EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

GVP Module X - additional monitoring of medicines

6th Stakeholders forum on the implementation of the new pharmacovigilance legislation

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  - Mandatory scope.
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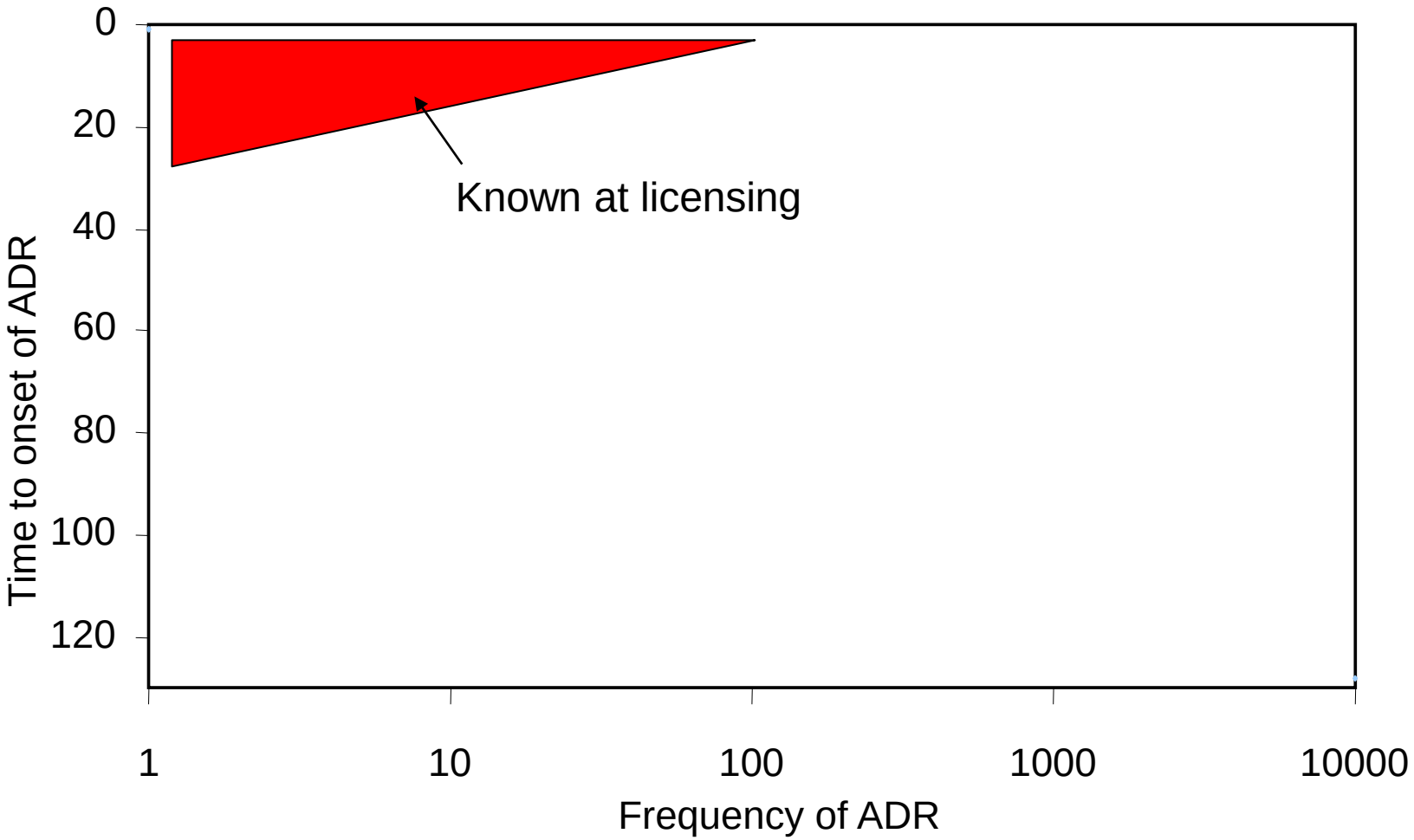
Background – the need for monitoring

- Limitations in pre-clinical toxicology and phase 1-3 clinical trials
  - Lack of experience on adverse effects
  - Exposure in small numbers of people
  - Short duration
  - Unlikely to detect ADRs:
    - Less frequent than 1/1500
    - With long latency
  - Lack of experience in special patient groups
    - Elderly, children, pregnancy, multiple disease, polypharmacy

Background – the need for monitoring



Background – the law (Reg 726/2004 whereas clause 17)

… some medicinal products are authorised subject to additional monitoring. This includes all medicinal products with a new active substance and biological medicinal products, including biosimilars, which are priorities for pharmacovigilance. Competent authorities may also require additional monitoring for specific medicinal products that are subject to the obligation to conduct a post-authorisation safety study or to conditions or restrictions with regard to the safe and effective use of the medicinal product. Medicinal products subject to additional monitoring should be identified as such by a black symbol and an appropriate standardised explanatory sentence in the summary of product characteristics and in the package leaflet. A publicly available list of medicinal products subject to additional monitoring should be kept up to date by the European Medicines Agency ……

Mandatory Scope

- Article 23(1) of Regulation (EC) No 726/2004

The list shall include the names and active substances of

- (a) medicinal products authorised in the Union that contain a new active substance which, on 1 January 2011, was not contained in any medicinal product authorised in the Union;
- (b) any biological medicinal product not covered by point (a) that was authorised after 1 January 2011.

Optional Scope

Can include at the request of the Commission or a National Competent Authority, and following consultation with PRAC, MAs where

- granted with conditions
- measures in the RMP, such as conducting Post Authorisation or Efficacy Studies
- Concerns over the adequacy of the PV system
- Exceptional circumstances

Due consideration should be given to the inclusion of generics

Creating & maintaining the list

- For mandatory scope products the EMA and NCAs will be responsible for automatic inclusion
- EMA will update CAPs within 15 days of grant
- RMS or NCA shall inform EMA within 15 days of grant for MR, DCP and national licenses
- For optional scope products CHMP, RMS, NCA shall consult PRAC before inclusion on the list
- PRAC recommendation will be sent to relevant body
- Final decision will be incorporated within 15 days

Creating & maintaining the list

- products will normally remain on the list for 5 years
- for mandatory scope products removal will be tied to the renewal procedure
- for optional scope products review will be tied to fulfillment of obligations i.e. RMP measures, PASS etc
- removal should apply to all generics unless there are different conditions
- extensions will take into account the completion of milestones, or as considered necessary
- products removed from the list can be added again

Creating & maintaining the list

Set up the list of medicinal products that are subject to additional monitoring:

- NUI was sent to all MS on the 13 July 2012 – Deadline for responses 1st October

Creating & maintaining the list

Information requested:

1) Medicinal products falling under the Mandatory scope

- MS to provide information on those medicinal products approved through mutual, decentralised and national procedures that fall under the mandatory scope
- All MS will need to provide the information due to different brand names and national links

Creating & maintaining the list

Information requested (Cont.):

2) Medicinal products falling under the Optional scope:

- **NCA** in case of purely NAPs
- **RMS** in case of MRP or DCP

Should identify the products concerned and fill in the template to request the PRAC advice, if appropriate.

Creating & maintaining the list

Responses to NUI:

- Good response on mandatory scope products
- Some additional products requested under optional scope
- Template for PRAC advice not always used
- Further information required
- 2nd NUI to be issued before PRAC to consider optional scope products

Transparency

- List to be published on EMA web portal
- Relevant products to be published on NCA web portals
- Links to product information and summary RMP to be established
- NCAs to have appropriate communications in place to inform patients and healthcare professionals
- NCAs to encourage reporting of ADRs

Good Vigilance Practice Module X

- Draft GVP X issued for consultation 27th June – 24th Aug
- Responses received from Trade Associations, companies, consultancies and NCAs
- Responses still being reviewed
- Comments/suggestions on specific wording
- Some key themes emerging

Good Vigilance Practice Module X – Key Themes

- Will reasons for inclusion on list be published?
- Will national schemes co-exist?
- Will MAHs know in advance of publication of their products?
- If included on NCA recommendation will it apply in all MSs?
- Can the 5 years be considered? it's too long?
- Keep the optional scope small/proportionate!
- How will we measure effectiveness of the system?

Conclusions

- Additional monitoring is a key public health deliverable of the new legislation
- Development of the list is ongoing
- Consultation on GVP Module X has raised interesting comments for consideration
- Still unanswered questions, clarity needed on timelines
- Transparency and good communications are key to delivering success

Thank you

Questions?