EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Update on development of pharmacovigilance information systems

PSUR repository, Article 57, EudraVigilance, Literature Monitoring, Fees: contact via the QPPV

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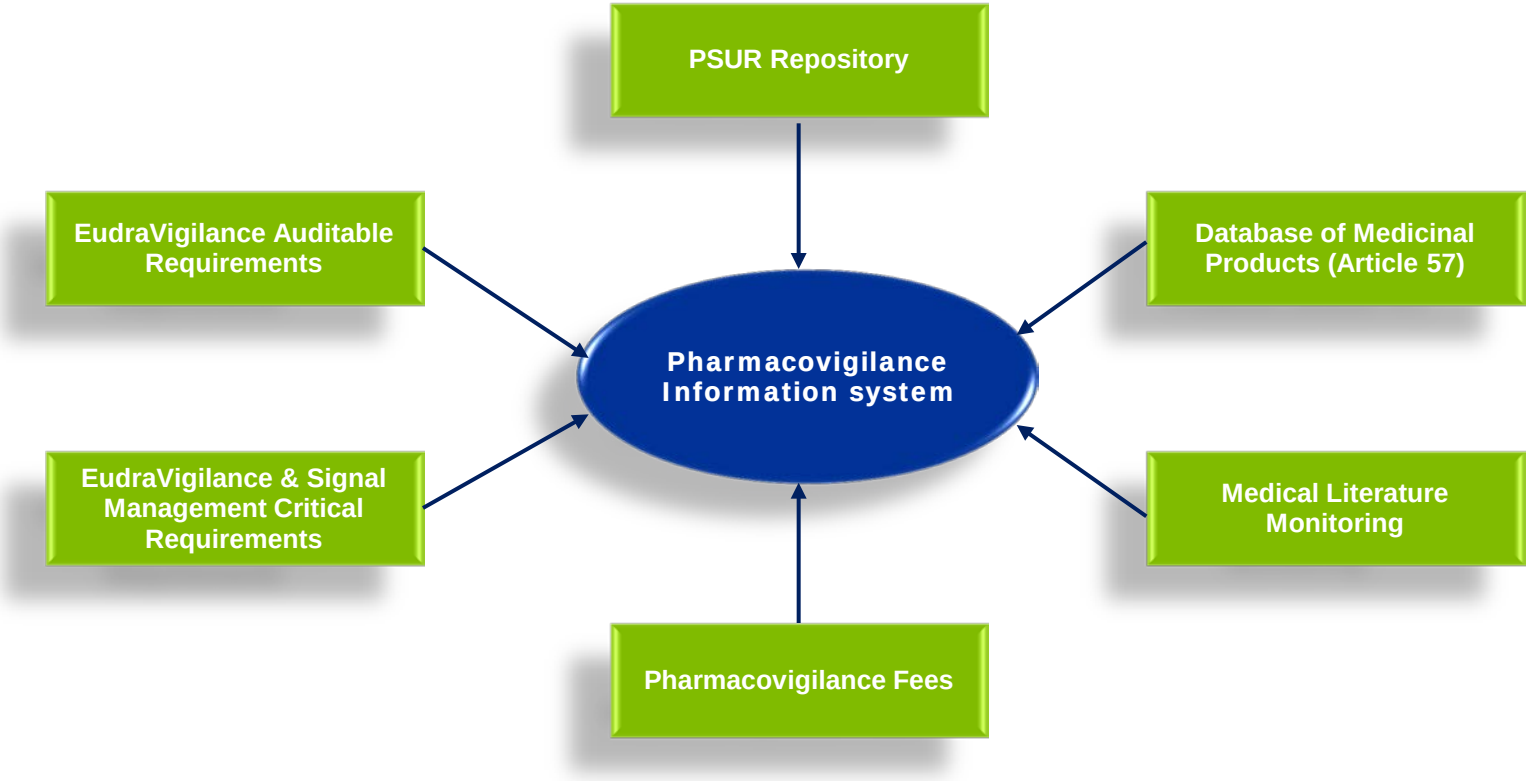
An agency of the European Union

Background

The new **EU Pharmacovigilance legislation** has been operational since July 2012. 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.

Projects supporting implementation of information system



Medical Literature Monitoring Project Information

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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)

Benefits

This will improve safety monitoring of medicines through better quality of safety information.

This will reduce the administrative burden on MAHs for the relevant substances.

High Level Timeline

EV-Auditable Requirements Project Information

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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;

Legal requirement for MAHs to monitor data they have access to in EudraVigilance.

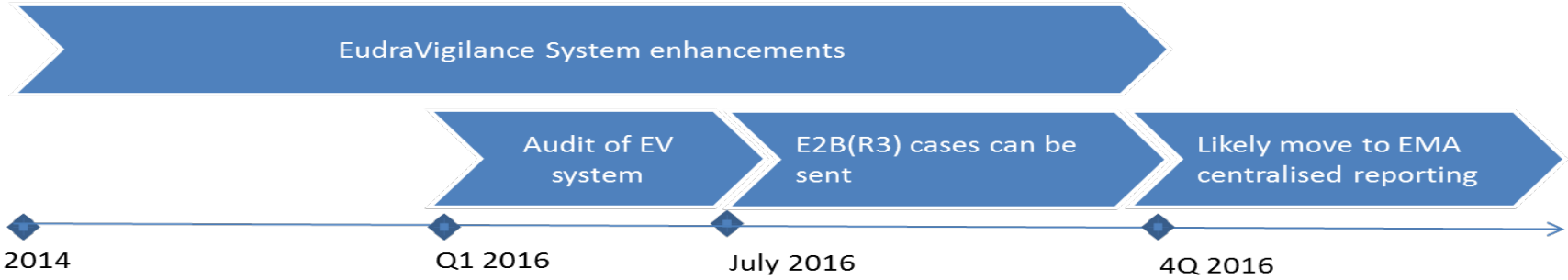
Benefits

Compliance with international data standards (and future compatibility with ISO IDMP standards based on Article 57 data) including backwards and forwards conversion tools for E2B(R2)/(R3) messages;

Improved performance and scalability of new system to cope with foreseen increase in users and volume of data;

Simplified reporting delivered

High Level Timeline



PSUR Repository Project Information

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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.

Benefits

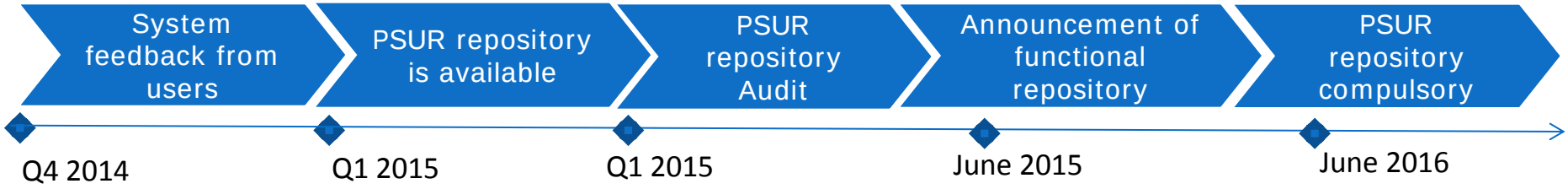
Provides a simplification of PSUR submissions benefiting pharmaceutical industry;

Once the use of the Repository is mandatory, it will include all PSURs, including those that follow the PSUR Single Assessment (PSUSA) and those PSURs which are not part of a Single Assessment;

Delivers a user interface to regulators to query and retrieve documents by use of metadata based on fields present in the list of EU reference dates (EURD list) for each active substance/combination of active substances;

Delivers a user interface to upload assessment reports and comments by the National Competent Authorities to the repository.

High Level Timeline



Art57 Project Information

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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

Benefits

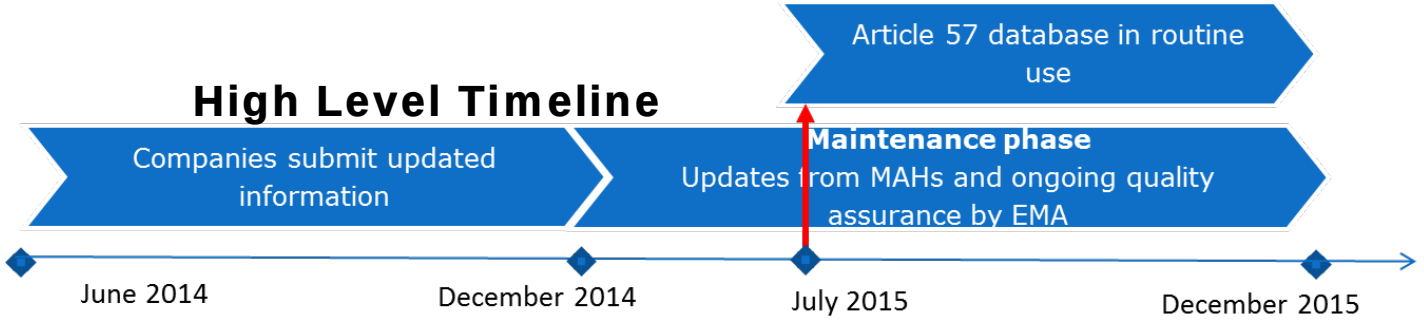
Facilitate the coordination of regulatory decisions and actions to safeguard public health and to fulfil regulatory actions and legal obligations including:

- literature monitoring service;
- repository of Periodic Safety Up-date Reports (PSURs);
- support referral procedures;
- support collection of pharmacovigilance fees;
- support identification of products and substances in reports of suspected ADRs

Strengthen transparency and communication with stakeholders by granting access to safety data, efficiently ex-changing data within the EU Network and international partners, and supporting communication between the Agency's Committees and the pharmaceutical industry;

Support the reduction of duplication of encoding and maintenance of the same information on medicines, thus reducing costs

High Level Timeline



PV Fees Project Information

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Scope

The Pharmacovigilance legislation foresees that Pharmacovigilance activities conducted at EU level for medicinal products for human use should be financed by fees paid by MAHs. The newly adopted Pharmacovigilance fees regulation allows the EMA to collect these fees;

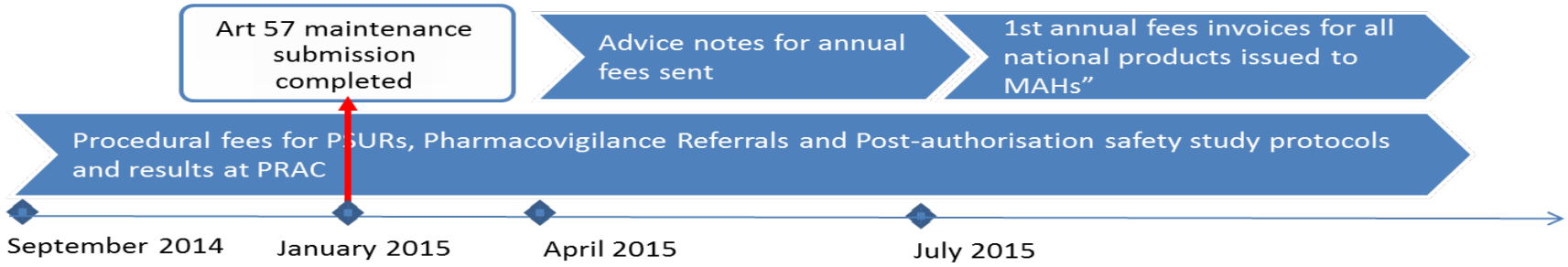
The income will be used to remunerate national competent authorities (NCAs) of the EU for the scientific assessment carried out by the rapporteurs and to contribute to the Pharmacovigilance-related costs of the Agency.

Benefits

In addition to remunerating procedures, supports the implementation and maintenance of measures from the 2010 Pharmacovigilance legislation including: literature monitoring, enhanced functionalities for EudraVigilance and the PSUR repository which ultimately provides public health benefits across Europe;

Delivers functionality for online payment of fees and updating of account details.

High Level Timeline



Pharmacovigilance Fees: contact via the QPPV

In March 2015 the advice notes for annual Pharmacovigilance fees will been sent out to allow companies to preview the list of ‘Chargeable Units’ subject to a Pharmacovigilance Fee. The information will be sent to the qualified person in pharmacovigilance, who will be required to check and ensure that the product information contained within them is correct.

This provides companies with an opportunity to update their data in the ‘Article 57 database’ prior to billing (chargeable units are derived from data in the Article 57 database).

Thank you for your attention

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