Pharmacovigilance- Content of the New EU Legislation and Challenges for BfArM

12th DGRA Annual Congress

June 15 to 16, Bonn

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Visit our website: www.bfarm.de/Pharmakovigilanz

About my Talk – Important Changes (overview)

- Definitions
  - e.g. for ADR and medication errors
  - ADR reporting and reporting requirements
- *The* PRAC: Pharmacovigilance Risk Assessment Committee
- Procedures
  - PSUR assessment
  - Post Authorisation (Safety) Studies (PAS, PASS)
  - Community procedures
- Transparency, web-portals

Definitions, ADR Reporting

- Adverse reaction: now broadened
  - ‘a response to a medicinal product which is noxious and unintended’
  - Meaningful clarification
- All serious ADRs worldwide!
  - Extension of reporting requirements
- Non serious ADRs as single case reports!
  - Extension of reporting requirements
- ‘Medication errors’ (not restricted by definition)
  - DE: only if resulting in an ADR

PRAC: Pharmacovigilance Risk Assessment Committee

- Now:
  - 1 representative and alternate per Member State, appointed by the MS after consultation of the EMA Management Board
  - 5 experts and alternates additionally appointed by the EC after consultation of the EP
  - Qualification and expertise in pharmacovigilance: ‘highest level’

PSURs (Periodic Safety Update Reports)

- Waiver for submission of PSURs for large groups of medicinal products, e.g.
  - generics (more than 10 years on the market?)
  - Traditional herbal medicinal products
- Legal basis for ‘worksharing’
  - Community Reference Date (‘harmonised birthdays’)
  - P-RMS concept

PASS - (Post Authorisation Safety Studies)

- Request by a National Competent Authority at the time of licensing or later at any time
  - No assessments of not requested PA(S)S by the PRAC (= our usual AWB)
  - DE: joint conduct of PASSs for groups of substances funded by the Community
- Assessment of study protocols and adoption through the Rapporteur or the Member State (usually the RMS)
- MAH: assessment and statement, whether the benefit-to-risk balance has changed

Community Procedures

- Art. 36 of Directive 2001/83/EC deleted
- Unclear distinction between Art. 31 and Art. 107i to 107m procedures
  - Criteria: urgent, non urgent
  - DE: ‘one size fits all’
    - one flexible ‘umbrella’-procedure was seen as ‘too revolutionary’

Medicinal Products or Substances under Intensified Monitoring

- Criteria for listing or deletion from the list
  - New active substance, new fixed combination
  - ‘biosimilars’
  - Significant change of the marketing authorisation, after consultation of the PRAC (e.g. new patient groups, new dosage form etc.)
  - Deletion possible at the next renewal or PSUR

Other Relevant Changes

- SmPC and package leaflet (PIL):
  - Summary of the most important properties of the drug at an highlighted place
  - Flagging of recent changes in the PIL
  - Signalling the intensified monitoring (‘on the list’)
- Public hearings in ‘referrals’
  - Divergent views of Member States
  - DE: mandatory participation of healthcare and patients or consumer representatives

Transparency, Web Portals

- Establishing national web portals with a link to the EMA web portal
- Publication on
  - Members of CHMP, CMD(h) and PRAC
  - Minutes on CHMP, CMD(h) or PRAC meetings
  - Risk Management Systems
  - List of medicinal products under intensified monitoring
  - Advice on how to report ADRs

Transparency, Web Portals (ctd.)

- Publication on
  - Minutes and ‘abstracts’ on PASSs
  - Initiation of pharmacovigilance ‘referrals’ (community procedures)
  - Announcement on public hearings
- Assessments, PRAC recommendations, CHMP/CMD(h) ‘opinions’
- Safety information originated by MAHs

Some Consequences and Challenges for BfArM

- Definitions and reporting requirements
  - Broadening of definitions: clarification
  - Relaunch of the ADR database needed
  - Availability of all reports from Germany essential
  - Signal detection more challenging
- PRAC
  - Clarification on co-operation with CHMP and CMD(h) needed
  - New mandate needed
  - Scope of work, workload and responsibility increased

Some Consequences and Challenges for BfArM

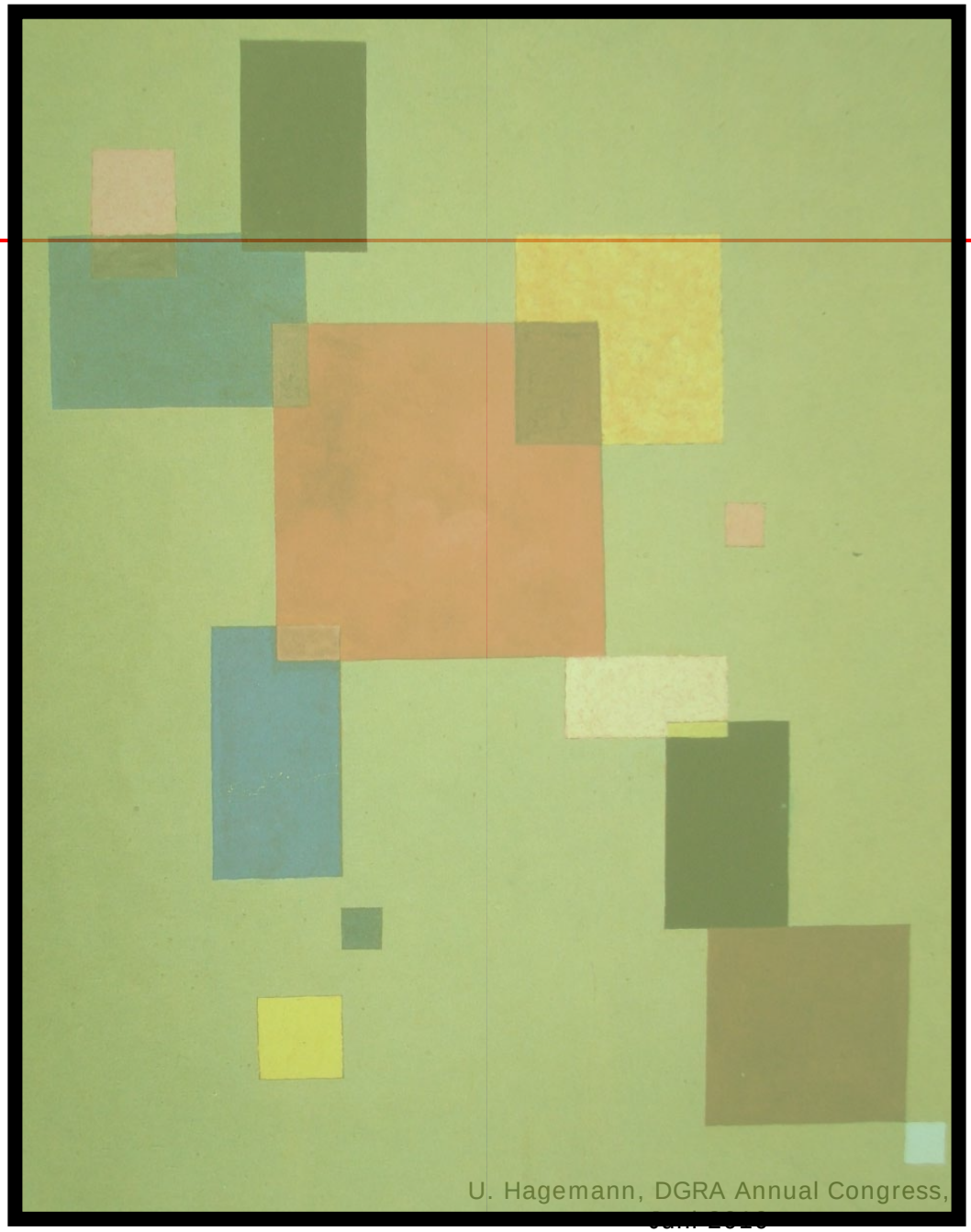
- PSURs
  - Waiver for submission of PSURs may create procedural problems when new safety issues on old substances come up later
  - Coordination by PRAC included
  - Worksharing project supported, but needs simplification
  - Complicated transitional provisions
- PASS
  - Focussing on relevant safety issues supported

Some Consequences and Challenges for BfArM

- Risk communication
  - List of medicinal products or substances under intensified monitoring
    - Needs public explanatory information
  - Most relevant properties in the SmPC and PIL
    - What is the most relevant?
  - Transparency
    - Positive experiences at BfArM

Proposals and Comments from the European Parliament

- Effects of drug use on the environment
  - Not included in the EC proposals
- Data privacy and ADR databases
  - Extensive interpretation of the data privacy Regulation may have major consequences
    - e.g. deletion of reports on request or when no longer needed
- Independent funding of pharmcovigilance activities



Wassily Kandinsky:
13 Rechtecke, 1930