EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Horizon scanning

Products in development and beyond

ECRD 2018, Vienna

Presented by Kristina Larsson on 12 May 2018
Head of Orphan Medicines, EMA

Content

- Horizon scanning at EMA, regulatory science strategy
- The orphan horizon

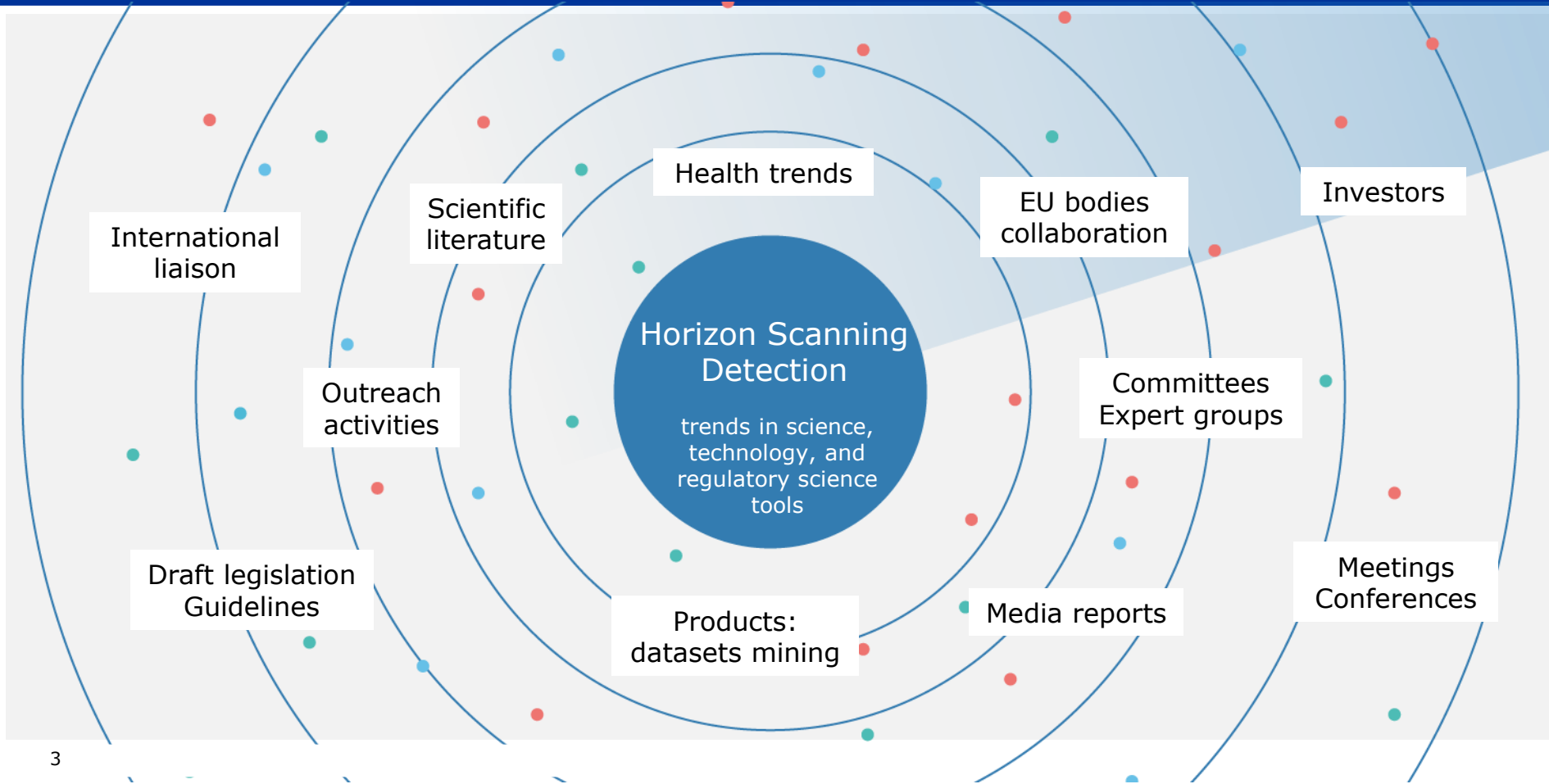
The foundation: what do we mean?

Elements that drive the approach to horizon scanning:

- Objectives / desired impact
- Scope of technologies / interventions
- Observation period
- Data sources and detection methodology
- Triage
- Reporting mechanisms

"Horizon scanning" means different things to different people.

Informing the Regulatory Science Strategy



EMA Horizon Scanning: specifications

Working definition: Horizon scanning is a systematic examination of information to detect early signs of important and potentially disruptive developments impacting on public health.

Objective: This enables the Agency to build the capacity, capability and collaboration it needs to leverage potential opportunities and address threats. By informing decision making, it influences policy-making in science and health. Clarifying the system in which the Agency operates it guides its evolution to improve access to innovative medicines in Europe

Stakeholders: EMA executive bodies, EU institutions, Network, Non-EU Regulators, developers, Academia, HCPs

Time to Horizon: Systematic: 3-10 years before MAA; Periodically: 3-20 years before MAA

EMA Horizon Scanning: Process

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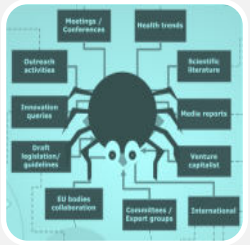
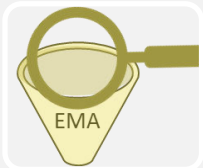
Detection



Signal Identification

Triage

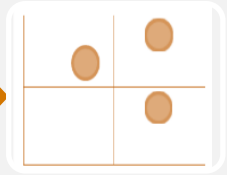
First Filtration



Preliminary assessment and Second Filtration

Impact estimation

Assessment



Prioritisation

Peer Review

Dissemination

Update

Engaging with partners and stakeholders

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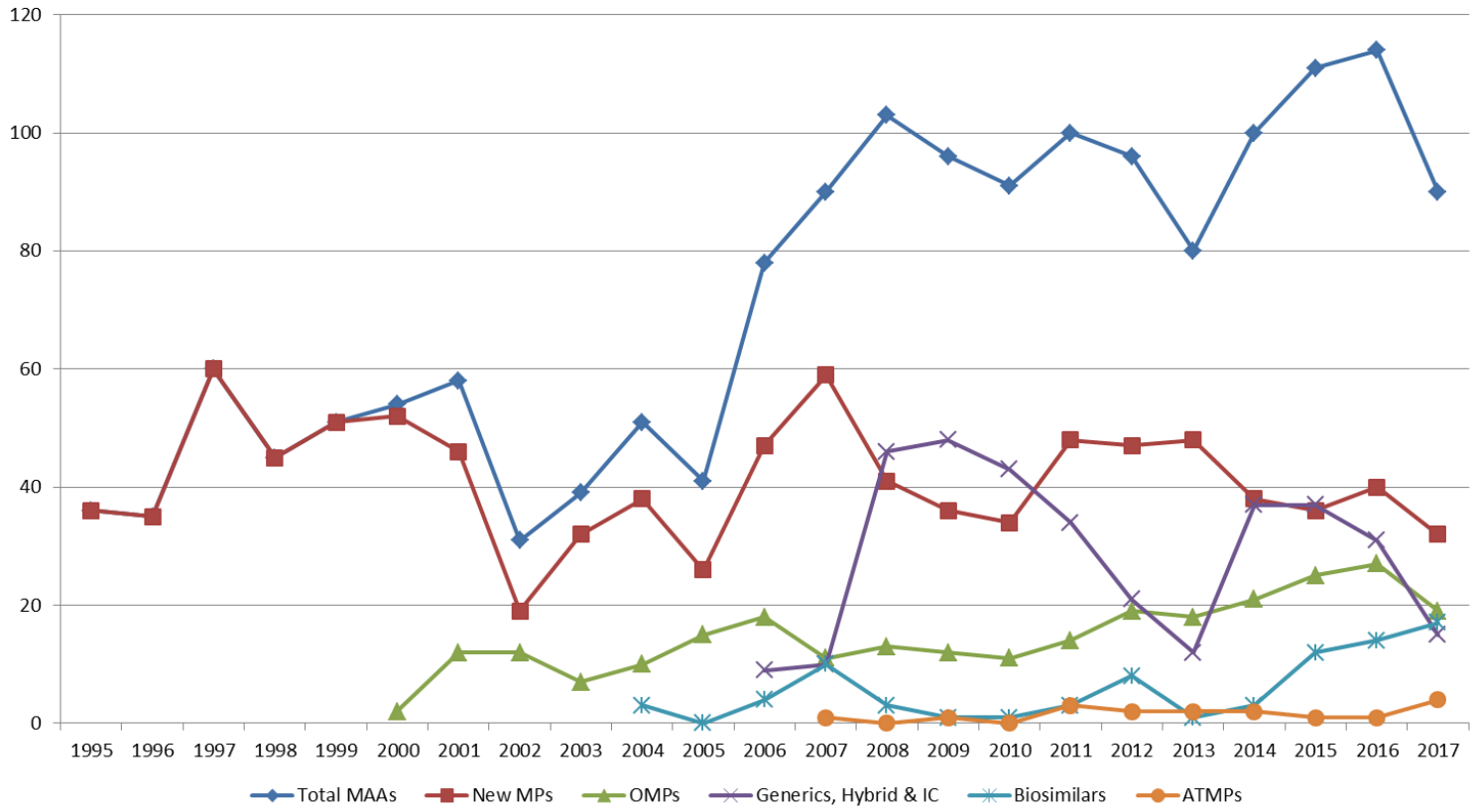
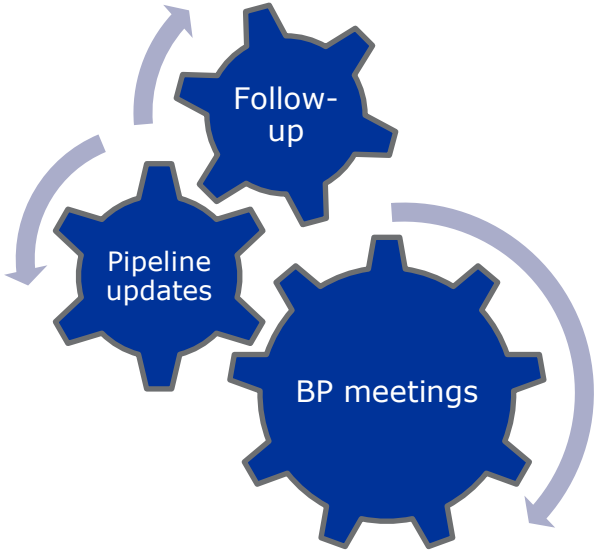
- Leveraging collaboration at EU and international level with partners
- Stakeholder engagement to avoid self-referential outcomes
- Identification of hotspots in the current regulatory science discussions

MAAs by type of applications



Business Pipeline – short to mid term forcast



- Meeting frequency driven by sponsor
- Early dialogue with EMA
- Instrumental in contributing to preparedness
- Confidential and mutually beneficial discussion
- Identify issues impacting your pipeline progress


orphans
patients
regulation
ERNs

Conclusions

- Regulators can be an enabler between science and healthcare systems by scanning the horizon, identifying the main gaps and connecting the various stakeholders together in order to bridge those gaps.
- EMA regulatory science strategy important to inform priority settings.
- Workshop planned for October this year.

Thanks to:
Enrico Tognana
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Any questions?

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