Improving processes – referrals as a case study

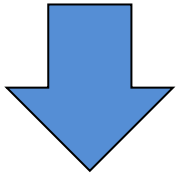
Stakeholders meeting 15 September 2015

Ulla Wändel Liminga
Scientific Director, PRAC member Sweden
Medical Products Agency

Acknowledgements: Ms Charlotte Backman, MPA;
Dr Tanïa Teixeira, EMA

Pharmacovigilance referrals

- **Tool for Member states, European Commission and Marketing Authorisation Holders to address issues of Union Interest**
- **Described in legislative texts that govern how medicines are monitored in the EU**



- **PRAC has now accumulated 3 years experience**

  - aims for continuous improvement

PRAC responsibilities – Pharmacovigilance referrals

Art.20

- Only CAPs (otherwise Art.107i or Art.31)
- Triggered by European Commission (EC)
- No maximum time limit in legislation
- CHMP => Commission Decision (CD)

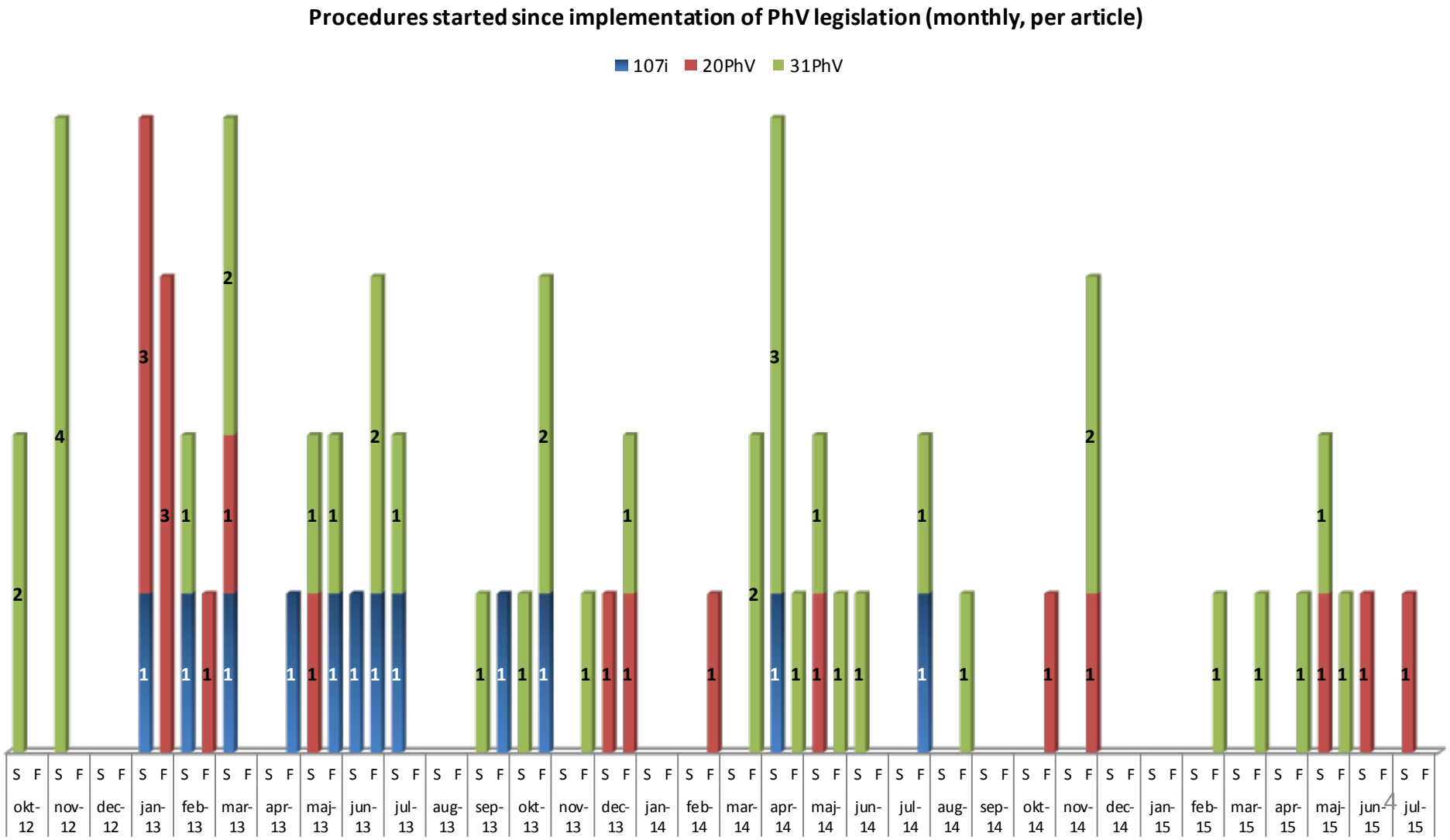
Art.31

- Union interest referral
- Triggered by EC, Member States or MAHs
- 150 days for PRAC recommendation (clock stops)
- CAPs + NAPs: if CAPs involved => CHMP => CD; if only NAPs => CMDh => CD only if majority

Art.107i

- Always for safety reasons (PRAC)
- Triggered by EC or Member States
- No clock stops (60 days after data is submitted)
- CAPs + NAPs: if CAPs involved => CHMP => CD; if only NAPs => CMDh => CD only if majority

Referrals started since July 2012



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Referrals - diverse and complex

- Diverse procedures
  - from one 'new' centrally authorised product to large number of 'old' nationally approved products
- Wide range of data sources
  - timely access of best evidence can be challenging
- Engagement of external stakeholder valuable
  - experts, health care professionals, patients etc
- Effective committee interactions

Improvements

- **EMA undertook a review to identify areas of improvement**
- **Listen to PRAC members and stakeholders, including industry**
- **Key areas for improvement identified**

  - ✓ Support to stakeholders from outset;
  - ✓ Support to network, (co-)rapporteur/Committee members;
  - ✓ Focused reviews (clear and targeted scopes);
  - ✓ Streamlined templates

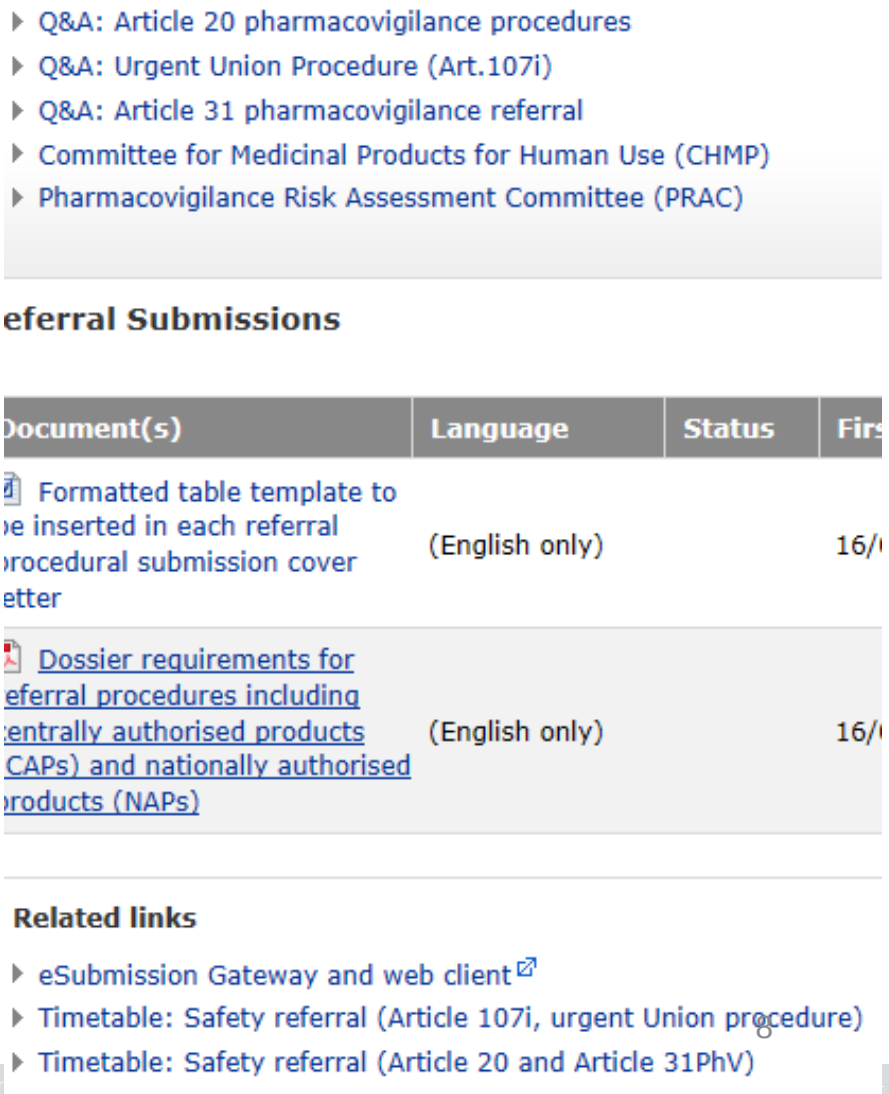
Support to stakeholders from outset (1)

- EMA team appointed from start
- Earlier notification of QPPVs
  - To QPPVs identified in Article 57 database of start of PhV referral procedures referred to PRAC;
  - Notifications provided by Wednesday before PRAC meeting if available, for information only;
  - Urgency may preclude advance notice;

Keep Article 57 database up-to-date

Support to stakeholders from outset (2)

- **Updated advice on EMA website / Q&As**
  - Q&As for all PhV procedures (20 PhV, 31 PhV, 107i)
  - http://www.ema.europa.eu/ema/index.jsp?curl=pages/regulation/general/general_content_000150.jsp&mid=WC0b01ac0580024d0d0
- **eSubmissions**
- **Dedicated contact from referral team and for technical support**



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http://www.ema.europa.eu:80/ema/index.jsp?curl=pages/regulation/document_listing/document_listing_000150.jsp&mid=WC0b01ac0580024e98

Support to network, (co-)rapporteur / Committee members (1)

- Early dialogue
  - EMA appointed team to support triggering party and discussions from outset
  - Scope defined/confirmed at PRAC
- New process for rapporteur appointment

Article	Rapporteur	CoRapporteur
20	Priority to PRAC Rapp for CAP(s)	Priority to PRAC CoRapp for CAP(s)
31	Open to all PRAC members except triggering MS	Open to all PRAC members
107.i	Open to all PRAC members except triggering MS	Open to all PRAC members

http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2009/10/WC500004163.pdf

Support to network, (co-)rapporteur / Committee members (1)

- Regular procedural support from EMA
- Regulatory/procedural advice as needed
- Additional data sources to enrich review
- Interactions with working parties, other Committees
- Early consideration of consultations (e.g. patients, public health professionals, healthcare organisations, other experts)

Focused reviews

- Focused list of questions (LoQ)/list of outstanding issues (LoOI);
- Explore alternatives to gathering administrative data from stakeholders;
- Explore data from other sources available to Committees;
- Best use of expertise available, consultations and timing;
- Timetable balanced between data needed, timelines for responses and urgency of the matter.

Streamline templates

- Simplify process;
- Concept of ‘living document’ for rapporteurs’ assessment report
  - Improve communication with stakeholders;
  - Improve predictability and visibility of changes with updated reports;
- Quality guidance and documentation to strengthen output

Upcoming initiatives

- Increase in know-how of process (experience with revised process and feedback from stakeholders and network) => continuous improvement aimed for
- Public hearings
  - Introduced by PhV legislation in certain circumstances;
  - Public consultation on rules of procedure document took place in 2014
- Encourage Marketing Authorisation Holders to work together on e.g. DHPCs, PASS studies

Thanks a lot for your attention !

Järvsö, Sweden