Fit for the PSUR repository?

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PSUR repository

Agenda:

- EURD List
- PSUR submission requirements
- PSUR repository legal basis and development
- Procedures in PSUR repository
- Fees
- PSUR repository – potential sources of error

EURD list

Comprehensive list of active substances and combinations of active substances contained in medicinal products subject to different marketing authorisations

- with the corresponding EU reference dates
- frequencies for submission of PSURs
- related data lock points

Information takes effect six months after the publication date

-- First publication of the EURD list: 1st October 2012.

-- EU single assessment of CAPs and NAPs started in April 2013.

-- Single assessments of NAPs only started in January 2015.

CAP =Centrally authorised products NAP =Nationally auth. products

EURD list

List of European Union reference dates and frequency of submission of periodic safety update reports

- EURD list is legally binding
- MAHs should submit a PSUR in accordance with the published submission deadline where it concerns an active substance or combination of active substances listed in the EURD list, even if marketed in only one Member State, unless exempted from submission.
- A medicinal product authorised only in one country should also follow the EURD list.

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2012/09/news_detail_001616.jsp&mid=WC0b01ac058004d5c1

EURD list

Procedure number for EU-single Assessment PSURs (PSUSA)

Format: "**PSUSA/00000000/YYYYMM**"

PSUSA: single assessment of PSURs
Eight digit number: unique identification number
YYYYMM: month and year of the DLP as published in the EURD list
EURD list is usually revised on a monthly basis.
Updates made to the EURD list when adopted by the CHMP and CMDh following consultation with the PRAC are highlighted.

The convention used to present the active substances and combinations of active substances has changed:
- A slash ('/') is used to separate the different active substances contained in a combination, this can be a fixed-dose combination or a combination pack.
- A comma (',') is used to indicate that a single PSUR assessment covering the different substances and/or combinations of active substances will be generated.

EURD list

Active substances and combinations

- In case a specific salt, ester, etc. is mentioned in the list: PSURs only referring to this salt, ester etc. should be submitted.
  In all other cases the name of the active substance will cover all salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives, as appropriate.
- If only the name of the acid or base is specified, products containing salts, esters, ethers, isomers, mixtures of isomers, complexes or derivatives of the acid or base will be part of the single assessment procedure
- If a specific fixed combination medicinal product is not listed on the EURD list, the MAH should inform the Agency.

EURD list

- At present the EURD does not include homeopathics and herbals (with the exception of some substances derived from plants – hypericin etc.)
- In the case of any questions and requests regarding the EURD list: eurdlist@ema.europa.eu.

PSUR repository – legal basis

Article 25a of Reg. (EC) 726/2004 requires the Agency (+EC and MSs) to set up and maintain a repository for PSURs and corresponding assessment reports.

Regulation (EC) No 726/2004, Directive 2001/83/EC and the Commission Implementing Regulation (EU) 520/2012: the PSUR Repository has to adequately support the following processes:

a. The **electronic submission** of PSURs and **PSUR assessment reports**

b. The **storage and retrieval** of PSURs and PSUR assessment reports by providing access, query and download functionalities by authorised users (NCAs, EMA, the Commission, PRAC, CHMP, CMDh)

As per Article 107b paragraph 1 and Article 28(2) Regulation 726/2004) all PSUR procedures shall be submitted **electronically**.

PSUR procedures

EU-single assessment (PSUSA)

For different marketing authorisations:
-- containing the same active substance/combination and
-- for which the frequency and dates of submission of PSURs have been harmonised in the EURD list →
PSURs jointly assessed → a single assessment report shared amongst all the MAHs taking part.

Resulting recommendation will apply to all identified products

Non-EU-single assessments: authorised only in one country and substances / products not on the EURD list

PSUR timelines

Timelines for PSUR submission:

- within 70 calendar days of the DLP (day 0) for PSURs covering intervals up to 12 months
- within 90 calendar days of the DLP (day 0) for PSURs covering intervals in excess of 12 months;

PSUR - submission

A PSUR is required for drugs with

- Full MA (Vollzulassung) / hybrid application
- Condition in the MA („conditional approval“)
- „Yes“ in the EURD list, even if no full MA

EURD list:

Are PSURs required for products referred to in Articles 10(1), 10a, 14, 16a of Directive 2001/83/EC as amended? YES/NO

Article 10(1): Generic applications
Article 10a: Well-established medicinal use (10 years)
Article 14: Homeopathic medicinal products (orally or externally, no specific therapeutic indication, sufficient degree of dilution)
Article 16a: Traditional herbal medicinal product

PSUR-submission

AT specific requirements:

- ***„zugelassene*** *homöopathische Arzneispezialitäten* (3-)“: PSUR required
- *„AMG §11 registrierte homöopathische Arzneispezialitäten“* (HOM-): no PSUR required.

- No PSUR required for „apothekeneigene Arzneispezialitäten“.

PSUR repository

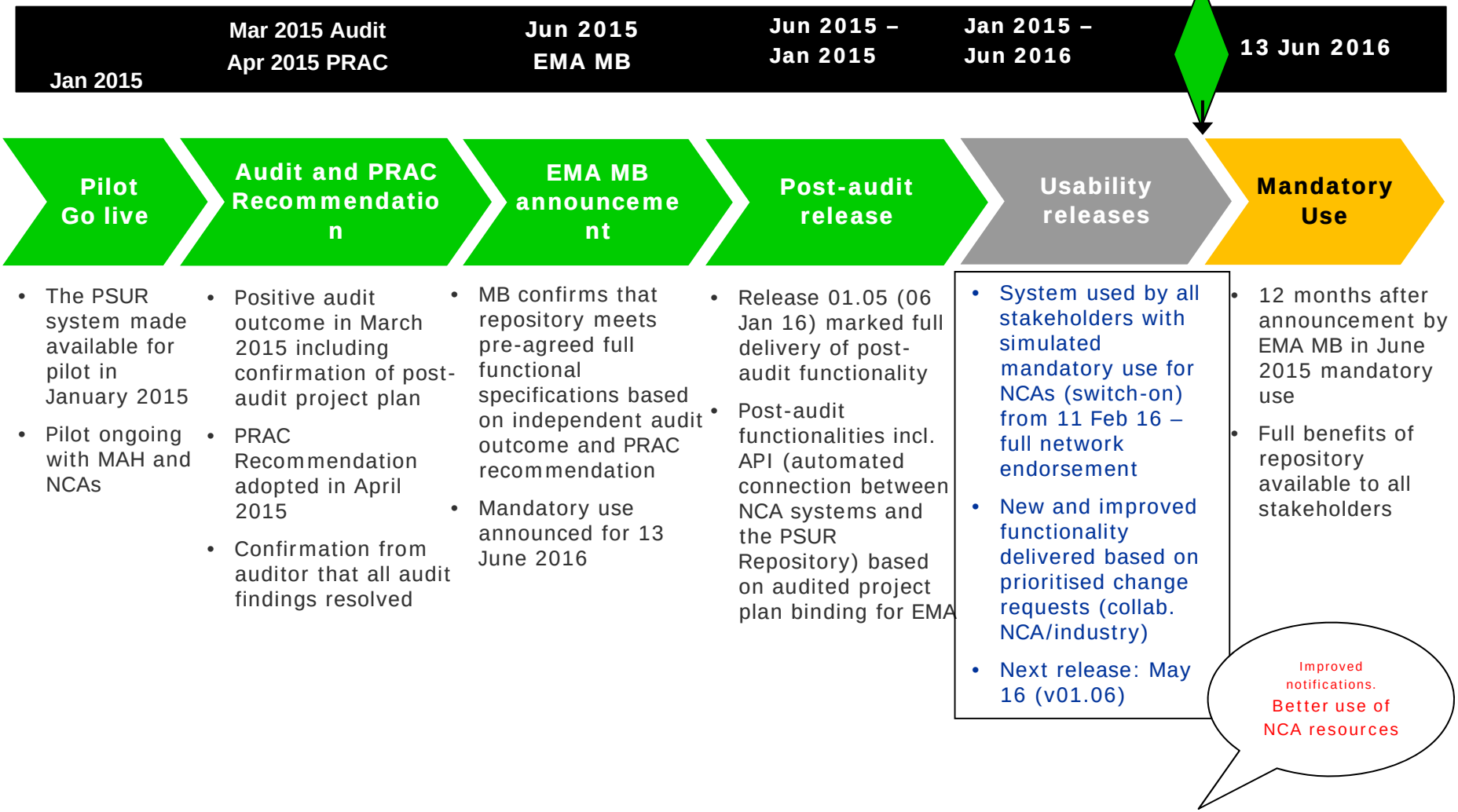
Timetable:

- Go-live - 26 January 2015
- Pilot - 26 January 2015 – 10 February 2016
- Switch-on: 11 February – 12 June 2016
- **Mandatory use: from 13 June 2016**

→ from this date all PSUR submissions across Europe only via this channel

→ AGES: no paper, CD-, e-mail-, CESP-submissions accepted for PSURs

PSUR repsoitory- A Phased implementation – main achievements



PSUR repository

From 13 June 2016 all PSURs have to be submitted to the PSUR Repository.

PSURs can no longer be submitted to National Competent Authorities.

Version 01.06 of the PSUR Repository was released on May, 14th 2016.

- delivery files for late submissions and improved connection to eSubmission Gateway, routing ID's will be automatically detected during the submission process.
- improved notifications and business rules within the PSUR Repository as well as the ability to reject technically invalid eCTD submissions.
- the release also provides fixes for errors that have been identified during the switch on phase.

PSUR repository

- Users should continue to report any issues they may have with the system through the PSUR Repository mailbox psurrepository@ema.europa.eu

- It is essential that all MAHs, who have not previously used the eSubmission Gateway / Web Client, should register to use the submission tools using the online registration form.
  Guidance on how to register: please refer to eSubmission Gateway and Web Client online registration guidance document.
  Existing eSubmission Gateway/Web Client users do not need to re-register.

- From 1 September 2015 all PSURs submissions should be sent with an XML delivery file

PSUR repository

Article 57 Data base

On 19 October 2015 the Agency launched a new service to national competent authorities, providing them with continuous access to key Article 57 data.

Information on:

- Qualified Person for PHV (QPPV) for each MAH
- Pharmacovigilance system master file (PSMF)
  (no need to submit a type IAIN variation to vary the marketing authorisation any longer)
- Basic data of products

PSUR repository

Pitfalls:

- Wrong zip-version used
- Non-EU Single Assessment: *„PSUR single assessment“* should not be ticked
- No entry of the product in the Art 57 database
- Unclear legal status (known active substance / generic etc.)

Worksharing

- PSUR single assessment (PSUSA) for NAPs started at the end of 2014 for products with Data Lock Points (DLPs) on or after 1st September 2014.
- Establishment of single assessment for NAPs→ finalisation of pending Worksharing procedures
- Abridged procedures for “old” Worksharing
- If possible relocation of WS procedures to PSUSAs

Link: http://www.hma.eu/348.html

PSUR fees

Information on national and EMA fees:

BASG homepage:

- http://www.basg.gv.at/pharmakovigilanz/phv-gebuehren/.

EMA:

REGULATION (EU) No 658/2014

- http://ec.europa.eu/health/files/eudralex/vol-1/reg_2014_658/reg_2014_658_en.pdf

Information on chargeable units:

- http://www.ema.europa.eu/docs/en_GB/document_library/Other/2015/07/WC500190190.pdf

Explanatory note on PHV fees:

- http://www.ema.europa.eu/docs/en_GB/document_library/Other/2015/03/WC500183456.pdf

PSUR fees

Fees cover:

- PHV procedures (PSUSA, PASS, PRAC referrals)
- Measures resulting from the 2010 pharmacovigilance legislation such as: literature monitoring (by EMA), EudraVigilance database and the PSUR repository.

Contacts and Websites

Sylvia Pach
Dept. Clinical Assessment of Safety and Efficacy

AGES-Gespräche
Vienna, 30.5.2016

PSUR repository contact

Preliminary contact point for specific PSUSA submissions is the EMA
psurquery@ema.europa.eu

Contact person at AGES for PSUSAs:
Ms. **Sylvia Pach**
E-Mail: cp@ages.at
Tel: (nat/internat): 050555 36830 / +43 50555 36830

Contact person at AGES for non-EU single assessment PSURs:
Mr. **Gerhard Nesetril**
E-Mail: gerhard.nesetril@ages.at
Tel: (nat/internat): 050555 36249 / +43 50555 36249
e.g. for information if PSUR has been received by AGES properly

PSUR repository contact

Helpful e-mail addresses:

Users should continue to report any issues they may have with the system through the PSUR Repository mailbox: psurrepository@ema.europa.eu.

If you have questions to a specific PSUSA procedure submission: psurquery@ema.europa.eu

Contact point for EURD-list: eurdlist@ema.europa.eu

Training registration for industry: eSubprogofficer@ema.europa.eu

PSUR repository contact

Helpful websites:

Access to Repository: user name and password to log into the repository using a web browser and navigate to https://psur-repo.eudra.org/psur-ui

E-Submission / PSUR repository guidance / Trainings
http://esubmission.ema.europa.eu/psur/psur_repository.html

EURD list:
http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2012/09/news_detail_001616.jsp&mid=WC0b01ac058004d5c1

FAQs:
http://www.basg.gv.at/pharmakovigilanz/faq-pharmakovigilanz/

VIELEN DANK
FÜR IHRE AUFMERKSAMKEIT

EURD list

Active substances and combinations of active substances	European Union reference date (EURD)	PSUR Submission Frequency	DLP	Submission date
Lactitol	03/09/1985	5 years	23.09.2015	22.12.2015

EURD list

Next DLP (For active substances or combination of active substances with a PSUR frequency of less than one year)	Next Submission date	Are PSURs required for products referred to in Articles 10(1), 10a, 14, 16a of Directive 2001/83/EC as amended? Yes/No	Publication Date (in accordance with Article 107c(7) of Directive 2001/83/EC as amended)	Notes
		No	01.10.2012	Lead MS added on 12/05/2015

EURD list

Procedure number of the PSUR single assess-ment (DLP)	Procedure number of the PSUR single assess-ment Proce-dure (Next DLP)	PRAC represent ative of the PSUR single assess-ment Proce-dure	(Lead) Member State of the PSUR single assess-ment proce-dure	Centrally autho-rised pro-duct(s) (CAP)	Nationally autho-rised pro-duct(s) (NAP)
PSUSA/00001819/201509		Jan Neuhauser	Austria		NAP

EURD list

- In the case of any questions and requests regarding the EURD list: eurdlist@ema.europa.eu.
- http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/10/WC500133157.pdf

Tabulation 2 "Request for additions"

Names of active substances or combinations of active substances	European Union reference date (EURD) as defined in DIR Article 107c(5)	Name of the medicinal product(s) containing the requested active substance combinations of active substances	Countries where the product(s) is/are authorised	MAH of the medicinal product(s)	Justification for inclusion in the list

EURD list

Tabulation 1 "Request for amendments"

Names of active substances/combinations of active substances	Ground of the Request	Request for change and details on justification	Name of the medicinal product(s) containing the requested active substance combinations of active substances	Countries where the product(s) is/are authorised	MAH of the medicinal product(s)
Copy the name as included in the EURD list	*Select the category from the drop down list of options based on DIR Article 107c (6)*	*Clearly define and justify here your request*	*List the relevant medicinal products*	*List the countries that each product listed is authorised*	*State the MAH of the medicinal product(s)*