EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Third Stakeholders forum on the Implementation of the new pharmacovigilance legislation

URGENT UNION PROCEDURE
(including concept of public hearings)

Presented by: Anthony Humphreys
London, 20 October 2011

SAFETY REFERRALS

TODAY'S TOOLKIT

SAFETY REFERRALS

TOMORROW'S TOOLKIT

The Future: 107(i)
NAP's +(MRP/DCP's)+CAP's

Initiated by → MS/EC
when **urgent action** is considered necessary

+ criteria

Time Limit → 60 days (PRAC)
30 days (CHMP / CG)

Consultation → HCP's

Public

MAHs

Written +/- public hearing

The Future: 107(i)
NAP's + (MRP / DCP's) + CAP's

Outcome →

PRAC recommendation

↓

CHMP Opinion

OR CG agreement

↓

Commission Decision

(CHMP - All)
(CG – no agreement)

- **+ / - Temporary measures**
- **Final measures**

Urgent Action to protect public health →

Until definitive decision may suspend marketing + use product

NO RE-EXAMINATION

Article 107(i)

Initiation

Pharmacovigilance activities – Data driven

+

Urgency – Who decides?

Criteria:

- ***consideration of***:
  - suspension / revocation of MA,
  - prohibition of supply,
  - refusal of renewal of MA;
  - new CI,
  - reduction in the dose,
  - restriction to the indications.

- based on ***safety*** concerns, from MAH:
  - interruption of the placing on the market,
  - MA withdrawn;

EC CAN initiate for NAP's
MS CAN initiate for CAP's

WEB PORTAL ANNOUNCEMENT

Stake Holders (not just industry)

Questions + MS AR will be public

Time limit to submit < 30 days

Triage data submitted

Announcement intention to have a public hearing: data gathering

TIME LIMIT

Post data collection written +/- oral → **PRAC 60 days No clock stop** → **30 days CHMP / CG No clock stop**

♦Legislation does not foresee clock stop

♦"URGENT" UNION PROCEDURE

♦Challenge to the assessment teams
Robustness of opinion quality process

PUBLIC HEARINGS *("MAY" PROVISION)* 1/2

➔ Information gathering

➔ position pre-assessment by PRAC

Or

➔ During assessment
Contribution to opinion making

Or

➔ Transparency at end of procedure to explain recommendation

PUBLIC HEARINGS *("MAY" PROVISION)* 2/2

Interactions with MAHs

- "request" for confidential discussions at PRAC
  - "right of defence" during procedure
- transparency during procedure:
  - release of assessment reports
  - need for additional information gathering

RAPPORTEUR APPOINTMENT

➔ Rapp/Co-Rapp appointed by PRAC taking into account existing expertise in the MS

➔ Close collaboration with CHMP Rapp / RMS

Process influenced by origin?
CAP / NAP / Safety Concern

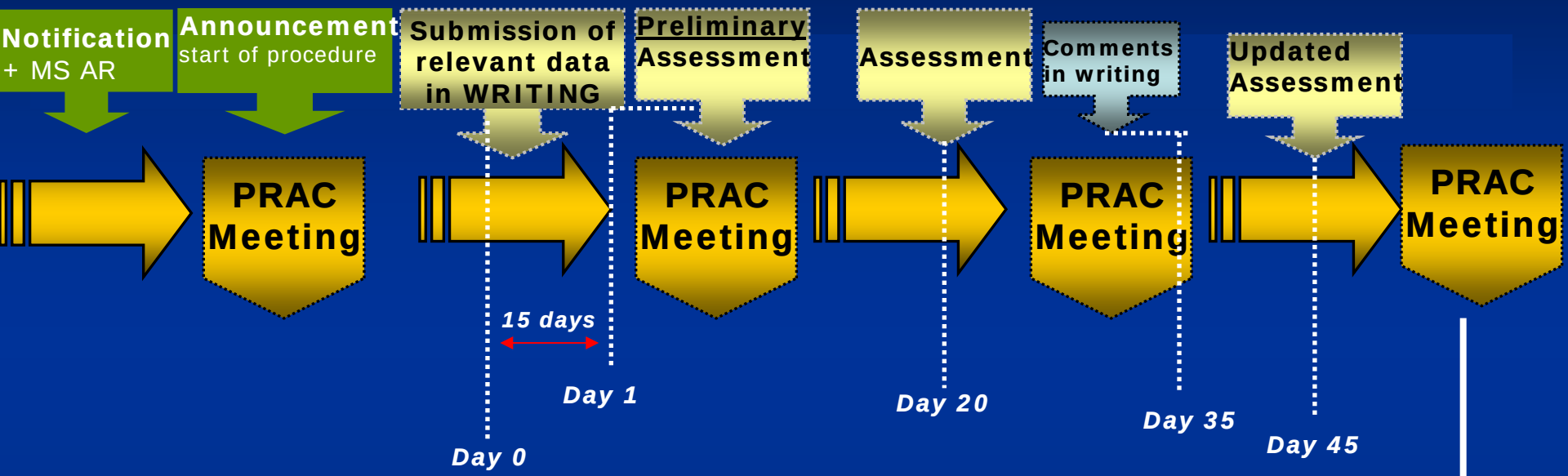
Requirement for independence from primary evaluation

PRAC POSSIBLE OUTCOME

- Variation
- Suspension
- Revocation
- Non-renewal

- PASS studies

- Risk Minimisation Measures



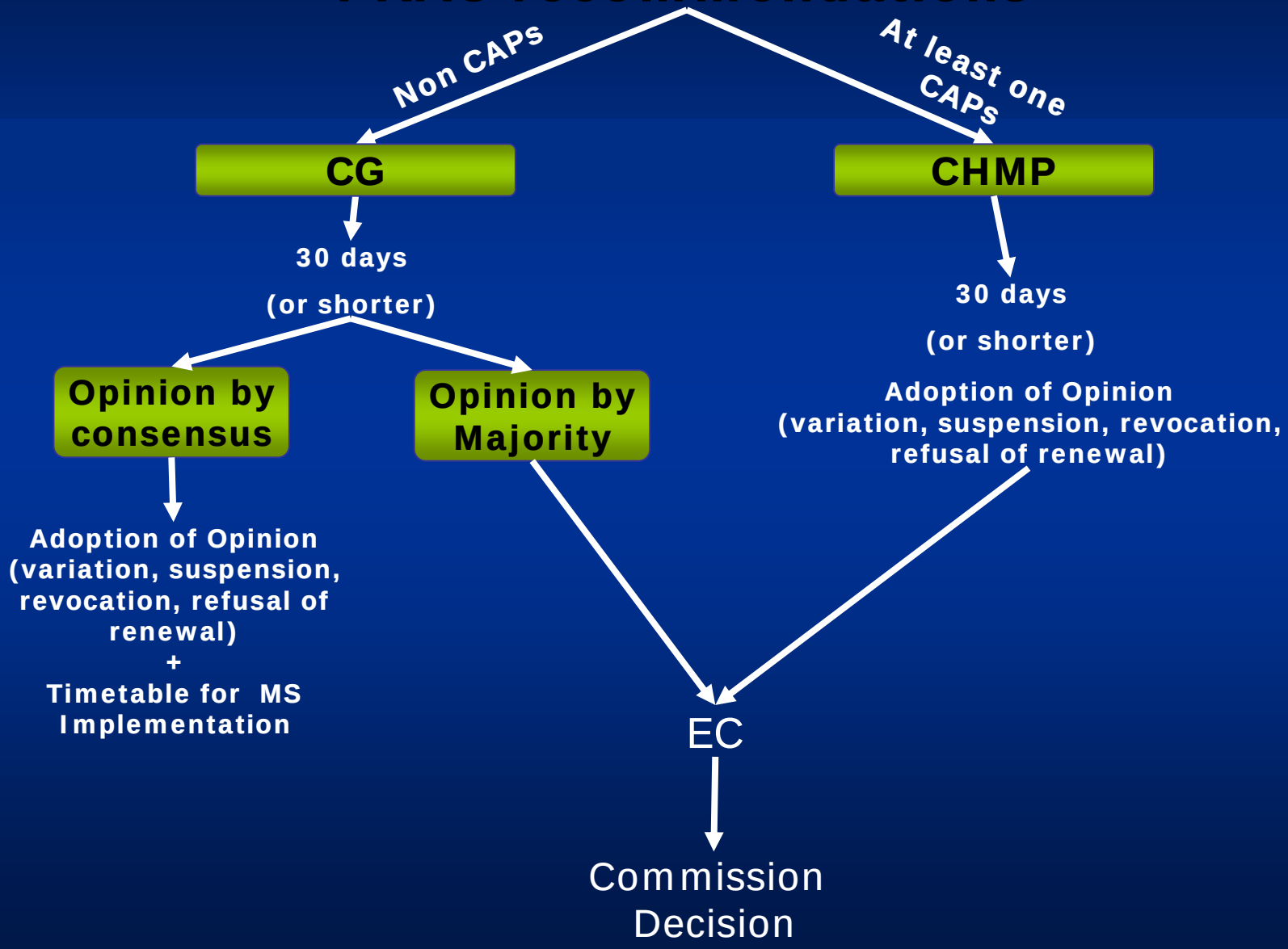
- Consideration of the matter;
- **Temporary measures** needed?
- **Public Hearing**?
- **Which data** to ask?
- **When** & **how** to submit?

- Public Hearing?
- Temporary measures;
- Preliminary discussion;

- Public hearings held;
- Non-Public hearing;
- Discussion;

PRAC RECOMMENDATION

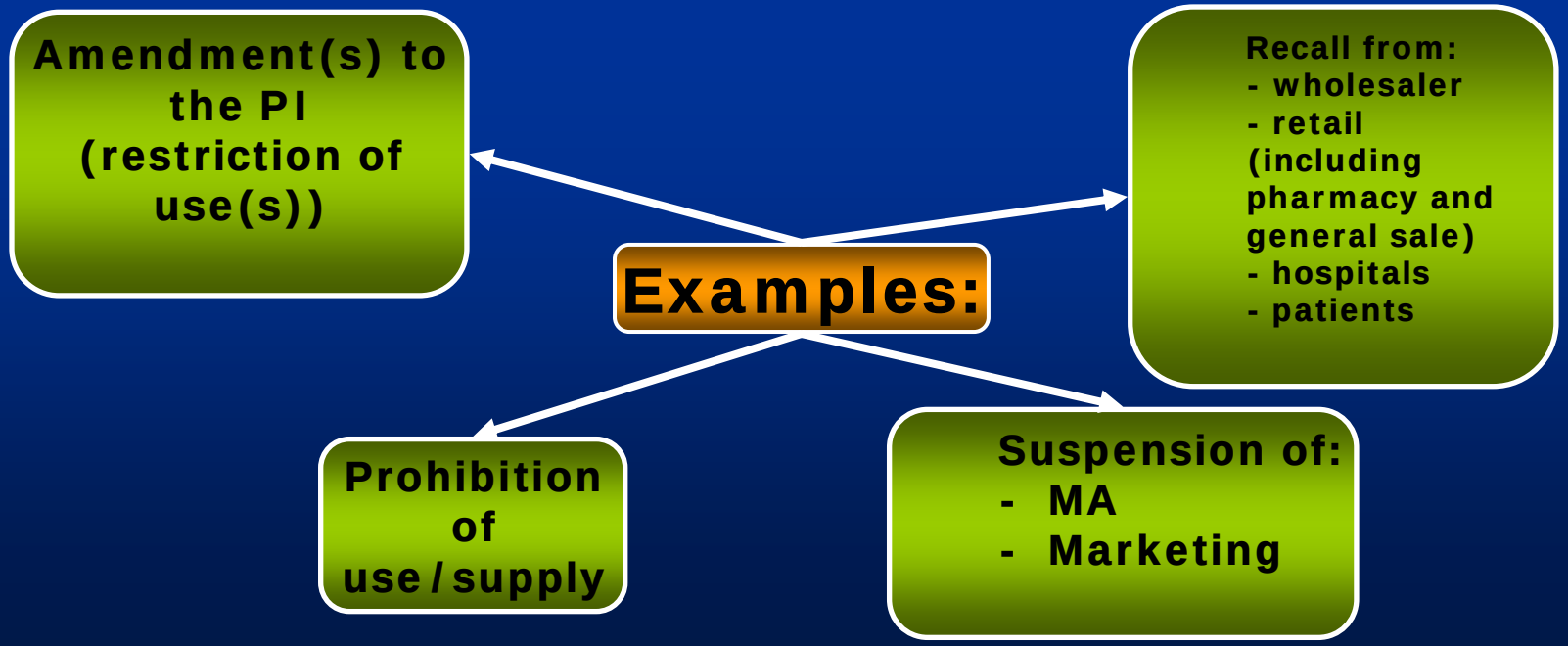
PRAC recommendations



Temporary measures at any time

Temporary measures implemented immediately

Overall procedure 6 months (MAX)



Quo Vadis Article 31 and Article 20

- Pharmacovigilance + urgency ➔ 107(i)
- Pharmacovigilance without urgency ➔ PRAC

+

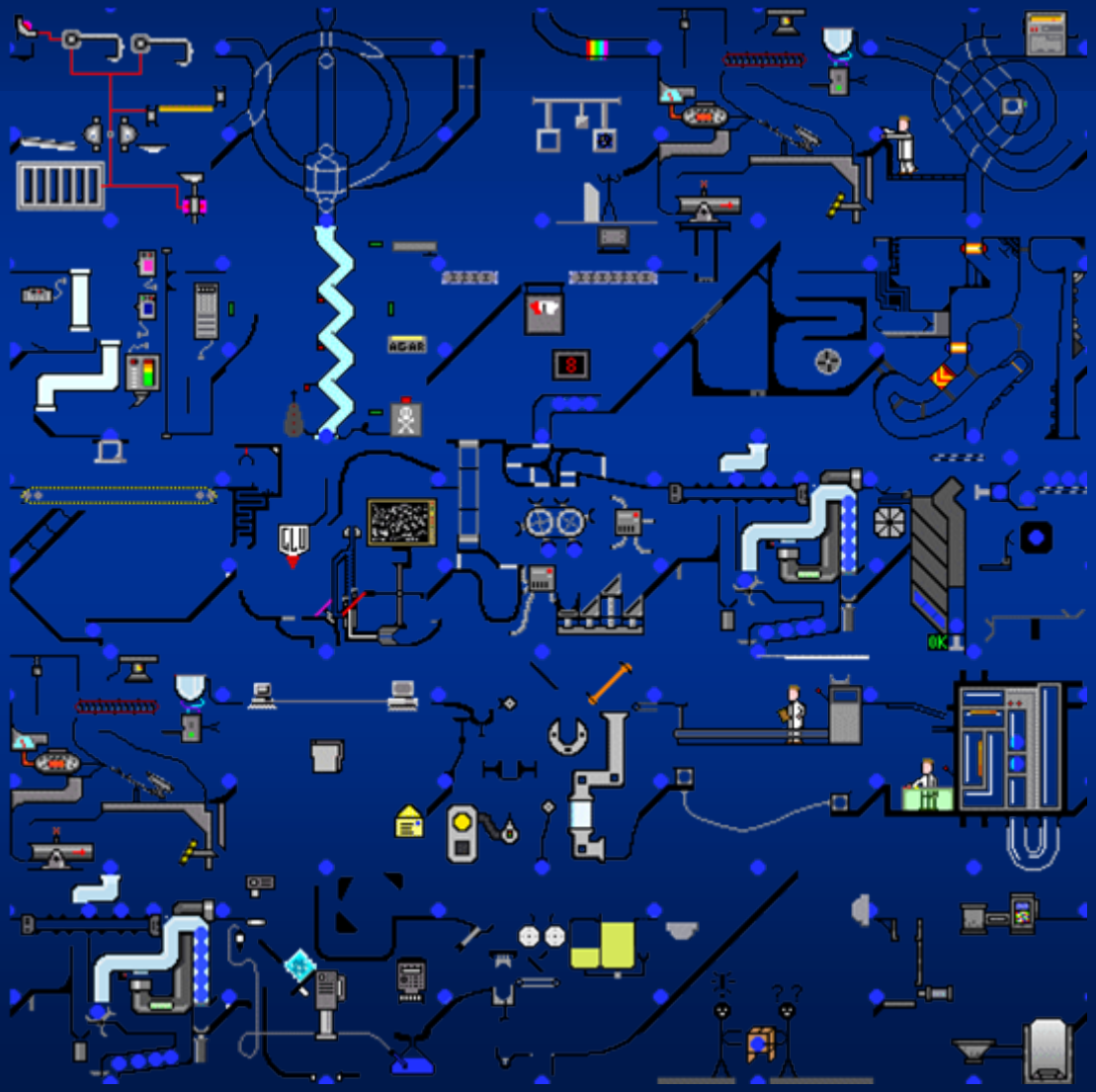
Public hearing

+

Art.32 procedure

Mapping of existing product cases

PRODUCT	ISSUE/ACTION	CURRENT LEGISLATION	NEW LEGISLATION	PRAC?	CHMP?
CLOPIDOGREL PRODUCTS	Quality issue related to inspections	Art 20 (x8)	Art 20	No	Yes
SOMATROPIN	Increase in mortality and risk of cancer in children	Art 20 (x3) + Art 107	Art 31	Yes	Yes
PANDEMRIX	- Narcolepsy in paediatric population - Prohibition of use in SE and FI	Art 20	Art 107i	Yes	Yes
BIPHOSPHONATE	Class review (stress fractures)	Art 20 (x9) + Art 31	Art 31	Yes	Yes
MODAFINIL	- Several safety issues - Changes to PI at national level - Benefit/Risk review	Art 31	Art 31	Yes	No
OCTAGAM	- Increase numbers of TEEs - Suspension of MA in DE and SE	Art 107	Art 107i	Yes	No
NIMESULIDE	Suspension of the MA in IE due to cases of fulminant hepatic failure	Art 107	Art 107i	Yes	No
SIBUTRAMINE	- Preliminary results of the SCOUT study - Increased cardiovascular risk - Consideration of suspension from DE	Art 107	Art 107i	Yes	No



Questions