EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

3rd industry stakeholder platform - operation of EU pharmacovigilance legislation

Referrals – Update from the Regulators

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Different types of referral

All pharmacovigilance referrals are described in the **legislative texts** that govern how medicines are monitored in the EU.

Tool for MS/EC/MAH to address issues of Union Interest.

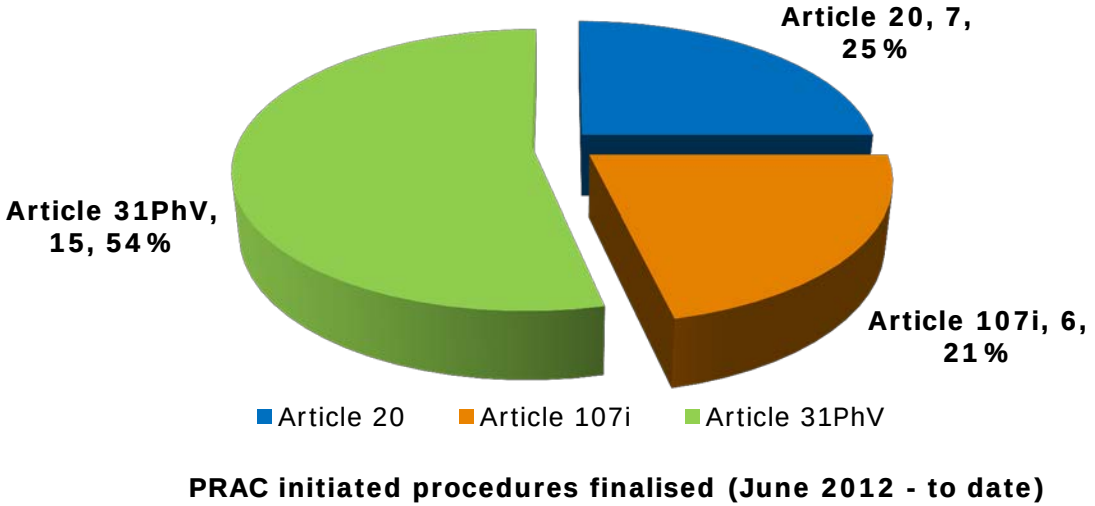
Pharmacovigilance referrals:

- Art 20 of Regulation (EC) 726/2004.
    - PRAC/CHMP
- Article 31 and 107i of Directive 2001/83/EC.
    - PRAC/CMDh (only NAPs) or PRAC/CHMP (CAPs involved)

Cumulative knowledge of Pharmacovigilance referrals

Approx 2.5 years experience

Total of reviews finalised: 28



PRAC initiated procedures finalised (June 2012 - to date)

Areas of improvement (1)

Communication (Notification)

- Referral announcement
  - Key: information in article 57 -> Important to be always up to date
  - Mailings -> email to QPPV
  - Visibility of EMA website
  - Possibility of informing QPPV in advance of PRAC meeting under investigation
    - As per signals or different option
    - Signed notification available
    - Urgency may preclude advance notice
    - Scope only defined at start of procedure at PRAC meeting

Areas of improvement (2)

Initiatives for more focused reviews

- Focused list of questions (LoQ)/outstanding issues (LoOI)
  - alternatives to gathering administrative data
  - data from other sources available to Committees
  - other consultations (e.g. SAGs)
- Timetables aim to strike a balance between data needed, timelines for responses and urgency of the matter
- Assessment report template

MAHs opportunities

- Increase in know-how of the process (new/updated Q&As)
- Article 57 up to date
- Dialogue with the PM/PA assigned
- Responses to LoQ/LoOI
- Responses in CTD (modular format)
- Oral explanations
- Joint efforts and worksharing (e.g. translations, PASS, DHPC)
- Clarification teleconference with rapporteurs/EMA if needed

Areas of improvement (3)

- New process for appointment of (co)-rapporteurs
  - Similar for other fee procedures, e.g. initial marketing authorisation applications
  - http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004163.pdf
- eSolutions
  - Submission via gateway (modular format, e.g. M1-M5)
  - MS adhering to CESP solutions (follow up)
  - Dedicated contact from referral team and from technical support
- Up to date guidance documents
  - New/updated Q&As to be published soon

Summary

- Referrals are regulatory tools described in legislation. Triggering party consider options available for safety issues.
- Accumulated knowledge offers insight to potential opportunities to streamline procedure
  - Early notification
  - Focused review
  - eSubmissions
  - Opportunities for MAHs
- Difficulties with regards to coordinated communication/studies noted
  - MAHs invited to collaborate e.g. DHPCs
  - PASS initiative

Thank you for your attention

Further information

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