Q & A's

Joep Scholl

Scientific assessor - Lareb

Anja van Haren
EudraVigilance Coördinator - CBG

bijwerkingen centrumlareb

CBG MEB

Receiving Lareb cases

bijwerkingen centrumlareb

CBG MEB

Will Lareb stop sending ICSRs to MAHs?

- On 7 Nov 2017 last Lareb export to MAHs
- From 22 Nov 2017 Lareb cases will be available via EV in ICH E2B(R3) format
- Acces granted at active substance level, based on Article 57 database

Are non-serious Lareb cases available for download from EV?

- Yes, MAHs will have standard access in EV to both serious as well as non-serious reports, including the Lareb reports.

Which E2B message format will Lareb use for submissions to EV?

- This is important to assess the impact on data when loading ICSR into the system with a Backwards Forwards Compatibility tool.
- From 22 November 2017:
  ICH E2B(R3) message format.
- EV will make ICSRs available for download in E2B(R3) format
  - Lareb cases submitted to EV before 22 Nov 2017 are converted to R3

How many Lareb cases can we expect ?

- It is not possible to give estimates of how many cases would be relevant for each individual MAHs product portfolio.

Lareb cases 2016

	Serious	Non-serious
Vaccine	7,6 % (± 150 cases)	92,4 % (± 1850 cases)
Other drugs	13,6 % (± 1350 cases)	86,4 % (± 8650 cases)

Which language is used in Lareb reports?

- E2B(R3) message format allows information in different languages.
- All data-elements in English, with exception:
  - Name of medical product as reported by primary source (G.k.2.2.)
  - Indication as reported by primary source (G.k.7.r.1)
  - Reaction as reported by primary source in native language (E.i.1.1a)
  - Case summary reporter's comments (H.5.r.1a)

What is the process for requesting follow-up for Lareb cases?

- Routine request for follow-up by the MAH is not foreseen.
  - GVP Module VI (Rev 2)

- If follow-up of an ICSR is necessary for a specific situation, a justification should be provided with the request, which should be addressed to Lareb (info@lareb.nl).

Follow up request

- For each case, the Lareb assessor determines if a follow up request is useful.
- You will be informed if (a part of) the follow up information will be requested within a month. Received follow up will be added to the report and sent to EV.

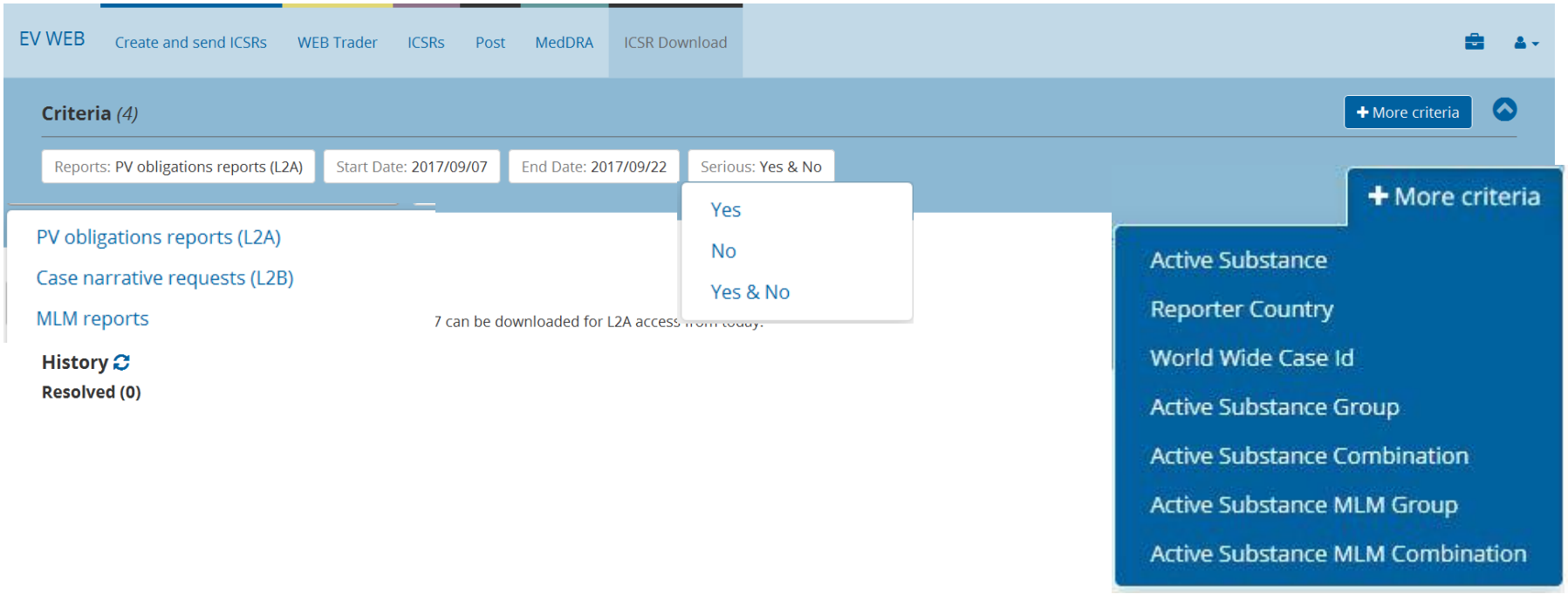
Cases in which no follow up is requested to the reporter (1)

- Information which is already asked in the initial reporting form (https://www.lareb.nl/nl/report-form/)
  - E.g. medical history, risk factors, concomitant medication
  - If possible, Lareb will provide null flavors through which becomes clear that the information is not received (e.g. batchnumber).

Cases in which no follow up is requested to the reporter (2)

- Medical confirmation for consumer reports
- A consent form for consumer reports to bring his/ her HCP directly in contact with the MAH
- Information which it is not likely the reporter has that type of information, e.g. an ECG and a pharmacist as reporter.

How does the download from EV work?

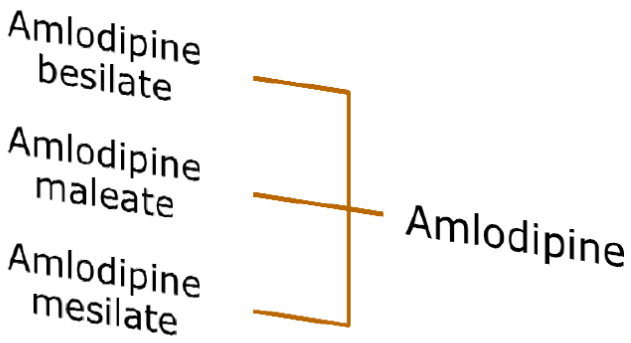


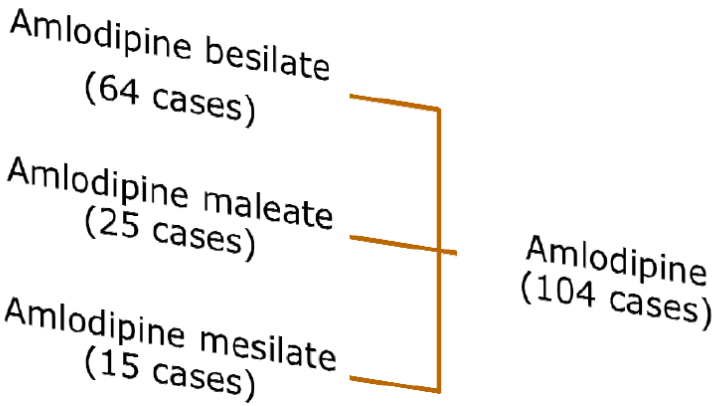
- Active substances are automatically selected
- Retrieve EEA ICSRs from NCA's & other MAHs

bijwerkingen centrumlareb

cBG MEB

At what active substance level is access provided?





Access is provided at active substance high level group - EMA can provide list of active substance groups associated with a specific MAH's organisation ID (provide Headquarter ID): https://servicedesk.ema.europa.eu

Will the downloaded ICSR have a narrative? (1)

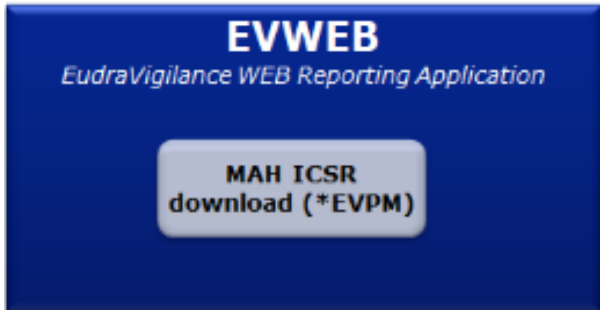
Download Level 2A access does **not** provide case narratives

MAHs can request extended set of ICSR data elements including case narrative ('Level 2B'):

- review of ICSR data is warranted in the context of signal management (GVP Module IX)
- a pharmacovigilance assessment procedure such as the PSUR
- when required by the PRAC in a referral or signal assessment procedure

Will the downloaded ICSR have a narrative? (2)

- QPPV (or deputy) can grant user rights to staff members who need access to Level 2B.



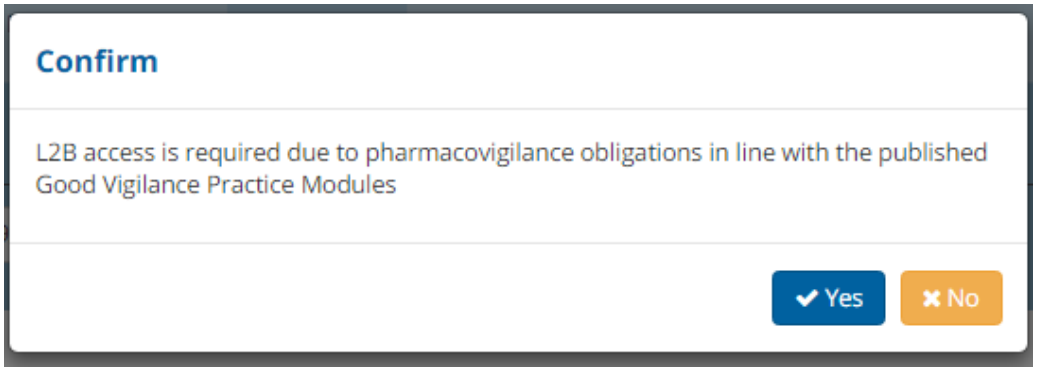
- Each request requires the confirmation of the confidentiality undertaking.
  (EudraVigilance access policy:
  http://www.ema.europa.eu/docs/en_GB/document_library/Other/2016/12/WC500218300.pdf)

How does a Level 2B request work in practice? (1)

Few simple steps in EVWEB:

- Enter (a list of) worldwide unique case identifier(s)

- Confirm that Level 2B access is required due to PV obligations in line with GVP modules

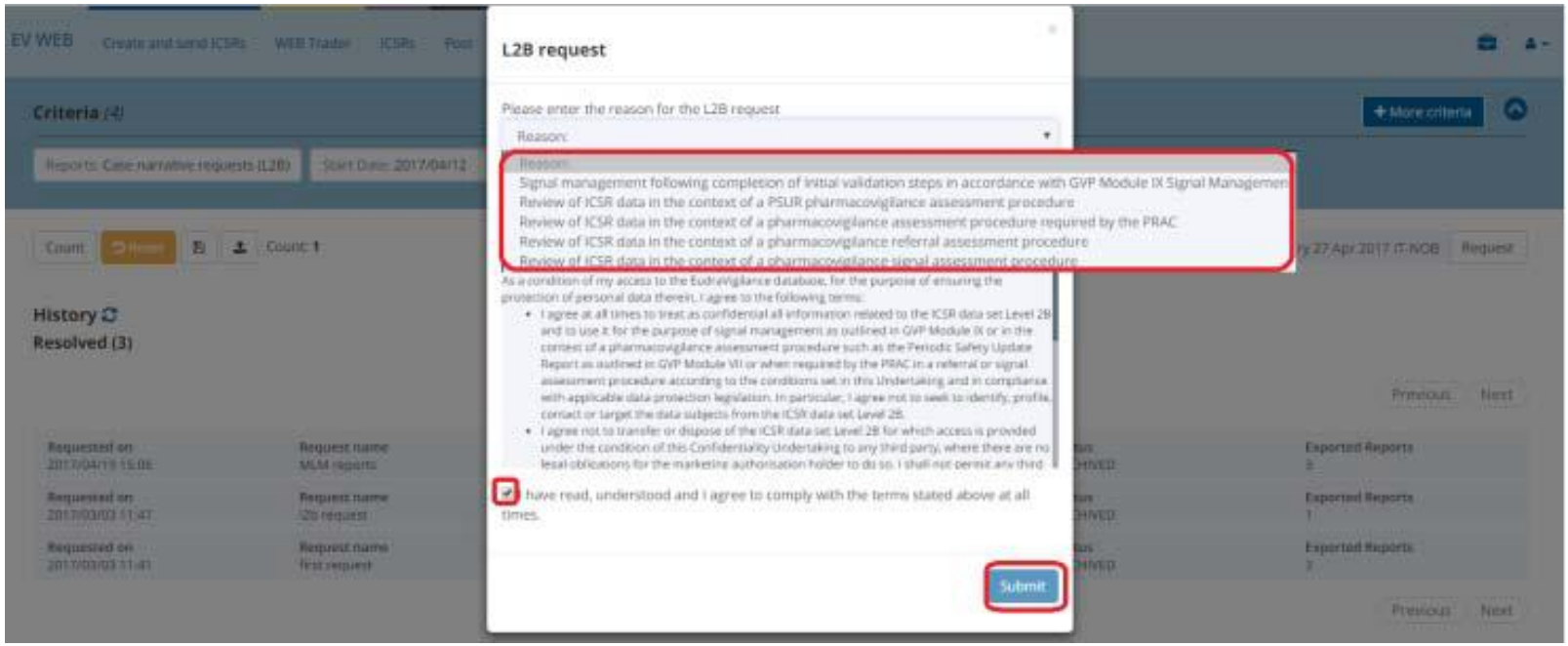


bijwerkingen centrumlareb

cBG MEB

How does a Level 2B request work in practice? (2)

- Select the reason for the request
- Agree with the terms related to protection of personal data



- ICSRs with narratives will be provided within minutes

bijwerkingen centrumlareb

CBG MEB

Submitting ICSRs to EudraVigilance

bijwerkingen centrumlareb

CBG MEB

What to do in case of system failure? (1)

- Please follow the instructions provided by the EMA:
  http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000686.jsp&mid=WC0b01ac0580a69261#What to do in case of system failure
- From 22 Nov submission of CIOMS forms is no longer supported
- There is no need to inform the MEB separately

What to do in case of system failure? (2)

If EVWEB/gateway are not available:

- Submit your ICSRs when EV becomes available again

- Reports submitted within 2 EMA business days of EV being made available again will have their reporting compliance calculated against the first day of system failure

Is there a requirement to use Dutch language when submitting ICSRs to EV?

- No, there is no such requirement. Both English and Dutch language are acceptable.

For literature cases: is there a national requirement to submit the published article?

- No, there is no such requirement.
  The published article only needs to be submitted upon request.

What to do when a downloaded Lareb case is a duplicate of a MAH case submitted to EV?

Send email to EMA with information on which cases are suspected to be duplicates (duplicates@ema.europa.eu)

- If EMA confirms that the cases are indeed duplicates, a master case will be created and this will also be made available for download

  See GVP Module VI Addendum I – 'Duplicate management of suspected adverse reaction reports'
  http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2017/08/WC500232765.pdf

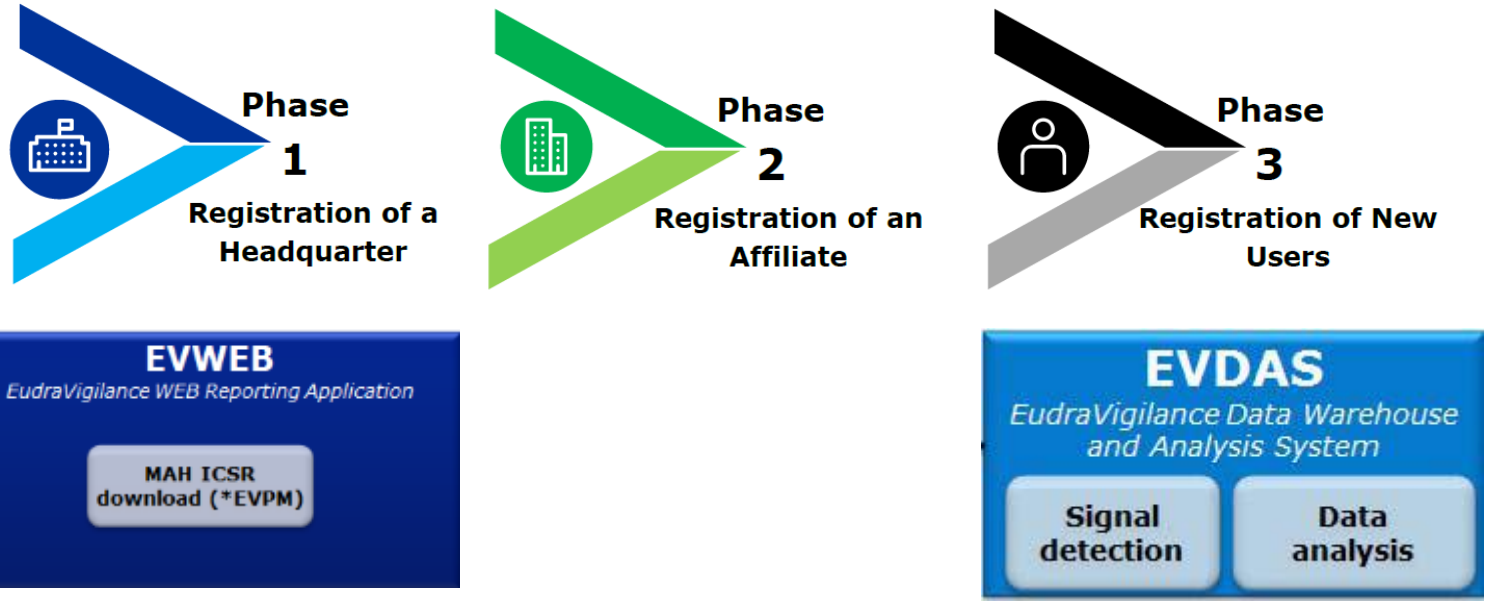
How to prepare for 22nd Nov?

bijwerkingen centrumlareb

CBG MEB

1: Review EV User Registration

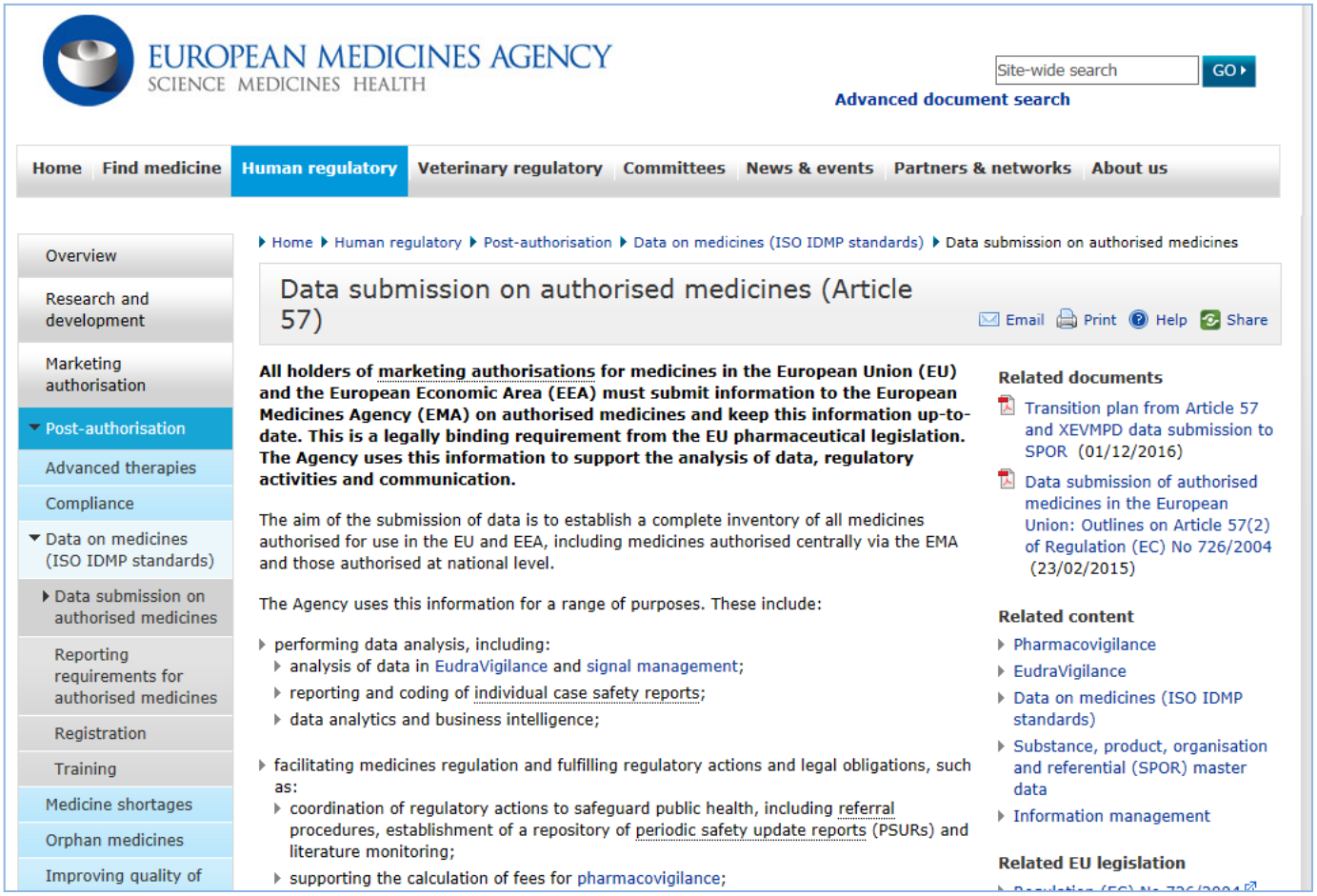
- Grant appropriate EV access to users
- Check that passwords are still working



Unlimited # users

5 users per MAH

2: Ensure Art57 data is up to date



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Site-wide search GO

Advanced document search

Home | Find medicine | Human regulatory | Veterinary regulatory | Committees | News & events | Partners & networks | About us

- Overview
- Research and development
- Marketing authorisation
- Post-authorisation
  - Advanced therapies
  - Compliance
  - Data on medicines (ISO IDMP standards)
    - Data submission on authorised medicines
    - Reporting requirements for authorised medicines
    - Registration
    - Training
  - Medicine shortages
  - Orphan medicines
  - Improving quality of

Home ▸ Human regulatory ▸ Post-authorisation ▸ Data on medicines (ISO IDMP standards) ▸ Data submission on authorised medicines

Data submission on authorised medicines (Article 57)

Email Print Help Share

All holders of marketing authorisations for medicines in the European Union (EU) and the European Economic Area (EEA) must submit information to the European Medicines Agency (EMA) on authorised medicines and keep this information up-to-date. This is a legally binding requirement from the EU pharmaceutical legislation. The Agency uses this information to support the analysis of data, regulatory activities and communication.

The aim of the submission of data is to establish a complete inventory of all medicines authorised for use in the EU and EEA, including medicines authorised centrally via the EMA and those authorised at national level.

The Agency uses this information for a range of purposes. These include:

- performing data analysis, including:
  - analysis of data in EudraVigilance and signal management;
  - reporting and coding of individual case safety reports;
  - data analytics and business intelligence;
- facilitating medicines regulation and fulfilling regulatory actions and legal obligations, such as:
  - coordination of regulatory actions to safeguard public health, including referral procedures, establishment of a repository of periodic safety update reports (PSURs) and literature monitoring;
  - supporting the calculation of fees for pharmacovigilance;

Related documents

- Transition plan from Article 57 and XEVMPD data submission to SPOR (01/12/2016)
- Data submission of authorised medicines in the European Union: Outlines on Article 57(2) of Regulation (EC) No 726/2004 (23/02/2015)

Related content

- Pharmacovigilance
- EudraVigilance
- Data on medicines (ISO IDMP standards)
- Substance, product, organisation and referential (SPOR) master data
- Information management

Related EU legislation

bijwerkingen centrumlareb

CBG MEB

3: Familiarise yourself with the changes

EMA EudraVigilance training webpage

- Pharmacovigilance
  - EudraVigilance
    - System overview
    - Registration
    - Electronic reporting
    - Access to data
    - Security
    - Change management
    - EudraVigilance training

3: Familiarise yourself with the changes

- Testing with the EMA may be required depending on the IT changes to your system

- If you are intending to use E2B(R3) conversions tool you should start testing it to see how it will work with your existing systems

4. Prepare for the go-live (1)

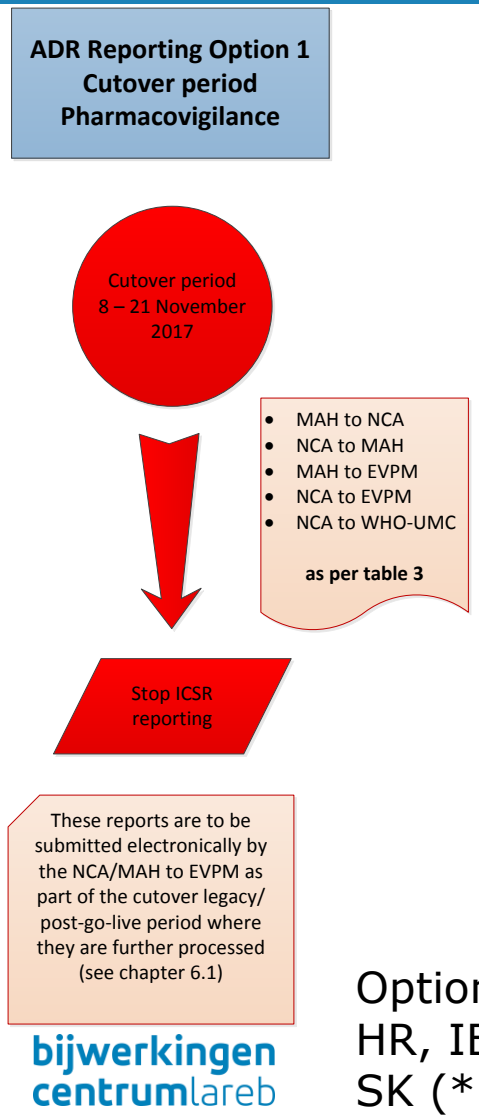
Launch of the new EV system requires a downtime period of 10 business days:

start: 8 Nov 2017 (00:00 a.m. UK time)
end: 22 Nov 2017 (9:00 a.m. UK time)

Key components of EV will not be available or only partially available

EV go-live plan will be published 1st week Oct

4. Prepare for the go-live (2)



- Submission of ICSR stops

  - last Lareb export on 7 Nov

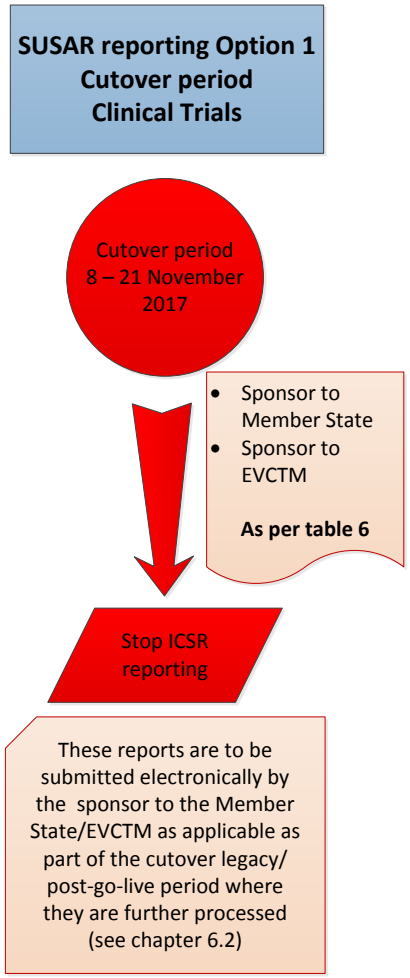
- No need for alternative arrangements for submission

- Start submissions to EV when system goes live on 22 Nov

  - Lareb cases available for download via EV

Option 1 applies to: AT, BE, BG, CY, EE, ES, FI, FR, HR, IE, LI*, LU*, LT, LV, MT*, NL, NO, PL, PT, SE, SI, SK (* to be confirmed)

4. Prepare for the go-live (3)



NL has taken same approach for SUSARs:

- Stop submitting to EV
- No need for alternative arrangements for submission
- Start submissions to EV when system goes live on 22 Nov

note:
continue submissions to METCs via Toetsing Online !

bijwerkingen centrumlareb

cBG MEB

4. Prepare for the go-live (4)

- Reports requiring submission from 8 to 21 Nov should be sent within 2 EMA business days following the go-live of EV
- Compliance calculations will be corrected for the downtime period + the 2 business days
- Events/observations which may affect the risk-benefit balance of a medicinal product, should be notified as ESI

5. From 22th Nov onwards

Submit and receive ICSRs only via EV

bijwerkingen centrumlareb

cBG MEB

Any other questions?

bijwerkingen centrumlareb

CBG MEB