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Stakeholder Engagement report 2022-2023: overview

PCWP-HCPWP joint meeting, 27 February 2024

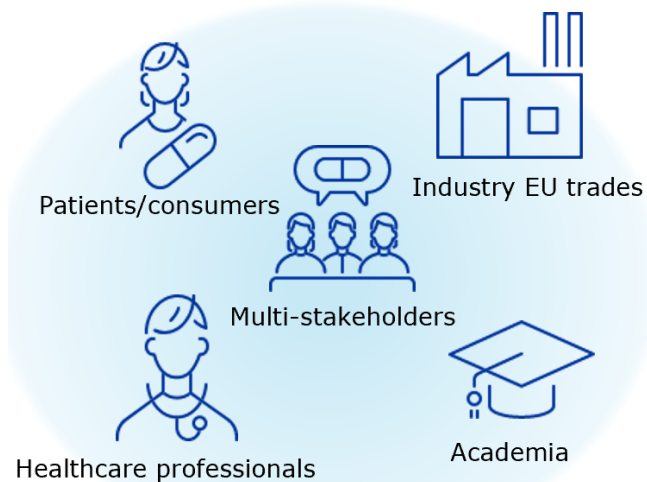
Presented by Maria Filancia

An agency of the European Union



EMA's biennial Stakeholder Engagement report 2022-2023

- First time all key stakeholder groups activities reported in one document.
- Emphasis on **multi-stakeholder** as well as **targeted engagement**.



Comprehensive overview of all key engagement initiatives in 2022-2023 where stakeholders' contribution was fundamental to ensure **patients' and animal health**



- Multi-stakeholder approach adopted whenever possible
- Identify bottlenecks and find solutions to certain major regulatory challenges such as:
 - Ensuring **availability** of medicines (e.g., medicines shortages, emergency task force).
 - **Innovation**, data analytics, digital tools and digital transformation (e.g., clinical trials, big data, AI, patient experience data).
 - Implementation of **Veterinary** Medicinal Product Regulation.
- The multi-stakeholder approach complemented targeted engagement established by the **frameworks of interaction**.



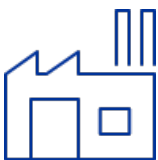
- Adoption of **CHMP early contact** as established methodology
 - extension to all medicines as of 2022, following successful pilot.
- Demonstrated added value of **patient engagement** in **early dialogue**: scientific advice as case study.
- Progress on **Patient Experience Data (PED)**
 - Multi-stakeholder Workshop in 2022
 - EU Network-wide initiative on PED launched in 2023.
- Ongoing engagement activities with organisations (e.g. PCWP, stakeholder meetings) and individual patient experts (e.g. SA, SAGs/AHEGs, document review).
- Updated Engagement Framework - reflects and confirms the importance of these relationships.



- Ongoing engagement activities with organisations (e.g. HCPWP, stakeholder meetings) and individual HCP experts (e.g. SAGs/AHEGs, document review).
- Review of current framework of interaction with HCPs.
 - Reflection process initiated
- **CHMP early contact**
 - Methodology extended to healthcare professional organisations (May 2023).
- June 2023: **10th anniversary** of HCPWP.
- **Policy Officers Group**
 - continued as valued complement to HCPWP, for deeper discussion with regulators on specific areas.



- Interactions with academic sector continued to grow:
 - Increase in applications for PRIME and orphan designations, scientific advice preparatory meetings.
- Pilot programmes launched on [repurposing](#) (2022) and [ATMPs development](#) (2023) for academic stakeholders
- Academia workstream within EMA consolidated for more tailored support
- Collaboration in [external research projects](#) - 30+ peer-reviewed publications.
- Collaboration with [funding organisations](#), e.g. European Commission agencies and national funders:
 - Recommendations for research funding proposals, regulatory and scientific input on specific elements in planned calls
- First in-house [Academia Info Day](#) held in November 2023



- Interaction at **strategic level** through **Industry Standing Group** establishment:
 - implementation of EMA extended mandate with inclusion of **new players** (medical devices & in vitro-diagnostics)
 - enhanced dialogue on cross-industry topics (e.g., clinical trial regulation, new pharma legislation proposal, COVID-19 lessons learnt).
- Open dialogue with annual **bilateral meetings**
 - needs and challenges posed by the evolving global scientific environment
- Continued interaction at **operational level** through the established platforms (**R&D, CP, PhV platforms**) and **interested parties' meetings**:
 - scientific support on new requirements/restrictions (e.g., titanium dioxide, PFAs, nitrosamines)
 - Challenges and opportunities linked to new legislation and initiatives (e.g., veterinary regulation, scientific advice, PRIME scheme).

- Increased interactions with its stakeholders over the last 2 years
- The **Report** recognises their **critical role** in the Network's response to the unprecedented challenges posed by the COVID-19 pandemic
- **Multi-stakeholder approach** in parallel to targeted interactions ensured open and efficient exchange of all stakeholders' perspectives
- **Stakeholders' contribution** will continue to be **pivotal** in addressing future challenges

Next steps:

- **March 2024:** report presented for awareness at Executive Board and Management Board
- **By June 2024:** publication on relevant corporate website pages

Any questions?

Further information

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