EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Pharmacovigilance legislation - what has been achieved and future priorities

Scanning the horizon for 2016 – 2018

Tenth Stakeholder forum on the Pharmacovigilance legislation
21 September 2016

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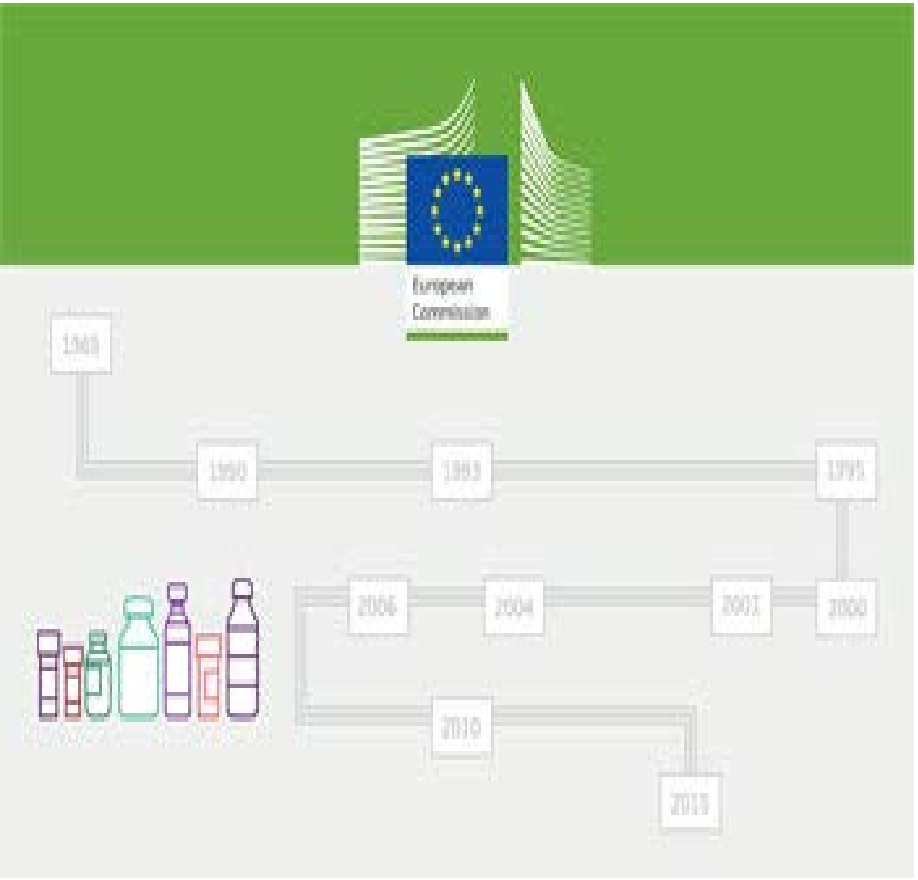
Scanning the horizon for 2016 – 2018

In this presentation:

- Take stock of where we are
- Explore the environmental influences impacting pharmacovigilance
- Predict system evolution over the coming years

Time: 2016



51 years of EU regulation

21 years of EMA

6 years since adoption of Pharmacovigilance legislation

4 years of PRAC

10th Stakeholder forum

Logical moment to look to the future……

Take stock of where we are

Past

- From individual cases to pharmacoepidemiology
- From local to international
- From exclusive to inclusive
- From opaque to transparent
- From pursued to require
- From safety to benefit risk

Looking forward

- **Planned, integrated** lifecycle drug development and surveillance
- Timely **access for patients** to safe and effective medicines
- Utilisation of **validated scientific methods**
- **Real world evidence**: quality, accessible, timely information
- **Best use of technology**
- **Meeting expectations** of a changing society
- **Making an impact** on health promotion and protection

Explore the environmental influences impacting pharmacovigilance

Axes of influence

1. **Time**: past, present, future
2. **Geographic**: local vs global
3. **Sectors**: pharmaceutical, devise, healthcare systems, patients safety
4. **Economic (cost)**: healthcare, medicines, studies, adverse reactions, unmet need
5. **Political**: peace, healthcare system, regulation, functioning market
6. **Societal**: more coming
7. **Technological**: more coming
8. **Scientific**: more coming

Environmental influences: Societal opportunities

- Patient and healthcare professionals ready to engage: reporting, assessing, values, deciding, enacting, feeding back
- Demographics: aging population, new arrivals in the EU
- Demand for evidence based for use of medicines in pregnancy, and children
- 24-hour news cycle, web-based communications
- Demand to fulfil unmet medical needs
- Demands for simplification
- Recognition that collaboration can deliver for health
- Better and more accessible real world evidence for decision support

Environmental influences: Technological opportunities

- **Product types** e.g. biologicals, advanced therapy medicinal products, combination products, vaccines
- **Tracing distribution** of medicines
- **Social media**: linkage, privacy, quality. Where to focus, how can the methodologists help us?
- **e-health**: smart phones for case reporting, for patient led cohorts, for recruitment, to support health decision-making
- **m-health**: patients self monitoring using mobile devices
- 2025 "**Oyster card**" for health (not a new idea, but getting closer to being possible)

Environmental influences: Scientific opportunities

- **Adverse Drug Reaction Reports**: long live ADR reporting;
- **Registries** –Need for better tools to support
- **Epidemiological methods** – PROTECT, ENCePP, EU-ADR, OMOP – infrastructure (access, governance, funding)
- **Signals**: implement best established methods
- **Genomics**: individual patient BR decisions
- **Benefit risk assessment methods** and decisions
- **Impact**: ensuring we add value and continuously improve

Short-term horizon

- Strengthened patient involvement: public hearings
- Healthcare professionals: risk minimisation recommendations
- Academia: collaborative framework
- Special populations: new guidance
- Training: curriculum EU-NTC
- New EudraVigilance: simplified reporting, better data, increased access
- PRIME medicines development
- Stronger scientific advice
- Simplified Risk Management Planning
- Big data, real world evidence – collaboration for access
- Registries – practical steps
- Making and impact: PRAC strategy
- Regulatory sciences: supporting better pharmacovigilance

Big picture

- **Planned, integrated** lifecycle drug development and surveillance
- Timely **access for patients** to safe and effective medicines
- Utilisation of **validated scientific methods**
- **Real world data**: quality, accessible, timely information
- **Best use of technology**
- **Meeting expectations** of a changing society
- **Making an impact** on health promotion and protection

…achieving better….through multiple small steps…

The future of pharmacovigilance

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