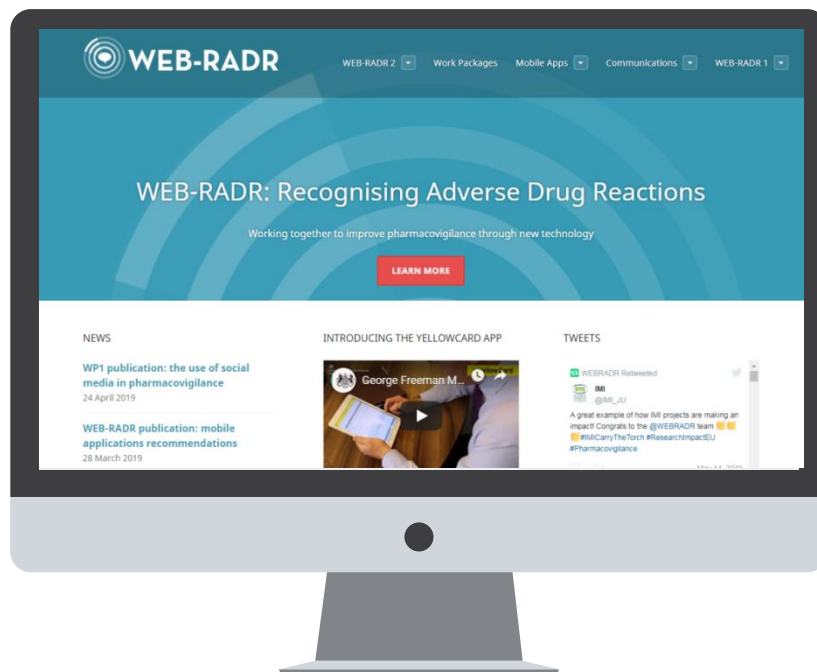
Workshops interviews
Press releases/news Targeted emails
Infographics factsheets Press briefings
Social media
Face-to-face meetings Reports Website
Newsletters Media requests
Videos External queries Webcasts





2016

WEB-RADR

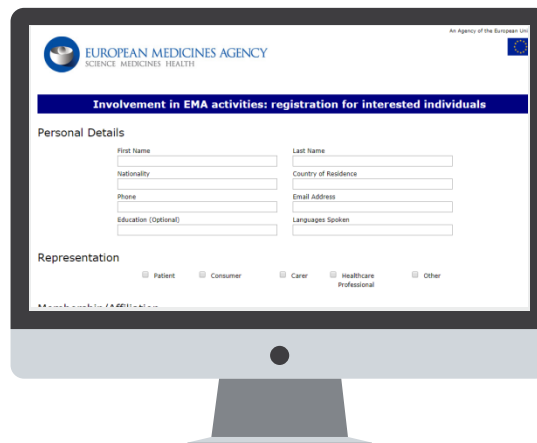
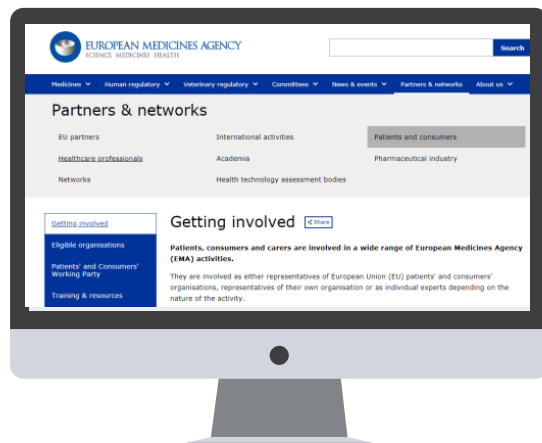


WEBRADR: <https://web-radr.eu/>



2016

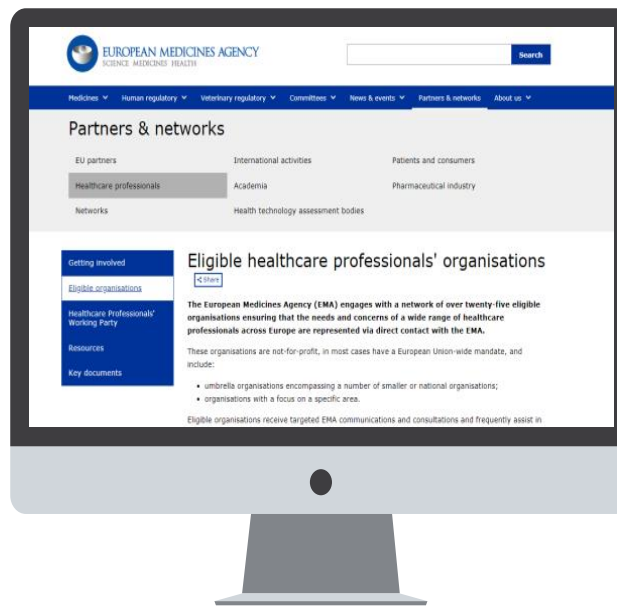
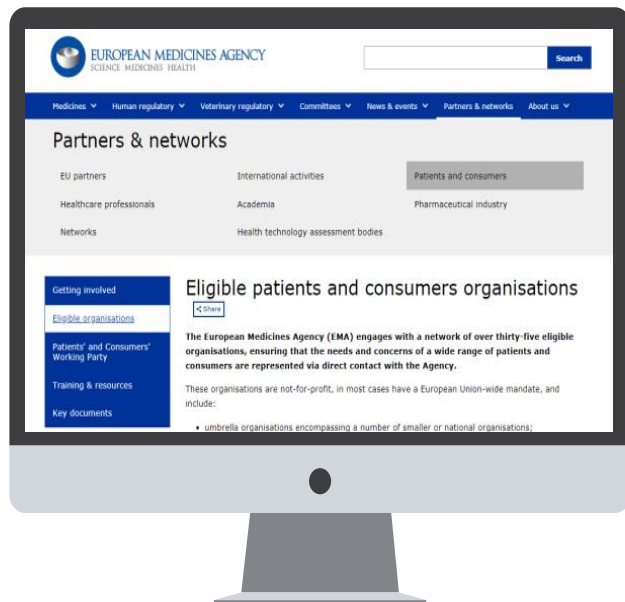
Individual patient database launch





2016

Organisation eligibility criteria: revised





2016

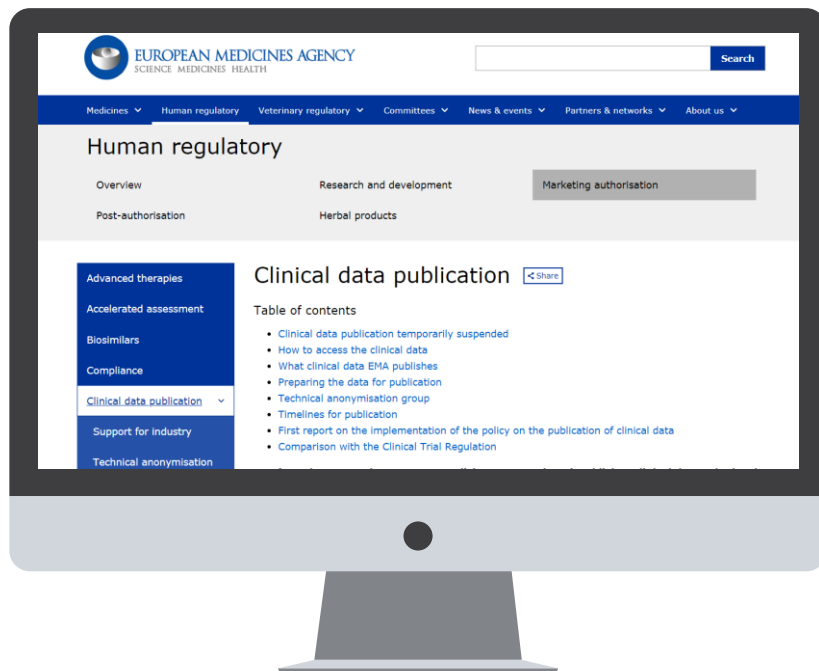
Patient registries workshop





2016

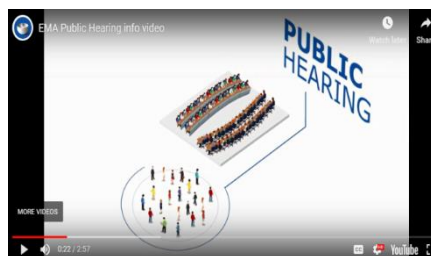
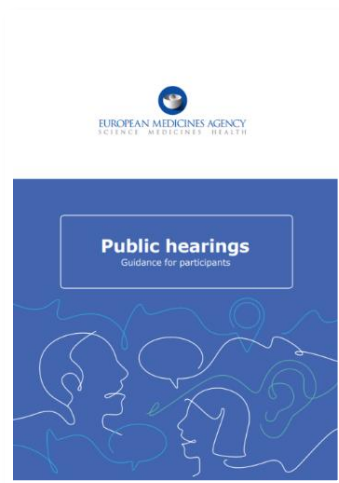
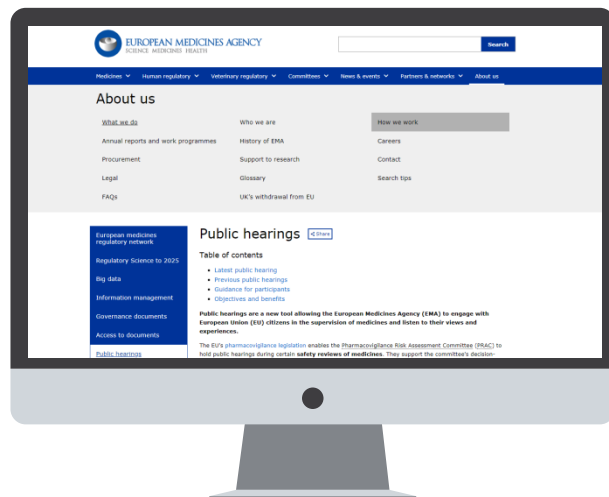
Clinical data publication; user testing





2016

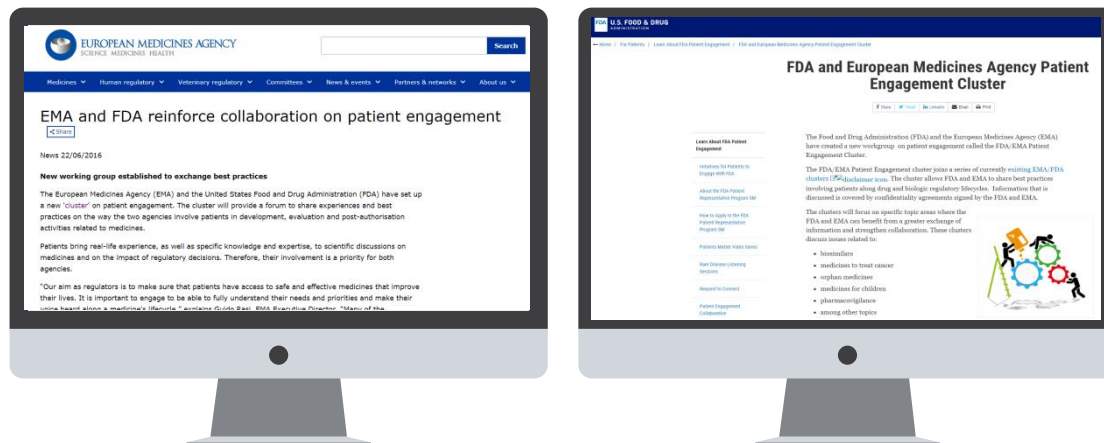
Public hearing preparations





2016

EMA and FDA: patient engagement



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





2016

Big data (workshop in medicines development)





2016

PCWP 10th anniversary





2017

Public hearing

Personalised medicine

Antimicrobial resistance

Biosimilars Academia

Involving young people

Perception survey

Patients in CHMP meetings

Additional monitoring

Availability of medicines

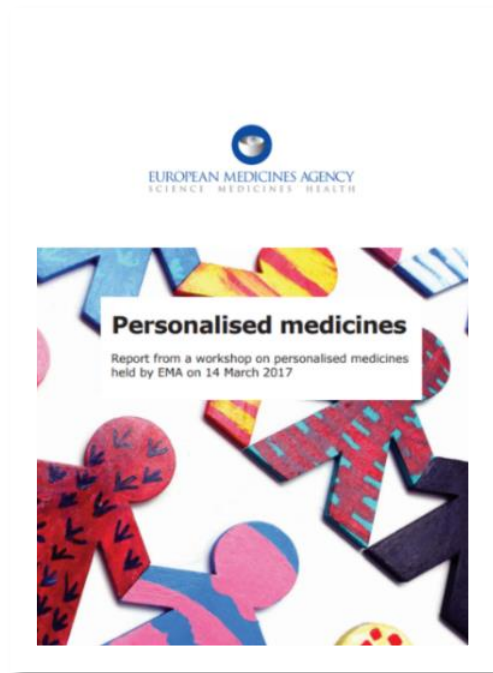
10th training day

EMA action plan



2017

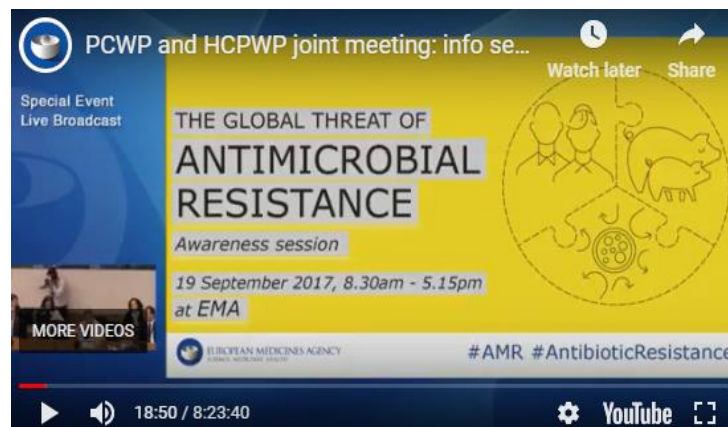
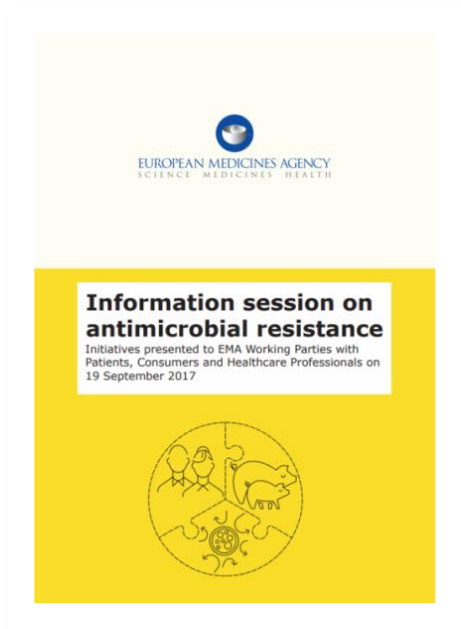
Personalised medicines workshop





2017

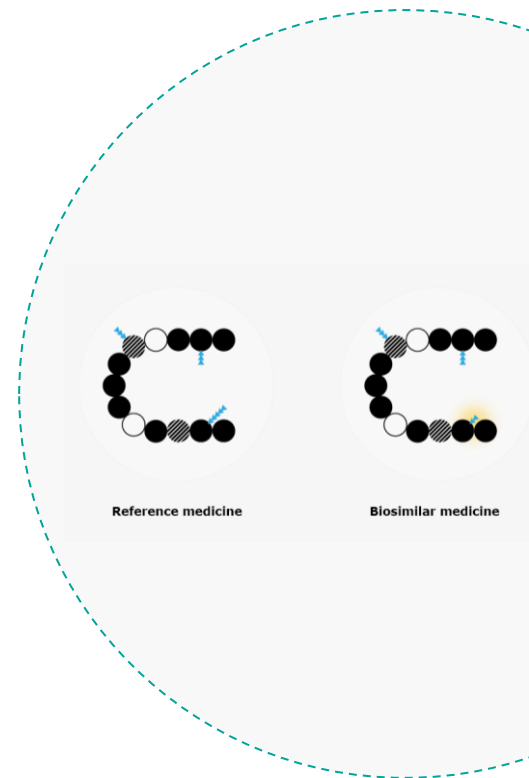
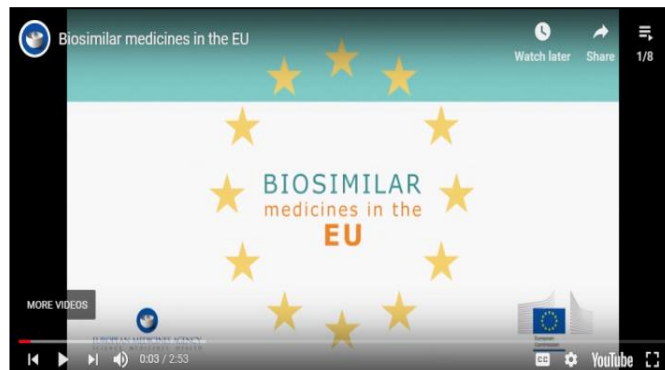
Antimicrobial resistance (AMR): information session





2017

Biosimilar medicines





2017

EMA communication: perception survey





2017

Organisation eligibility assessment: streamlining process

ELIGIBILITY



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 fulfill 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



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

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

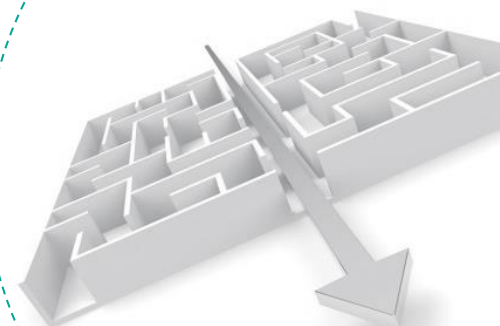
1. Introduction and purpose

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.





2017

EMA/EUnetHTA work plan 2017-2020



EunethTA: <https://www.eunethta.eu/about-eunethta/history-of-eunethta/>



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 Forum¹, 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 remit 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

EMA and EUnetHTA will work together to develop and implement a joint work plan for the years 2017-2020.

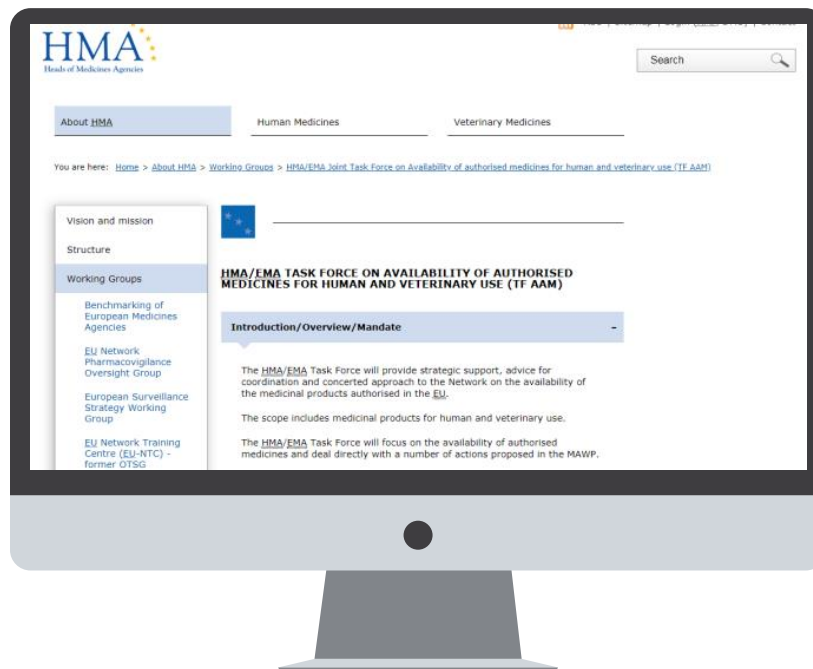


eunethta



2017

Availability of medicines: HMA/EMA Taskforce



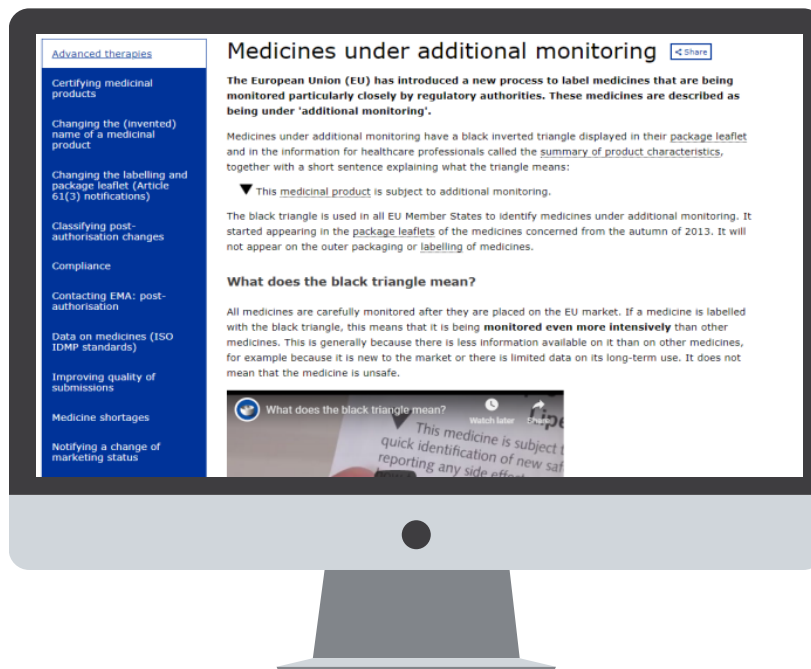
HMA: <https://www.hma.eu/522.html>





2017

Additional monitoring: impact survey



What does the black triangle mean?



The European Union (EU) has introduced a new way of identifying medicines that are being monitored particularly closely. These medicines have a black inverted triangle displayed in their package leaflet, together with a short sentence that reads:

▼ "This medicinal product is subject to additional monitoring."

All medicines are carefully monitored after they are placed on the EU market. However, medicines with the black triangle are being monitored even more closely than others.

This is generally because there is less information available about them compared with other medicines, for example because they are new on the market.

It does not mean that the medicine is unsafe.

How to report side effects

You should report any suspected side effects with a medicine you are taking, particularly if it displays the black triangle.

You can report side effects to your doctor, pharmacist or nurse.

You can also report side effects directly to your national medicines regulator, using the reporting system in your country. Information on how to do this can be found in the package leaflet of your medicine or on your national medicines regulator's website.

By reporting side effects, you can help medicines regulators assess whether the benefits of a medicine remain greater than its risks.





2017

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.

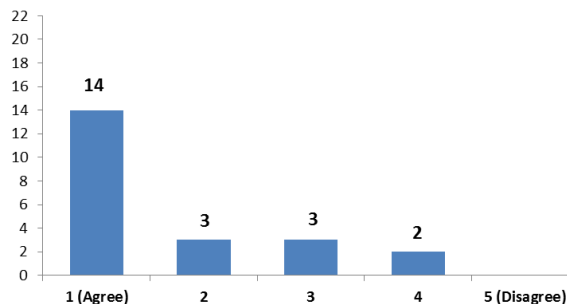
2. Involvement in benefit/risk discussions

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

Overall the presence of the patient(s) was beneficial





2017

1st public hearing: Valproate medicines





2017

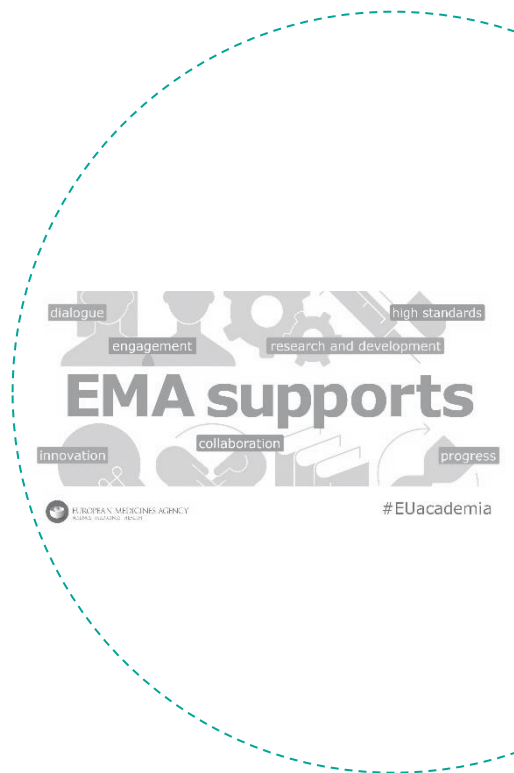
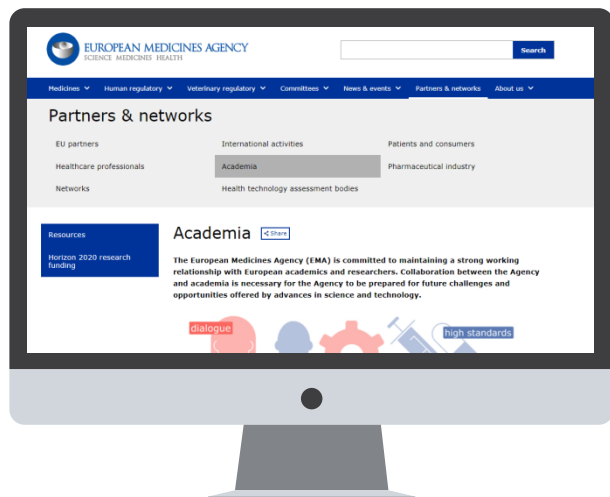
Involving young people: principles adopted





2017

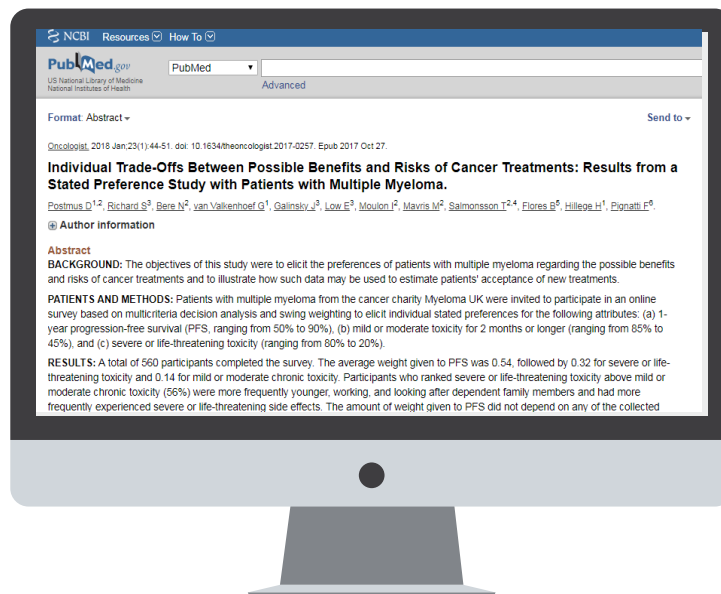
Academia framework: adopted



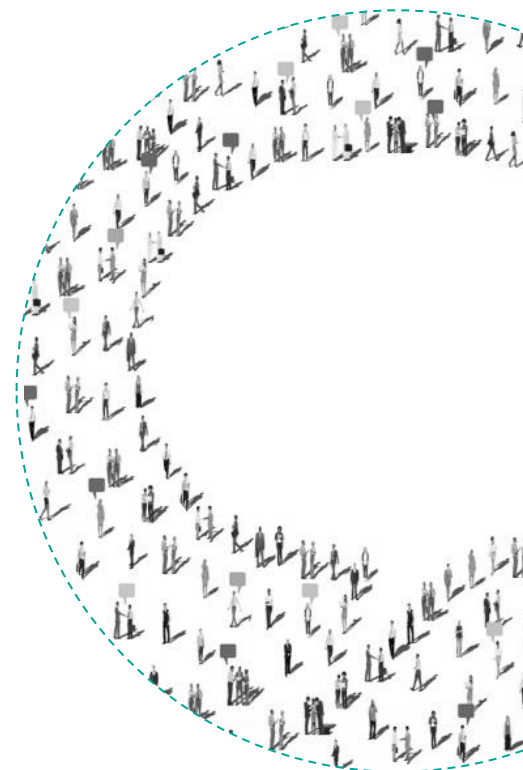


2017

Patient preference study in multiple myeloma



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





2017

10th annual training day

EMA Annual training day for patients and healthcare professionals

EMA provides training and support to ensure the voice of patients and healthcare professionals is heard all along the regulatory lifecycle of medicines.

About

EMA's annual training day is one of many engagement methodologies and resources used to support the involvement of stakeholders in its work. This initiative was first started for **patients and consumers** in 2007.

- Participants learn about **EMA, medicines evaluation** and practice by participating in **examples of real procedures**
- In 2017, **healthcare professionals and young people** were included in the training day for the first time
- Based on **feedback** received and regulatory updates, the content and format of training day is adapted each year

Objectives

- Understand how medicines are **authorised and monitored** in Europe
- Appreciate where and how patients and healthcare professionals can use a **hands-on approach**

The topics covered are:

- Scientific Advice
- Scientific Advisory Groups
- Document review (Medicines overview and safety communications)

Outcomes

A total of **297** participants trained to date.

Trained participants have subsequently become **members of**:

- Management Board
- Scientific committees
- Working parties

Have been invited as **experts in**:

- Scientific advice
- Scientific advisory groups
- Review of document
- Written consultations

Overview

2017 - 71 participants 2007 - 2017

53 patients and consumers
11 healthcare professionals
4 young people
3 academics

Total number of participants per year

Additional resources

Videos - EMA bite-sized introductory information on YouTube:

- EMA Basics Catalogue
- How are medicines approved
- Keeping medicines safe

EMA Annual Training Day 2017

- Highest ever number of participants (71)
- 51 patients and consumers
- 11 healthcare professionals
- 4 young people
- 3 academics

20 countries represented

Country	Participants
United Kingdom	10
the Netherlands	8
Sweden	7
Spain	6
Slovakia	5
Portugal	4
Poland	3
Norway	2
Hungary	2
Italy	2
Ireland	2
Germany	2
Greece	2
France	2
Czech Republic	2
Cyprus	2
Belgium	2

works
e-learning
online
WEBINAR
seminar
educational
training



2017

Medicine information: EMA action plan



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

EMA action plan related to the European Commission's recommendations on product information¹

The European Medicines Agency (EMA) recognises the importance of the European Commission report² 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



2018

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)

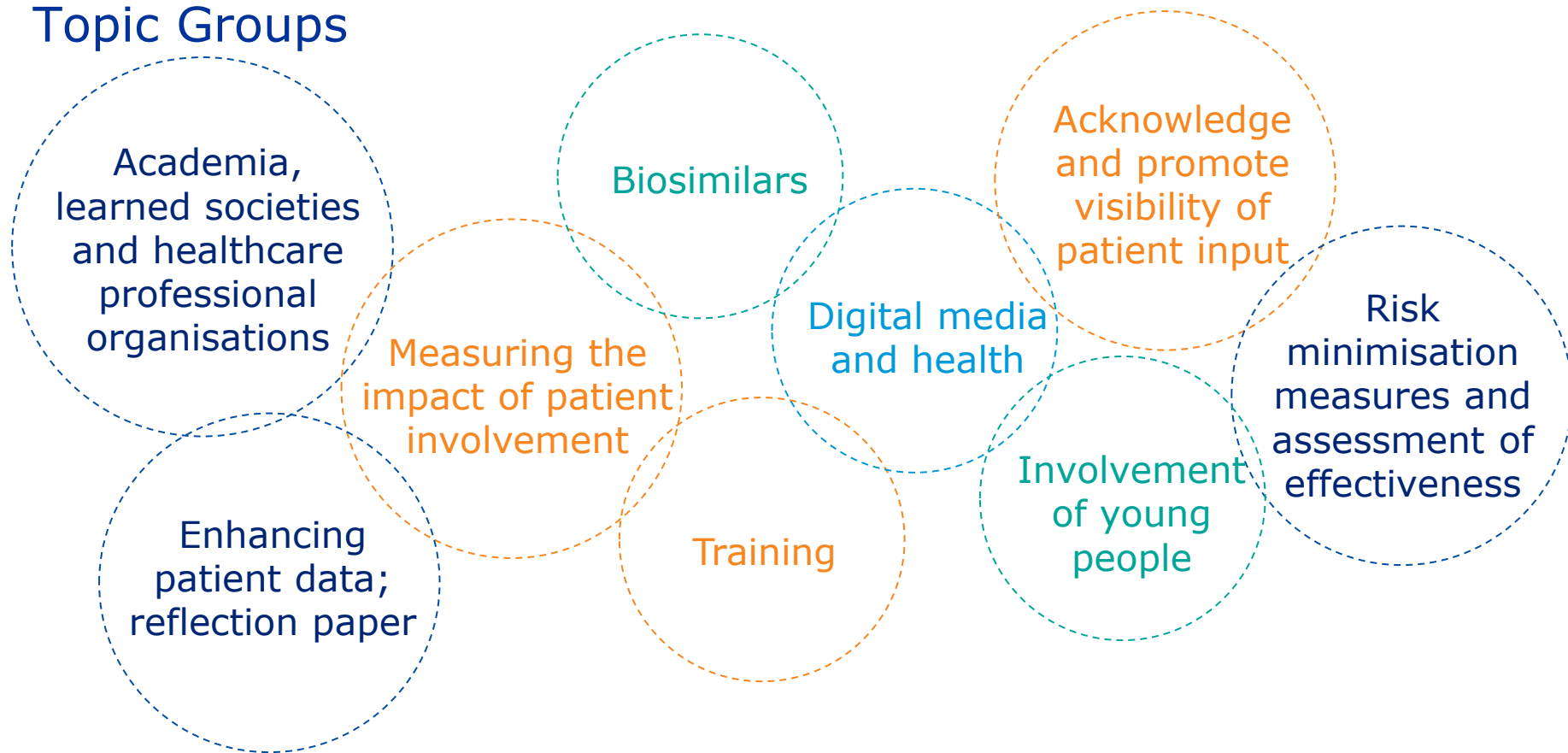
Chairpersons	Status
EMA: Juan Garcia Burgos	Endorsed by PCWP and HCPWP 14 March 2018
HCPWP: Gonzalo Calvo	Adopted by COMP, CAT, CHMP, PDCO and HMPC March 2018, and by PRAC April 2018
PCWP: Kaisa Immonen	





2018

Topic Groups





2018

Real World Evidence in medicine development

Regulatory Perspective on Real World Evidence (RWE) in scientific advice

EMA Human Scientific Committees' Working Parties with Patients' and Consumers' Organisations (PCWP) and Healthcare Professionals' Organisations (HCPWP)

Presented by Jane Moseley on 17 April 2018
Senior Scientific Officer – Scientific Advice Office

An agency of the European Union

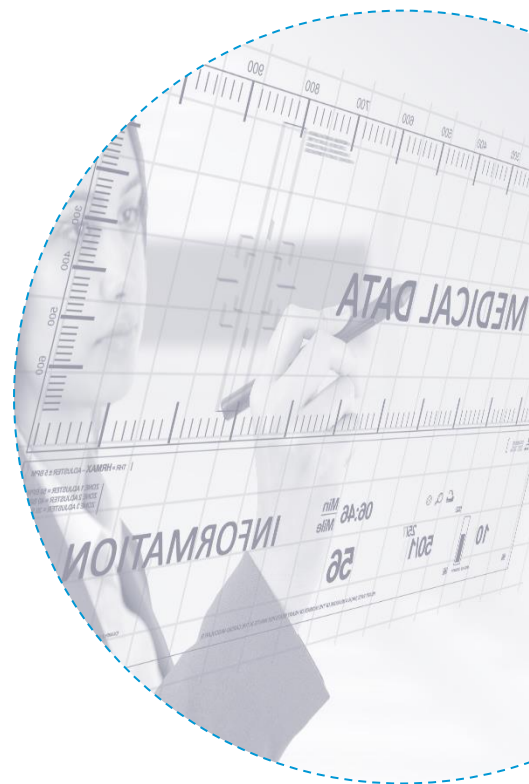
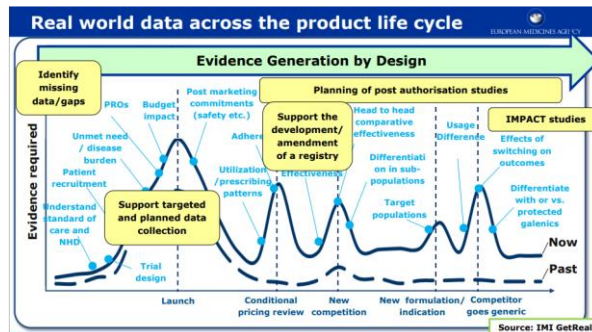
EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Real world evidence (RWE) – an introduction; how is it relevant for the medicines regulatory system?

London, EMA, April 2018

Hans-Georg Eichler
Senior Medical Officer

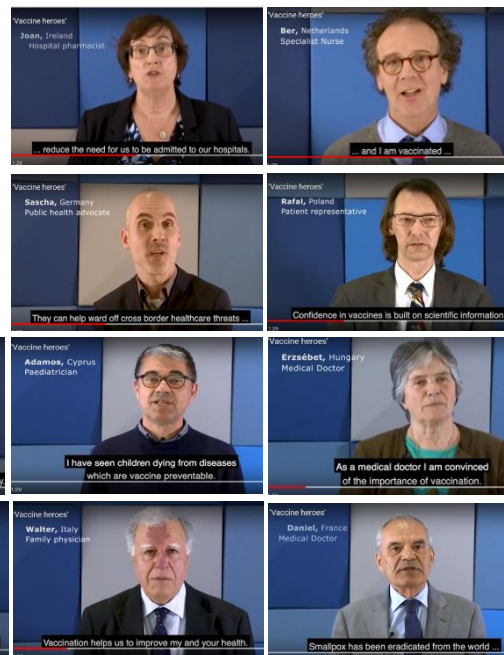
An agency of the European Union



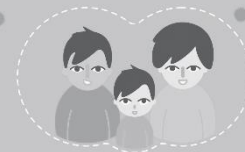


2018

European Immunisation Week



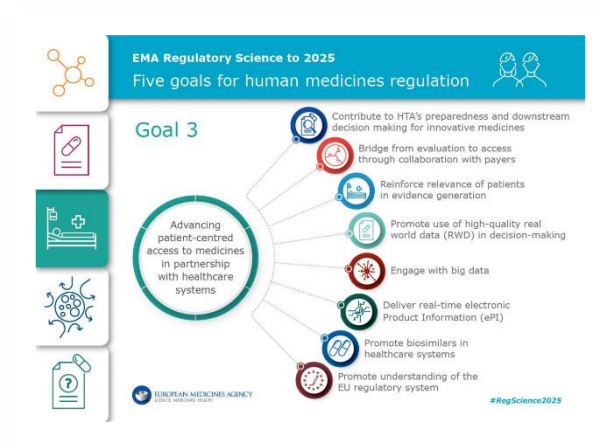
Protected together, #VaccinesWork





2018

EMA Regulatory Science to 2025



CONSULTATION





2018

Additional monitoring: awareness survey





2018

Availability of medicines: HMA/EMA workshop





2018

2nd public hearing: Quinolone and Fluoroquinolone medicines



Public Hearing: quinolone and fluoroquinolone medicines

Wednesday, 13 June 2018

Pharmacovigilance Risk Assessment Committee (PRAC)



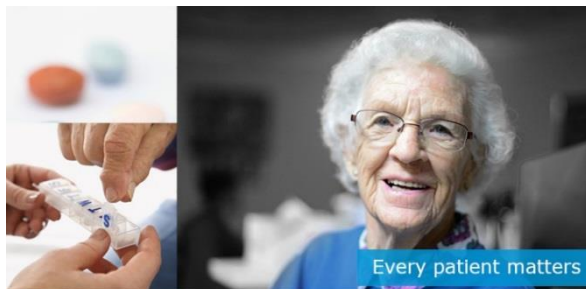
#EMAPublicHearing #antibiotics





2018

Good Pharmacovigilance Practices (GVP)

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#OlderPatients

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SCIENCE. MEDICINES. HEALTH.

#YoungPatients

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**



2018

Patient registries: initiative update



1 5 November 2018
2 EMA/763513/2018

Discussion paper:

3
4
5
6
7
8 **Use of patient disease registries for regulatory purposes –**
9 **methodological and operational considerations**

10
11
12
13 The Cross-Committee Task Force on Patient Registries
14

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

CONSULTATION



2018

Electronic product information: Multi-stakeholder workshop



Medicines Human regulatory Veterinary regulatory Committees News & events Partners & networks About us

European Medicines Agency (EMA) / Heads of Medicines Agencies (HMA) / European Commission (EC) workshop on electronic product information (ePI) [Share](#)

Date: 28/11/2018
Location: European Medicines Agency, London, UK

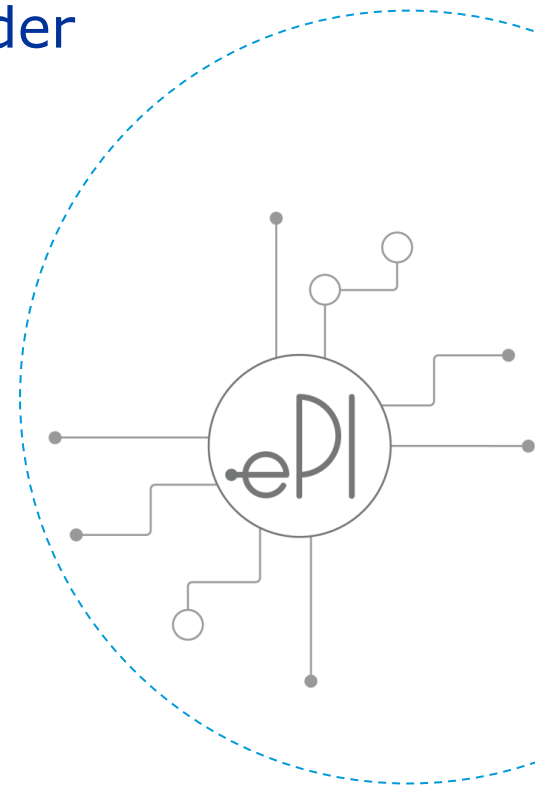
The objectives of this joint workshop are to agree with all stakeholders on common key principles for the use of electronic summary of product characteristics (SmPC) and package leaflet formats in the European Union (EU) and create a draft proposal of these key principles for public consultation.

The European Commission, HMA and EMA are working together to facilitate the development of electronic tools to improve access of patients and healthcare professionals to product information in the EU. Electronic formats bring new opportunities for summary of product characteristics and package leaflets.

As more Europeans gain access to information technologies, it is important to agree with all stakeholders on common key EU principles as to how electronic formats can be used to provide product information to EU citizens in accordance with existing legislation.

Video

EC/HMA/EMA workshop on electronic Product Information (ePI) Session 1



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



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:



4 February 2019
EMA/56112/2018 Rev. 3
Stakeholders and Communications Division

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.

During its 15 December 2011 meeting, the EMA Management Board endorsed a "Framework of interaction between the EMA and healthcare professionals" (EMA/68885/2010) 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, HMP, PCDO and PRAC).

To meet this in
(formerly known
Consumers' Or
...



4 February 2019
EMA/109592/2018, Rev. 1
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/68885/2010) 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, HMP, PCDO 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

Keeping MEDICINES safe

4,000 experts from 50 national authorities

EMA and the European Commission collaborate to keep about 500,000 medicines safe in the EU market

EUROPEAN MEDICINES AGENCY
AN AGENCY OF THE EUROPEAN UNION

What happens to my side effects report?

Keeping MEDICINES safe

If side effects are unusual a flag is raised and EU experts take an even closer look. This can lead to a change in how the medicine is prescribed.

You can play a role in making medicines safer by reporting side effects directly to your national medicines authority.

EUROPEAN MEDICINES AGENCY

Did you know?

Keeping MEDICINES safe

All the important information about how to take your medicine is in the package leaflet.

In the EU the information on the best use of your medicine gets continuously updated. Read the package leaflet carefully and talk to your doctor or pharmacist about it.

EUROPEAN MEDICINES AGENCY

Did you know?

Keeping MEDICINES safe

In the European Union you can buy medicines safely online.

Just look out for the common logo that helps you identify legally operating online pharmacies and retailers.

EUROPEAN MEDICINES AGENCY

Did you know?

Keeping MEDICINES safe

Experts from all over Europe, representatives of patients' and healthcare professionals' groups meet every month to discuss and analyse the latest information on the safety of medicines.

EUROPEAN MEDICINES AGENCY





Members voice: sharing practices

Health literacy initiative
for young patients



Patient Access
Partnership (PACT)



PGEU GPUE

Pharmaceutical Group of European Union
Groupement Pharmaceutique de l'Union Européenne

State of Health in the EU: the
Community Pharmacy Contribution



Guidance
documents



EU network of patient
contact point for
pharmacovigilance



Patient
registries

Online training for MS nurses
project, MS Nurse Professional



Challenges and
Constraints of Insulin
Source & Supply



Guideline on
biosimilar for
nurses



Twitter use
training



EFIM

European Federation of Internal Medicine



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

EUROPA UOMO

The Voice of Men with Prostate Cancer in Europe

We are here for
our fellow patients



Committee members on the working parties



COMP



CAT



CAT



CHMP



PRAC

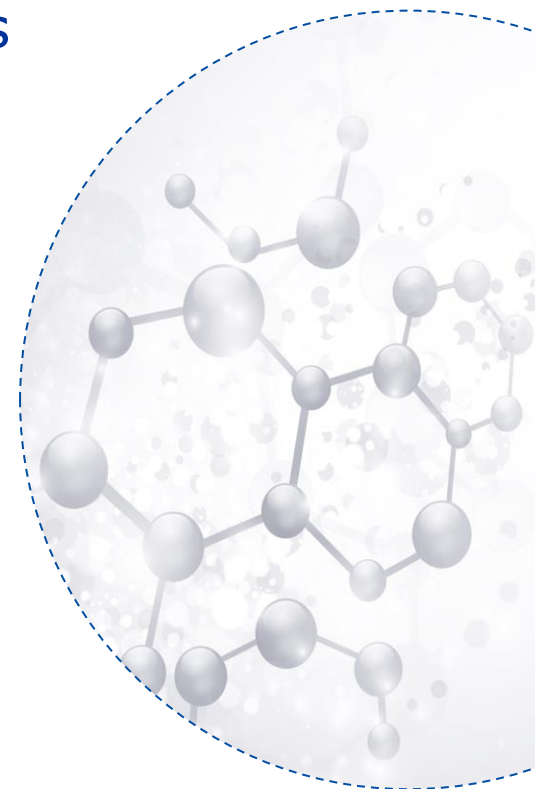


HMPC





EMA initiative to explain evaluation procedures





Thank you!

**For your continued
time and effort...**

**May the next 3
years be equally
fruitful!**