



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Patients' involvement in the regulatory pathway

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Partnering for Patients conference on "Advancing patients centricity – from theory to practice"

## **Session 1: EU planning and strategy to advance patient centricity**

Presented by Juan Garcia Burgos on 28 May 2021  
Head of Public and Stakeholders Engagement Department





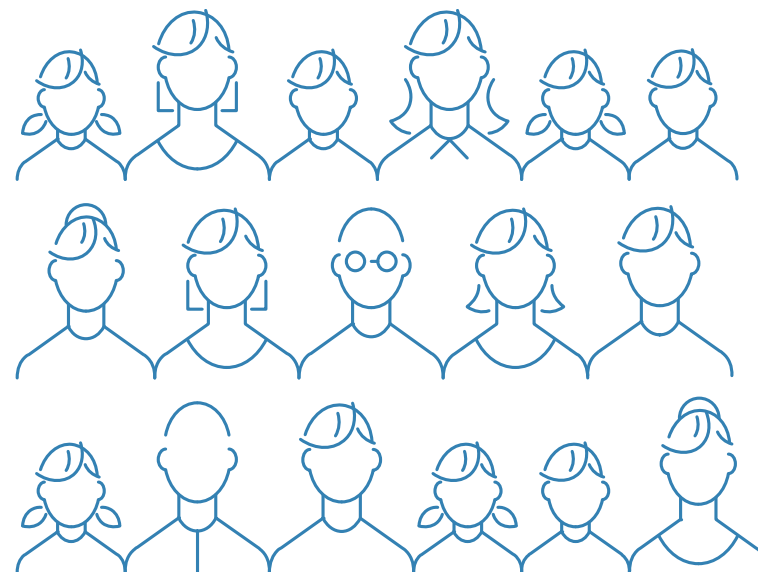
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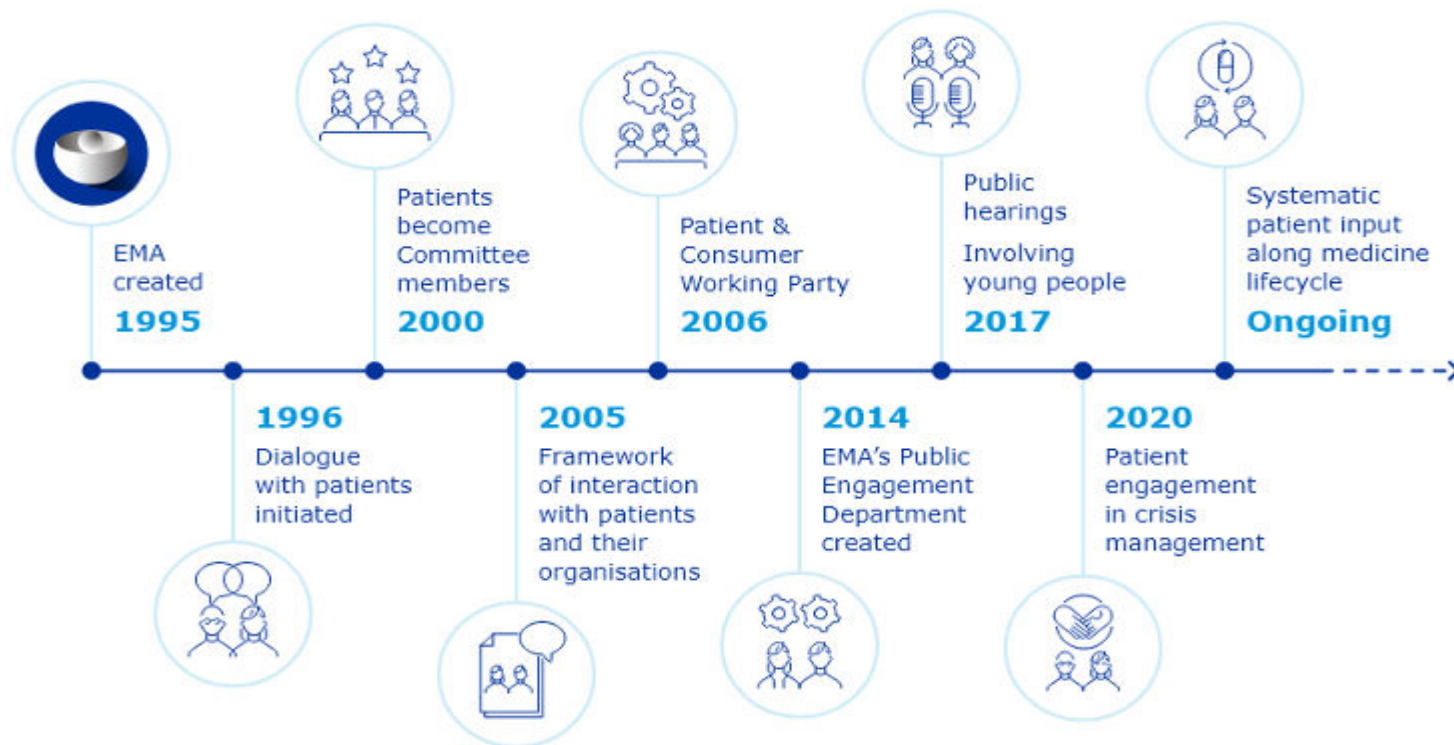
The presenter does not have any conflict of interests.



## Patient engagement: **Integral element of EMA activities**



# A progressive journey...



# Patient involvement along the regulatory lifecycle



- **Developed together with patients!**
- **Added value well acknowledged!**
- **Mutual benefits optimised!**

COMP: Committee for Orphan Medicinal Products  
 CAT: Committee for Advanced Therapies  
 PDCO: Paediatric Committee  
 CHMP: Committee for Human Medicinal Products  
 PRAC: Pharmacovigilance and Risk Assessment Committee  
 SAWP: Scientific Advice Working Party

 COMMITTEES & EXPERTS MEETINGS  
 DOCUMENTS FOR THE PUBLIC

## Patients to contribute directly to scientific discussions

- Committee (full voting) membership
- Scientific advice procedures
- Scientific Advisory Groups (SAGs) / Ad-hoc expert group meetings
- Committees/Working Parties direct consultations (f2f /questionnaires/surveys)
- Stakeholder meetings
- Public hearings
- EMA workshops & public consultations on development /update of regulatory guidance
- Review of labelling, risk minimisation measures and safety communications (appropriate language / increase awareness)

# Increasing and varied involvement throughout many different EMA activities

## Representing their *community*

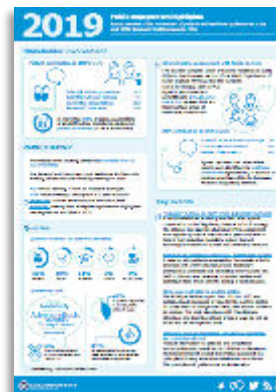
- Management Board
- EMA Scientific Committee Members

## Representing their *organisations*

- Working Party (PCWP or HCPWP)
- EMA consultations
- Workshops

## *Individual experts*

- Scientific Advice / Protocol Assistance Procedures
- Scientific Advisory/ad hoc expert Groups
- Scientific Committee consultations
- Review of documents



Patient involvement in medicine-related activities

# Networks

**Organisations;** representing EU patients or consumers may express an interest to work with EMA, (eligibility criteria & application form: [EMA website](#))

## Patients and Consumers Working Party



**Individuals;** patient or carer can register to work with the EMA (application form on [EMA website](#))

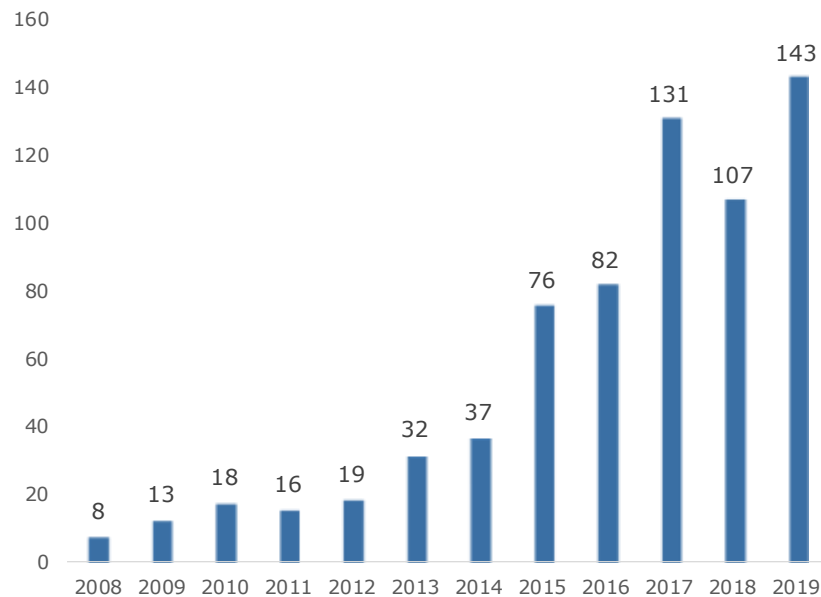


**EMA/FDA collaboration;** sharing practices

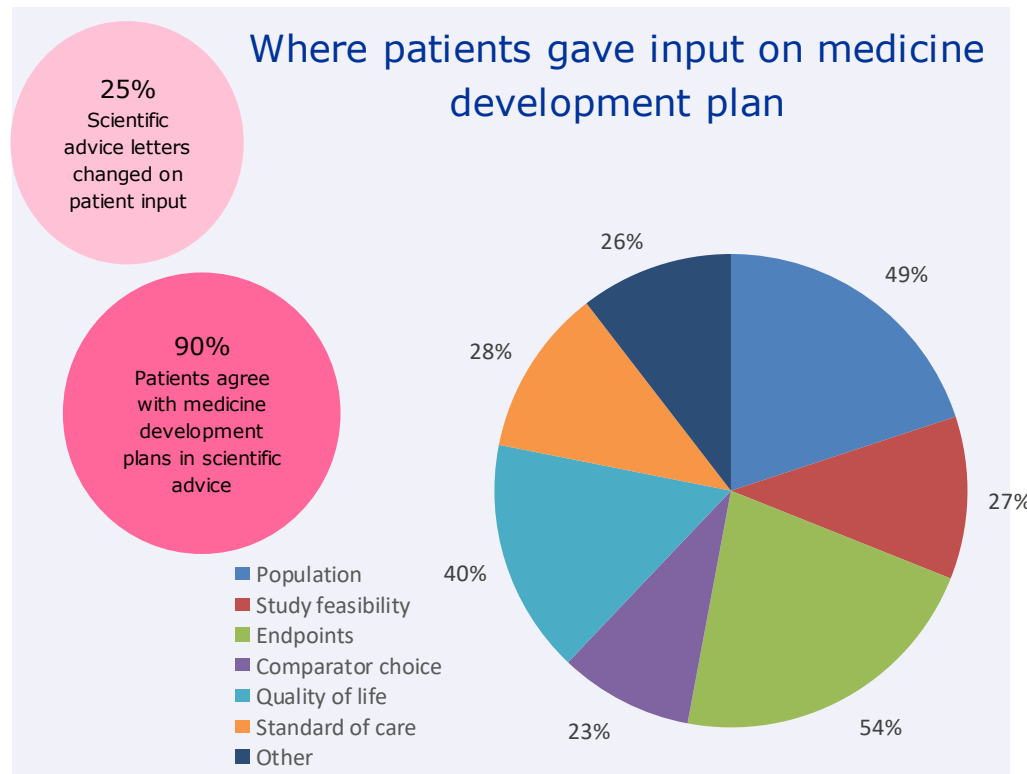


# Patient involvement in Scientific Advice procedures at EMA

Involvement since 2008



Where patients gave input on medicine development plan



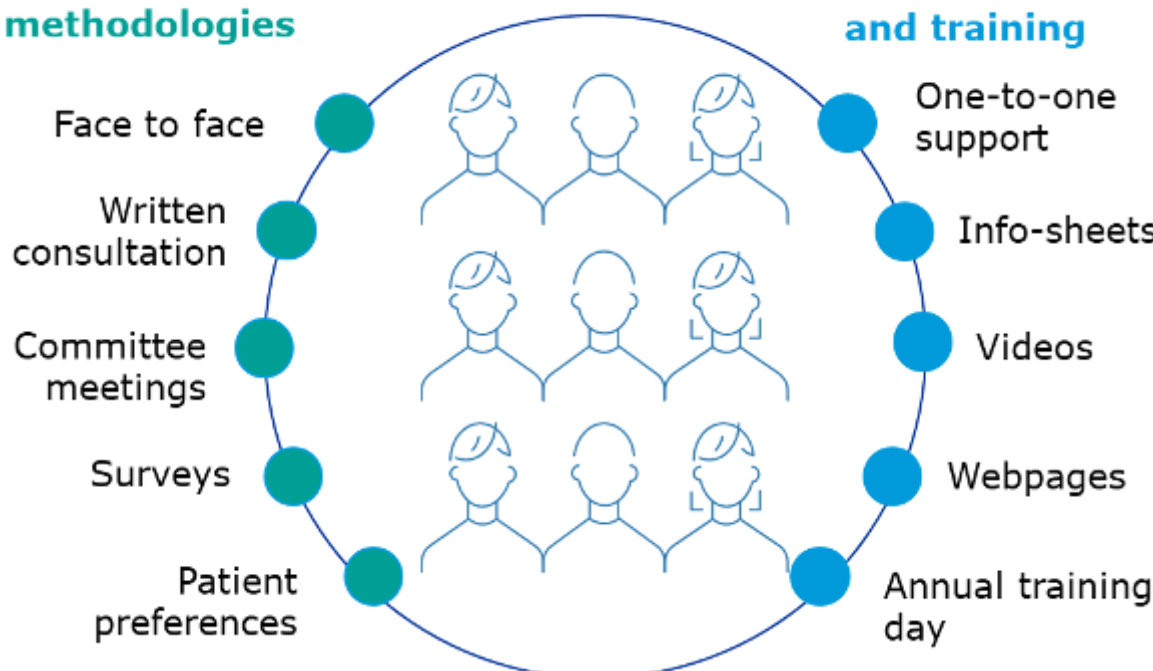


# Vital elements

One size does not fit all!

## Flexible engagement methodologies

## Appropriate support and training



# Engaging patients during COVID-19

**In a crisis context, engagement with patients more important than ever**

- **Not an improvised task**

- requires skills and well-grounded process with defined stakeholder roles
- implement collaborative approach
- monitor stakeholder opinions

- **Critical elements in crisis management**

- stakeholder mapping
- established engagement methodologies
- scenario-planning
- impact assessment

# Engaging patients during COVID-19

## **In a crisis context, engagement with patients more important than ever**

- Voices of civil society in scientific committees
- Patient and healthcare professional representatives in EMA COVID-19 Taskforce
- EMAs COVID-19 communications reviewed by patients/healthcare professionals
- Patients and Healthcare professionals disseminate EMA's COVID-19 communications to their communities
- Regular updates on COVID-19 pandemic to EMA's Networks (e.g. PCWP)
- EMA responds to queries and concerns from general public
- Public stakeholder meetings

# EMA public meetings

**11 December 2020**

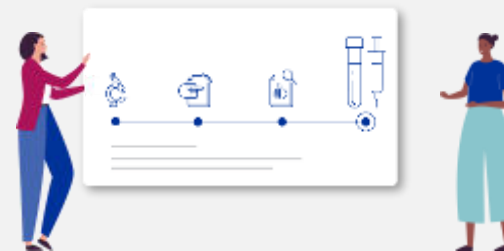
BROADCAST LIVE



Inform the public and stakeholders about EU regulatory process for approval of COVID-19 vaccines and EMA's role in their development, evaluation and approval

**8 January 2021**

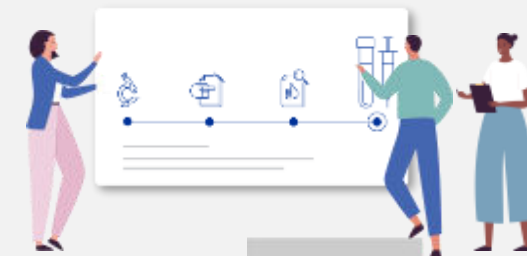
BROADCAST LIVE



Explain the basis for the approval and use of new vaccines, how their safety will be monitored and their roll-out at national level

**26 March 2021**

BROADCAST LIVE



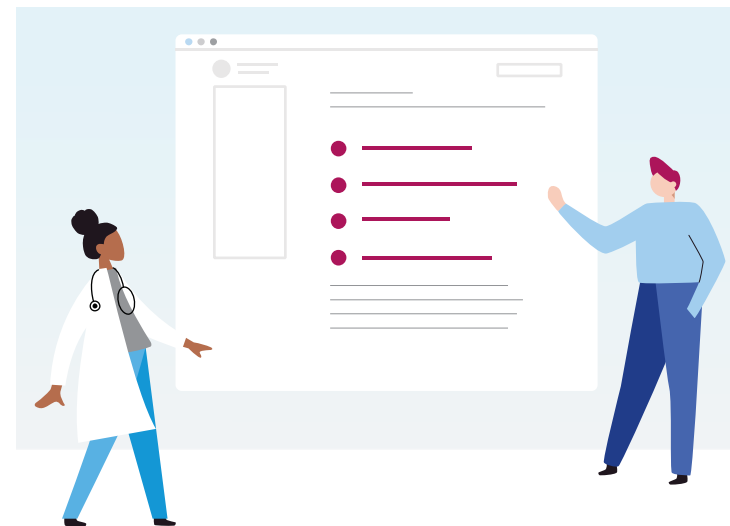
Update to EU citizens about the continued assessment, approval and safety monitoring of COVID-19 vaccines, as well as their expected impact at community level

**Listen to the public and stakeholder groups** on their needs, expectations and any concerns, so that these can be considered in the relevant regulatory processes.

# Engaging patients during COVID-19

## Added value

- Gather critical input into crisis-related activities in the context of COVID-19
- Support specific considerations, such as discussions on vaccines, associated social challenges, vaccine deployment, vaccine hesitancy, etc
- Anticipate, prevent, mitigate and recover from emerging issues during a public health crisis
- Channel public health messages directly to patients, healthcare professionals and citizens
- Reinforces legitimacy of actions and trust in the scientific outcomes and the EU system



## Key learnings for successful engagement

- **Who** to engage with?
  - Create diverse group of stakeholders to consult
  - Criteria for organisations / individual participation
- **How** to engage?
  - Test and implement various engagement methodologies
  - Provide appropriate support and training
  - Be transparent - share relevant information / outcomes
  - Monitor and report on engagement
- **When** to engage?
  - All along the medicines lifecycle; begin early and don't stop!



## Looking ahead

Engagement well established at EMA, but need to evolve with scientific advances, enhanced knowledge on engagement, and external changes that will affect the Agency;

- Update framework of interaction covering two levels of complementary engagement:
  1. Expand methodologies for individual patient input during regulatory assessments
    - Systematic early interactions
    - Focus groups
    - Enhance use of public hearings and open stakeholder meetings (using digital tools)
    - Enhance engagement in innovation, horizon scanning and regulatory science
    - Further develop engagement during crisis management
  2. Enhance generation and use of patient experience data and provide guidance



## Looking ahead (cont..)

- Expand capacity and network outreach
- Enrich training and support with new tools and content
- Exchange methodologies across decision makers (e.g. HTAs)
- Contribute to multi-stakeholder projects (e.g. IMI)
- Work with patient organisations and researchers testing new methodologies (e.g. patient preference elicitation)
- Progress patient engagement in a global context (e.g. ICH, CIOMS)
- [EMA Regulatory Science Strategy to 2025](#) and [Joint European Medicines Agencies Network strategy to 2025](#), developed in consultation with stakeholders, defines future direction of engagement; driving collaborative evidence generation to improve quality of regulatory evaluations



# Any questions?

## Further information

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