EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

# Update on the List of Union Reference Dates and Frequency of PSUR submission

**Third Stakeholders Forum on the implementation of the new Pharmacovigilance legislation, 20 October 2011**

Presented by Almath Spooner, Irish Medicines Board and PhVWP

# Legal basis

- Article 107c (paragraphs 4 and 7) of Directive 2010/84/EU,

and

- Article 26(g) of Regulation (EU) 1235/2010

The Agency "*shall make public a list of Union reference dates and frequency of submission of periodic safety update reports by means of the European medicines web-portal*"

# Interpretation

- URD list will include a comprehensive list of active substances and combinations of active substances for which Periodic Safety Update Reports (PSURs) shall be submitted as determined by the Committee for Medicinal Products for Human Use (CHMP) and the Coordination Group (CG) after consultation of the Pharmacovigilance Risk Assessment Committee (PRAC).

The submission frequency defined on the list will **overrule**

1) any condition laid down in the Marketing Authorisation (MA) of the products concerned.

2) the standard submission frequency in accordance with Article 107c, paragraph 2 of Directive 2010/84/EU .

# PSUR requirements

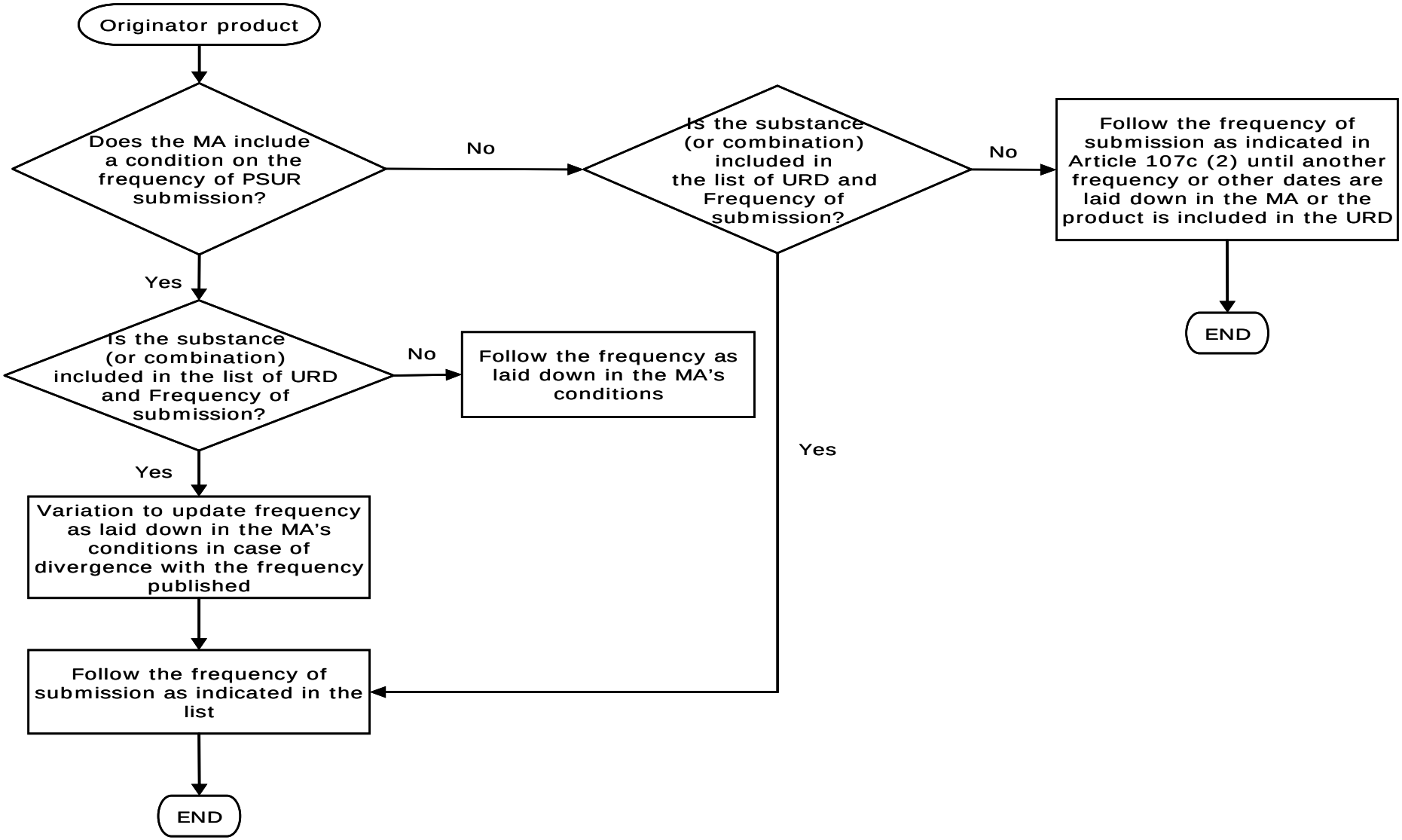
PSURs for medicinal products for which MAs were granted before July 2012 should be:

- ✓ submitted in accordance with Article 107c paragraph 2 of Directive 2010/84/EU and Article 28 (2) of Regulation (EU) 1235/2010, i.e. "*every 6 months during the first 2 years following the initial placing on the market, once a year for the following 2 years and at three-yearly intervals thereafter*",

<u>unless otherwise detailed</u>

- ✓ As a condition of the MA **or,**
- ✓ On the List of Union Reference Dates (URD) and frequency of submission.
- ❖ PSURs also need to be submitted immediately upon request from a Competent Authority.

# PSUR Submission Requirements



# Generics, well established use, homeopathic and THMPs

As per Article 107b (3) of Directive 2010/84/EU, by way of derogation, Generics (Article 10(1) Dir. 2001/83/EC), Well-established use (Article 10a Dir. 2001/83/EC), Homeopathic (Article 14 Dir. 2001/83/EC) and Traditional Herbal (Article 16a Dir. 2001/83/EC) medicinal products are exempted from submitting PSURs unless:

1) The MA provides for the submission of PSURs as a condition;
2) Requested by a Competent Authority on the basis of the grounds defined in legislation.
3) The active substance is included on the List of URDs and the requirement for submission of a PSUR according to the harmonised frequency is indicated on the list in accordance with Competent Authority consultation.

# Substances included on the list

- List of substances extracted from the EVMPD*
- Substances included on the Work Sharing list
- Substances included on the Synchronisation list
- List of Centrally Authorised Products (CAPs)

➢ List will aim to be comprehensive.

➢ Concept of risk proportionality inherent to submission requirements

* List of URD to be cross referred and updated in line with the "*list of all medicinal products for human use authorised in the Union*" that the Agency is to set up as per the Article 57(b) of Regulation (EU) No 1235/2010, and to the "*list of medicinal products that are subject to additional monitoring*" as defined in Article 23 of Regulation (EU) No 1235/2010.

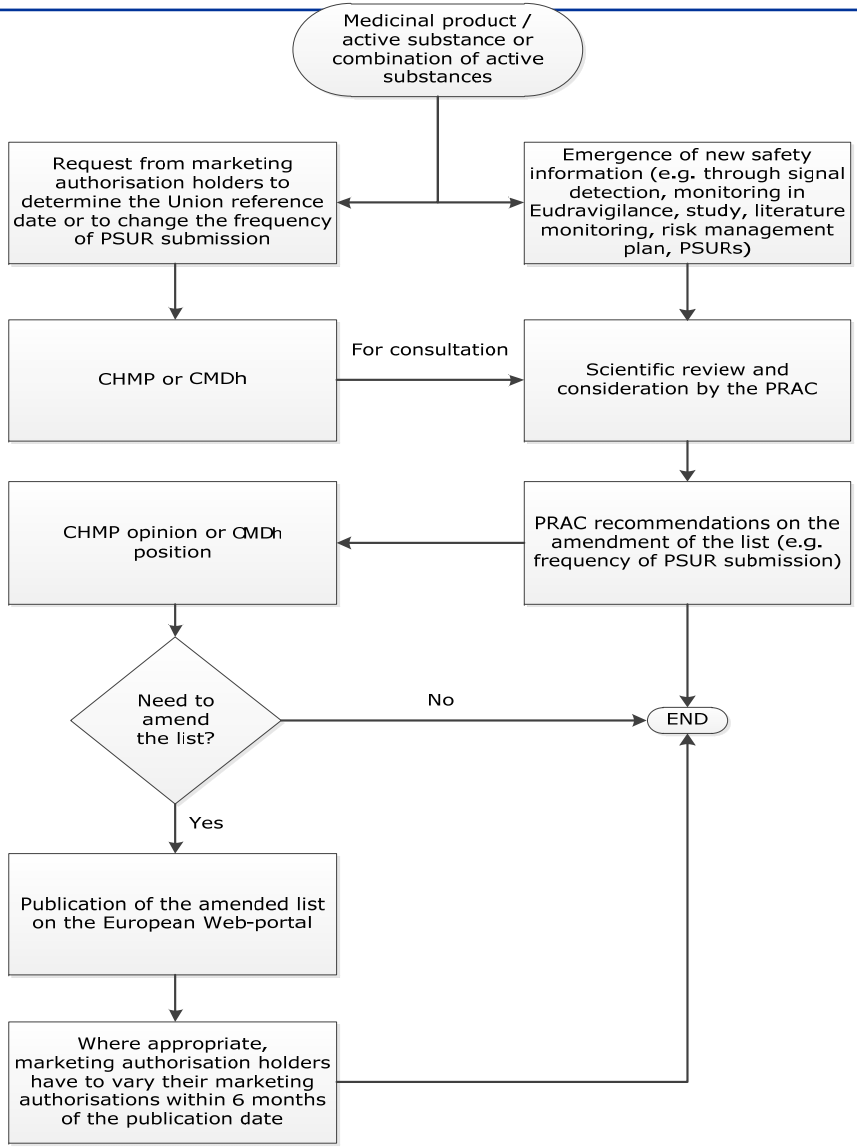
# Development of the URD list

- Frequency of submissions will be determined based on a risk based approach. EU network consultation on the development of the list is ongoing.
- As no *routine* PSURs for generics, WEU, homeopathics and THMPs are foreseen, the list will aim to clearly indicate the situations where MAHs of generics, WEU, homeopathics and THMPs are required to submit PSURs.
- URD list will be agreed by the CHMP and CG after PRAC consultation.
- List will be dynamic – regular review and amendment , responsive to the emergence of relevant new information.

# Presentation of the list

- ✓ substances name
- ✓ URD
- ✓ Frequency of submissions
- ✓ Data Lock Point (DLP)
- ✓ appointed Rapporteurs / Member State

# Adoption and Maintenance of the list



# Amendment of the MA

- As required in Article 107c paragraphs 4 and 7 of Directive 2010/84/EU, for already authorised medicinal products with a condition in the MAs that determines the frequency of PSURs submission, MAHs should submit a variation in order to update these MAs with the new frequency, within six months after the adopted List is made publically available by the Agency.
- According to Article 107c paragraph 1 of Directive 2010/84/EU, "*the frequency with which the periodic safety update reports are to be submitted shall be specified in the marketing authorisation*" for the products authorised after July 2012.'' Options to take account of this requirement in the context of application of the URD list are being explored and stakeholders will be updated as proposals are matured.

# PSUR Submissions

At the end of the transitional period and following audit, EMA Management Board will announce functional repository.

Subsequently, stepwise implementation of associated deliverables has been proposed:

1) Phase 1 - Centralised electronic submissions.
2) Phase 2 – Implementation of Electronic format.

Stakeholders will be updated as proposals are matured.

# Consultation on the URD list

- EU regulatory network consultation to guide the development of the URD list is ongoing.
- Public consultation on a draft URD list is foreseen.
- The principles for the development and maintenance of the URD list will be described in the GVP module on PSURs.
- Stakeholders will continue to be updated.