



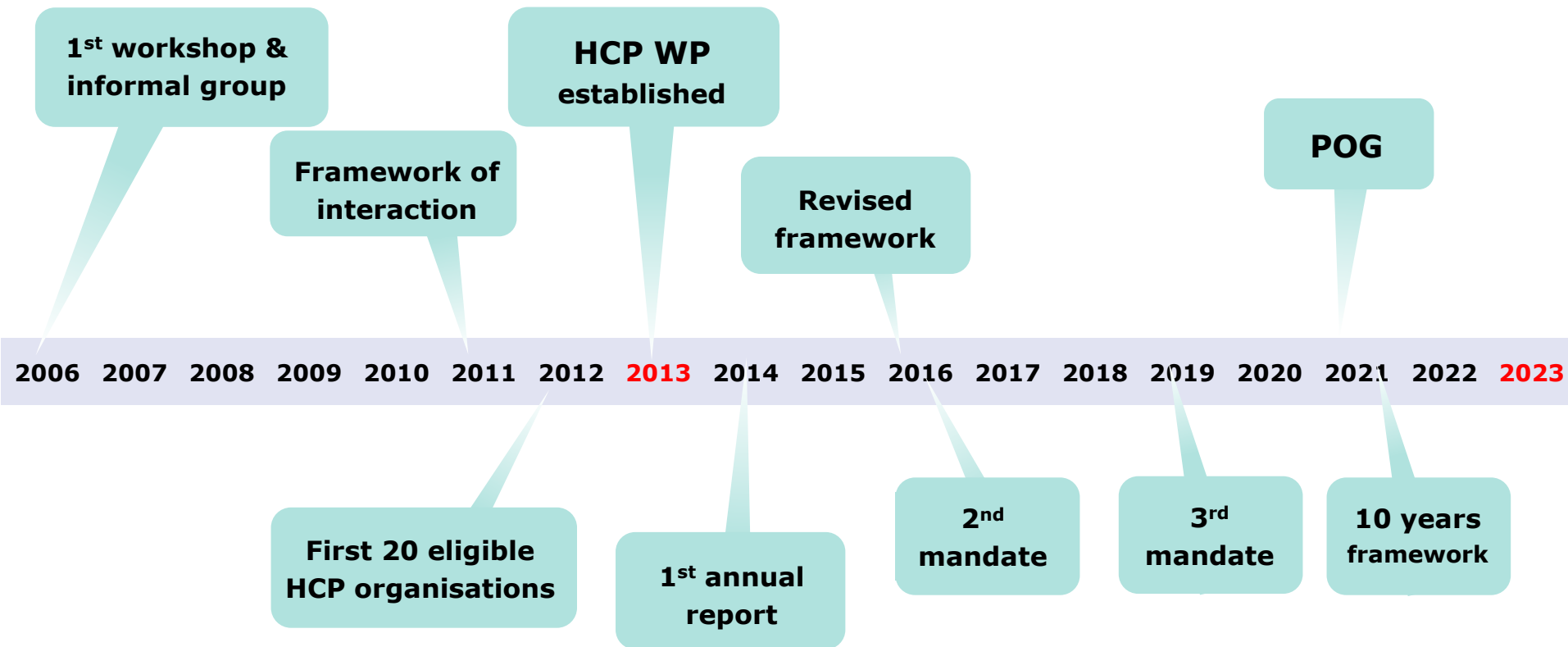
EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# 10 YEARS HCPWP

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Highlights of HCPWP involvement in EMA activities







**What  
did we  
do?**

**Activities**  
**Topics**  
**Collaborations**  
**Concepts**  
**Initiatives**



# Information on medicines: priority since the start

EC report on product information document SmPC  
 EMA EPAR templates  
 action plan PL HCPWP  
 on product e-PI topic group:  
 information SmPC information  
**Information on medicines**  
**on vaccines Workshop:**  
 Medicines labelling communication  
 User testing about medicines





# Evaluating & communicating benefit-risk

**Geriatric medicines Risk communication**  
**Workshop on methodologies for B/R evaluation**

**Pregnancy & breast feeding CHMP early contact Survey & participation in scientific advice**  
**Workshop on B/R communication**





# Pharmacovigilance: from monitoring to safer use

**RMP** **ADR** Eudra  
**summaries** **reporting** **vigilance**  
**Additional monitoring** **Risk**  
 Nitrosamines **Black** **management**  
**Medication** **triangle** **PRISMA**  
**errors** **Impact**  
**Public** **HCPWP topic** **DHCPs**  
**hearings** **group on** **review**  
**RMMs** **EU**  
**Off-label use** **Falsified** **legislation**  
**medicines**





# Clinical trials: collaboration for better medicines

**Covid-19**  
**Joint ICH trials** **Decentralised drafting group**  
**EU legislation review** **CSR**  
**ICH GCP** **E6 E8** **Multi stakeholder platform** **Clinical trial**  
**ACT EU** **transparency**  
**data paediatric** **Workshop on CTR** **clinical registry based**  
**EU CT portal** **research studies**





# Medicines shortages: working together is key

**EU Shortages reporting**  
**guidance on by organisations**  
**shortage prevention pilot**

**Pandemic response & shortages** **EMA-HMA**  
**Task Force**

**Guidance for public Multi-**  
**authorities on stakeholder**  
**communication workshops**

**HCP-POs common position**

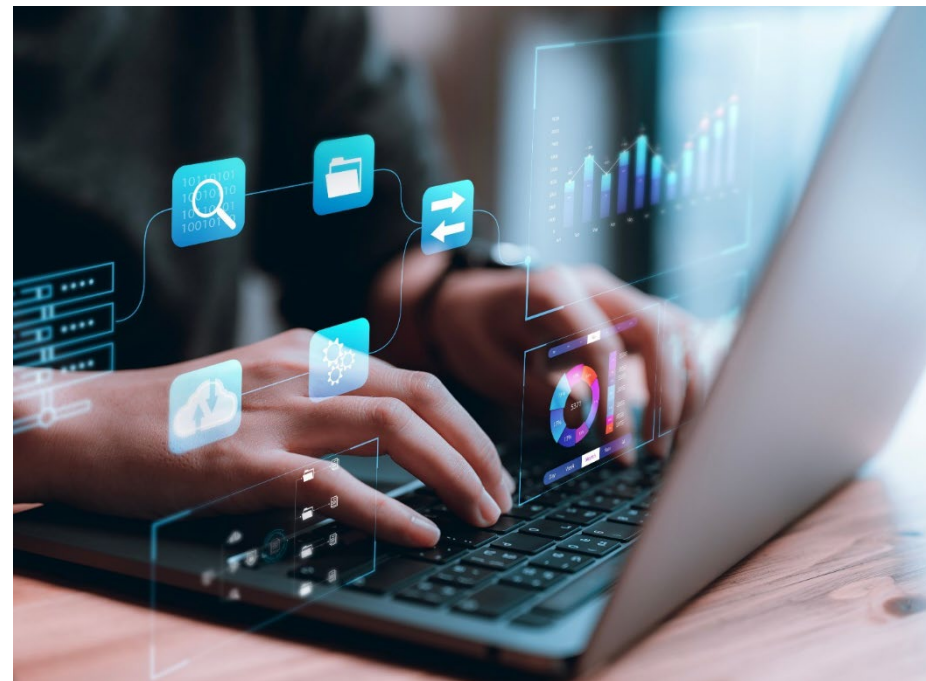






# Digital transformation: ongoing (r)evolution

collaboration  
 Pilot on patient registries  
 mHealth  
 Secondary use of data  
 Big Data  
 Steering  
 Patient experience data  
 Topic group  
 Group  
 RWD  
 digital media  
 EHDS  
 Data protection  
 GDPR  
 DARWIN EU  
 ERN model  
 workshop  
 Data analytics  
 in EHDS  
 RWE  
 Data  
 anonymisation workshop





# COVID-19 pandemic: importance of dialogue

**Communication** Public health messages  
 Combating **COVID-19** safety updates  
 misinformation **Vaccines** & effectiveness Vaccine confidence  
**Vaccines safety & effectiveness**  
**HCPs on Transparency**  
**EMA ETF** Public stakeholder meetings  
**Therapeutics**





# Biosimilar medicines: from “new” to “normal”

**Q&A**  
**biosimilars**

**EMA**  
 communi  
 cation **plan**

**EMA Guide**  
**for HCPs**

**Biosimilars**  
**and shortages**

**EMA**  
**action plan**  
 on  
**biosimilars**

**Interchangeability**  
**EMA/HMA statement**

**Information**  
**EC session**  
**stakeholder**

**Biosimilars WG**  
**meeting with**  
**stakeholders**  
**workshops**





# Antimicrobial resistance: an emerging priority

**Information Stakeholder**  
**session European survey**  
**on AMR Antibiotic**  
**ECDC survey Awareness**  
**on HCP Day EMA messages**  
**perceptions for EAAD**  
**multi stakeholder**  
**workshop in pipeline**





# Innovation & access to medicines

**HCP survey**  
implications of  
innovation for  
clinical practice

**Workshop on  
approval challenges  
for immunotherapies**

**PRIME** **EMA-HTA  
interface**

**EMA**  
adaptive  
licensing

**ATMPs** **Personalised  
medicine**

**pilot** **Repurposing** **Adapt-**

**10 years report** **EUNetHTA** **Smart  
conditional MA**





# Governance and strategy: HCPWP input

Multistakeholder engagement strategy

Workshop on  
EMA extended  
mandate

EMA Network  
Strategy to 2020 Eligibility  
criteria

EMA Network  
Strategy to 2025: with GPs  
early engagement

Workshop:  
EMA 25 years

Regulatory Science to  
2025 multistakeholder  
workshop

HCPWP topic  
group on  
academia

Regulatory science research agenda  
collaboration with  
academia  
Policy on  
Transparency





# HCPs on EMA committees & advisory boards

## EMA MB

Wolf-Dieter Ludwig  
Denis Lacombe

## PDCO

Johannes Timaniau

## COMP

Katerina Kubackova  
Daniel O'Connor  
Elisabeth Johanne Rook

## HMPC

Steffen Bager  
Olga Maria Palomino

## CHMP

Dinah Duarte  
Fatima Ventura

## CAT

Olli Tenhunen  
Bernd Gansbacher  
Alessandro Aiuti

## PRAC

Kirsten Mhyr  
Filip Babylon  
Jane Ahlqvist-Rastad  
Raymond Anderson  
Roberto Frontini



## Big Data Steering Group

Ioanna Agache

## DARWIN EU Advisory Board

Aldo Maggioni

## EMA Emergency Task Force

Anita Simonds  
Tiago Villanueva



## HCP and EMA co-chairs



Gonzalo Calvo



Ulrich Jaeger



Rosa Giuliani



Isabelle Moulon



Juan García Burgos





# The HCPWP Secretariat



Ivana Silva



Zhenya Shtereva



Kaisa Immonen



Nicola Martin



Malika Holleyman

**10**

**YEARS**

**HCPWP**