



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Strengthening interaction with stakeholders

Eighth Stakeholders forum on the implementation of the Pharmacovigilance legislation

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An agency of the European Union





What is this presentation about?

- Who are our stakeholders?
- Why do we care?
- What have we already done to improve interaction with stakeholders?
- What are our plans for the future?



Who are our key stakeholders?

- Patients
- Health Care Professionals
- Industry
- Academia



Why do we care?

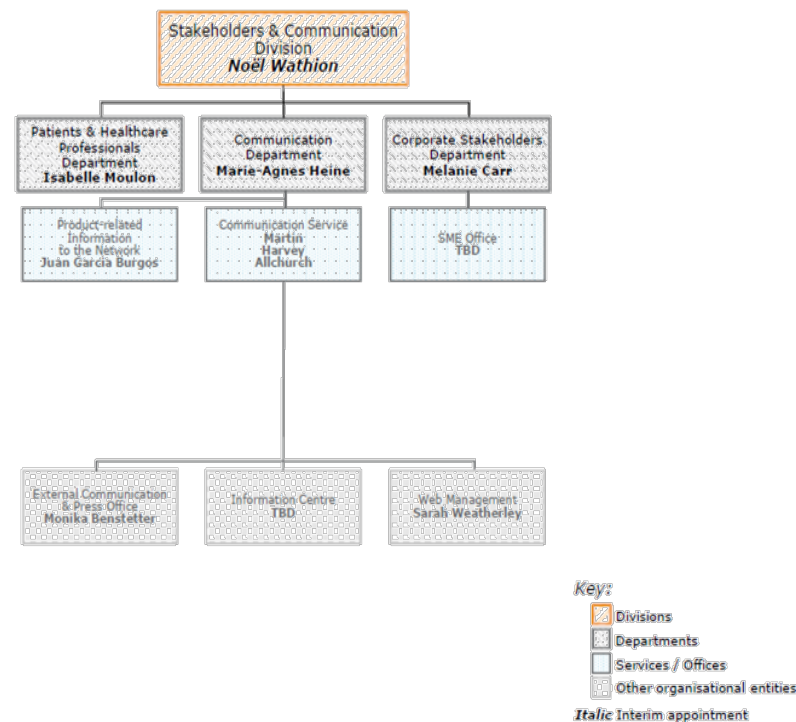
- To build trust and confidence
- To strengthen transparency
- To capture expectations and needs
- To enrich scientific assessment
- To help ensure that recommendations are understandable and effective
- To share experiences and best practices



What have we already done to improve our interaction with stakeholders?

1. **New Division** for Stakeholders & Communication

- Stakeholder database includes more than 600 organizations



What have we already done to improve our interaction with stakeholders?

2. Improved involvement of stakeholders in Creating **frameworks of interaction** and cooperation with different groups of stakeholders.



- Framework for interaction with PATIENTS and CONSUMERS (2005, under revision)
- Framework for interaction with HEALTHCARE PROFESSIONALS (2011)
- Framework for interaction with INDUSTRY (to be adopted by 2014)
- Framework for interaction with ACADEMIA (under development)

What have we already done to improve our interaction with stakeholders?

3. Other interaction with stakeholders

- **Monthly newsletter** with most recent information on medicines
- Participation of stakeholders in all **public workshops**
- **Public consultations** on new initiatives
- **User-testing** of communications targeted to patients
- **Sharing** product-related information with sponsors prior to publication
- Involvement of patients and healthcare professionals in **benefit-risk assessments**

What have we already done to improve our interaction with stakeholders?

4. Pharmacovigilance legislation – a welcome opportunity to strengthen relations
- Regular **meetings**
 - More and earlier communications on **safety issues**
 - Quarterly **updates** and publication of **minutes and agendas**
 - Inclusion of patients and healthcare representatives as **full members** of the PRAC
 - **NEW:** consultation on PRAC **public hearings**

What are our plans for the future?

1. Development of new EMA communications strategy with clearly identified players and communication objectives
 - Perception survey
 - Structure and resources needed to meet stakeholders' expectations and needs
 - Review and adaptation of communication products and channels for different stakeholder groups



Outlook

The Stakeholder & Communications Division looks forward to working with all of you to

- strengthen EMA's engagement and collaboration with key stakeholders
- increase trust and transparency
- address public health challenges

Thank you!