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SCIENCE MEDICINES HEALTH

New pharmacovigilance systems and services

17 September 2015, PCWP/HCPWP joint meeting

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Background

The new **EU Pharmacovigilance legislation** has been operational since July 2012. The legislation sets out to strengthen the promotion and protection of EU public health through: better planning, better data collection, fast and robust decision-making, effective risk minimisation; clarity of roles, transparency; engagement; simplification.

To deliver simplification, the legislation foresees various information systems to enhance Pharmacovigilance, particularly to support the **collection**, **management** and **analysis** of **data**, **information** and **knowledge**.

These systems will contribute to public health through optimisation of the safe and effective use of medicines. They should also facilitate Pharmacovigilance, delivering rationalisation and efficiency gains, involving the processes and systems of EMA, NCAs and MAHs.

Pharmacovigilance Projects

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Projects & Outputs	Benefits Delivered
Article 57 Database *European database of all medicinal products*	• Support PV Procedures which facilitates coordination of regulatory decisions • Supports the product index for EudraVigilance • Reduction of duplication
EudraVigilance Auditable Requirements *Enhanced adverse reaction collection and management system*	• Simplified reporting delivered • Data will be higher quality, improving searchability & analysis efficiency • Increased access to stakeholders
Medical Literature Monitoring *Delivery of literature monitoring service to MAHs*	• Improved safety monitoring of medicines through increased data quality • Reduction in costs for industry literature monitoring activities
Pharmacovigilance Fees *Collection of fees to cover costs of conduct of certain PV activities*	• Member State rapporteurs paid for certain PV assessments • Annual fees support implementation & maintenance of IT systems and services
PSUR Repository *Centralised repository for PSURs and assessment reports*	• Provides a simplification of PSUR submissions for industry • Repository will include all PSURs and assessment reports

Driven By

Effective programme management which ensures successful delivery of changes

1995 2015 EMA

Provides public health benefits across Europe

EU medicinal product database (Article 57)

SCOPE:
To deliver **structured and quality assured information on medicinal products** authorised in the EU that can support EU terminologies of products, substances, and organisations used to power pharmacovigilance and regulatory systems in the EU

What has been achieved

- ✓ The current Article 57 initial data re-submission produced over 500k medicinal products (EV Codes) updated in the Art57 database;
- ✓ EMA continues its co-operation with Industry to ensure Article 57 correctness and completeness.

Immediate next steps

- In 2015 the Agency will launch a service for the National Competent Authorities to make available the relevant information from the Article 57 database.

EU medicinal product database (Article 57)

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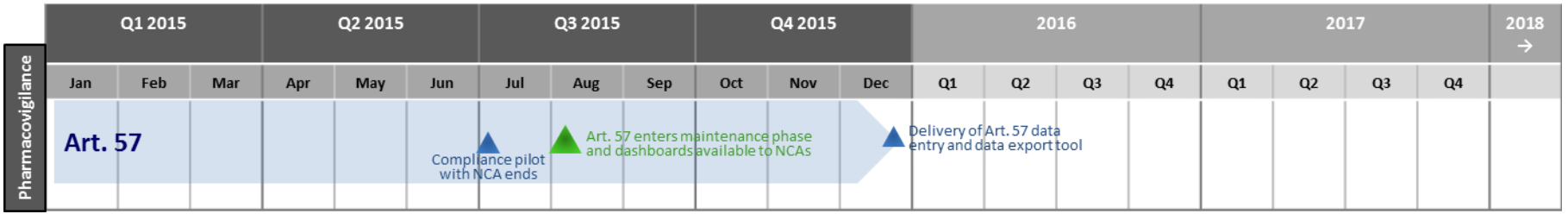
How will we benefit the Stakeholders?

- ✓ Data can support identification of products in EudraVigilance;
- ✓ Facilitates the coordination of regulatory decisions and actions to safeguard public health. Now routine use in Pharmacovigilance;
- ✓ Strengthens transparency and communication with stakeholders by granting access to safety data
- ✓ Discussion on wider stakeholder access to support healthcare, including cross-border access to medicines
- ✓ Efficiently ex-changing data within the EU Network and international partners, and supporting communication between the Agency's Committees and the pharmaceutical industry;
- ✓ Provides Administrative simplification once database is fully functional. Changes in QPPV and PSMF locations may be updated through the Article 57 database only, without the need for a variation.



EudraVigilance Auditable Requirements

SCOPE:

There is a legal requirement for an **enhanced adverse reaction collection and management system** (EudraVigilance) that delivers better health protection through **simplified reporting, better quality data and better searching, analysis and tracking functionalities**. Enhanced detection of new or changing safety issues allows more rapid action to protect public health.

Next Steps

- The EudraVigilance Stakeholder business change management plan will be launched in October 2015. This document details the IT & business changes to be made by stakeholders;
- Revised EudraVigilance Access Policy is being finalised and is expected to be published in Q4 2015. This foresees much greater access for the general public (while protecting personal data);
- The move to centralised reporting by industry is foreseen for mid 2017.

EudraVigilance Auditable Requirements

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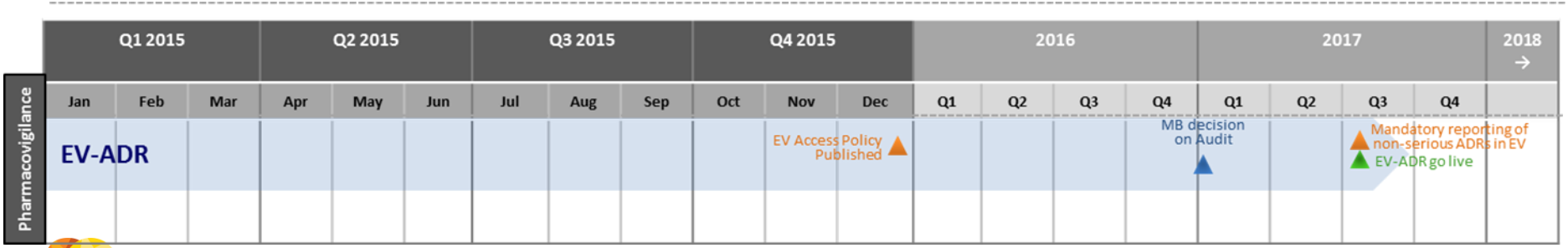
How will we benefit the Stakeholders?

- ✓ All EU reports from industry will be forwarded to the country of origin;
- ✓ More data in EudraVigilance (currently 6 million reports);
- ✓ Much greater access to the data for stakeholders;
- ✓ Simplified reporting will be delivered for MAHs (no more industry report direct to the Member States);
- ✓ Enhanced signal detection and data analysis tools will be provided to support safety monitoring to member states.
- ✓ Earlier detection of safety issues



Medical Literature Monitoring (MLM)

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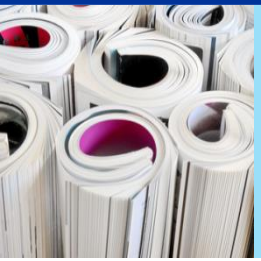

SCOPE:
Legal requirement for EMA to **monitor selected medical literature for reports of suspected adverse drug reactions** containing certain active substances and to **enter individual case safety reports** into the EU adverse reaction database (EudraVigilance).

News

- ✓ The full operation of the European Medicines Agency's **medical literature monitoring (MLM) service was launched on 1st September 2015.** The service now include all of the 100 herbal and 300 chemical substance groups.

Next Steps

- ✓ An independent audit of the service provider's internal quality management and control systems and of the service will be conducted in December 2015 (then 2-yearly there after).

Medical Literature Monitoring (MLM)

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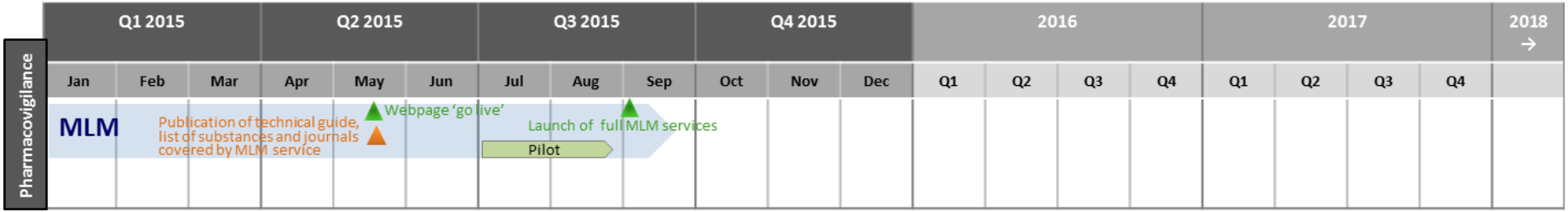
How will we benefit the Stakeholders?

- ✓ Improves safety monitoring of medicines through better quality of safety information;
- ✓ Reduces the administrative burden on Marketing Authorisation Holders (MAHs) for the relevant substances;
- ✓ MAHs will have access to up-to-date results of MLM activities and ICSRs generated, allowing them to repost ISCRs to other regulatory bodies (outside EU) in a timely fashion;
- ✓ Supports signal detection activities by the EMA, National Competent Authorities (NCAs) in EEA and MAHs;
- ✓ Better data in EudraVigilance supports earlier and more reliable detection of safety issues.



PSUR Repository

SCOPE:
Legal requirement for EMA to set up a repository for periodic safety update reports (PSURs) and their assessment reports; to allow centralised PSUR reporting and to enhance access to data and information, thereby supporting benefit risk assessments of medicines.

What has been achieved?

- ✓ The electronic repository for PSURs and their assessment reports was launched by the Agency on 26th January 2015;
- ✓ On 12 June 2015 the EMA Management Board announced that PSUR Repository has achieved its full functionality and the use of the repository in the European Union will become mandatory on 13 June 2016;

Next steps

- ✓ From the **13 June 2016** onwards industry stakeholders will no longer be obliged to submit PSURs to National Competent Authorities, the only requirement being the submission to the PSUR Repository.

PSUR Repository

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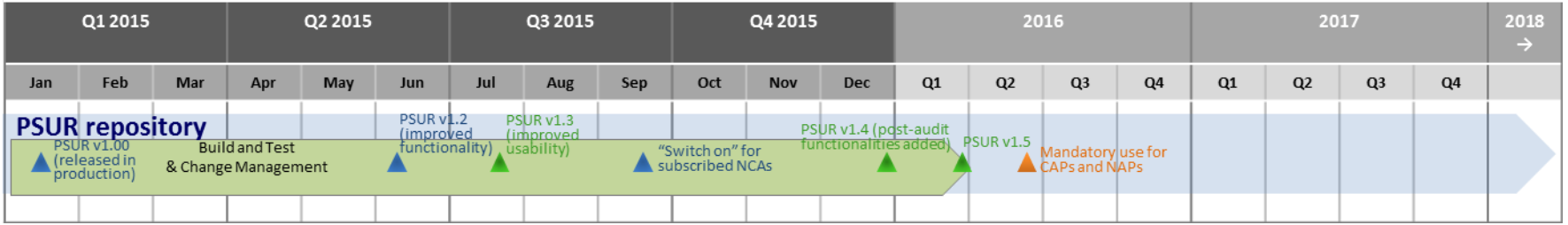
How will we benefit the Stakeholders?

- ✓ 31 national agencies sharing one document management system for PSURs;
- ✓ One EU benefit risk assessment leading to earlier updates to product information.



Pharmacovigilance Fees

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SCOPE:

- The newly adopted Pharmacovigilance fees regulation allows the EMA to **collect fees from MAHs for PV activities** conducted at EU level for medicinal products for human use.
- The income will be used to **remunerate national competent authorities** (NCAs) of the EU for the scientific assessment carried out by the rapporteurs and to **contribute to the Pharmacovigilance-related costs of the Agency**.

What has been achieved?

- ✓ Procedural fees (PSURs, referrals and study assessments) charged from August 2014
- ✓ **The 1st annual pharmacovigilance fee invoices were issued in July 2015;**

How will we benefit the Stakeholders?

- ✓ **NCAs will be paid** for carrying out certain PV procedures.
- ✓ The funding will assist in **improving the quality of PV activities** undertaken.

Conclusions

We are at an important point in our projects with major deliverables scheduled throughout 2016 and 2017 to support business activities of the revised pharmacovigilance legislation and to improve the relevant business functions to maximise the benefits for stakeholders.

Greater access for patients and healthcare professionals to data and information held by regulators.

Thank you

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