Lifecycle of a new medicinal product

with emphasis on pharmacovigilance

Presented by: Nathalie Bere
Patient interaction / Medical Information Sector
PRE-SUBMISSION

- Orphan designation?
- Paediatric review
- Scientific Advice?
- Clinical trials
EVALUATION

EMA - CHMP - PRAC

D1 Start  D80 AR  D120 LoQ  D150 JAR  D180 LoOI/OE  D210 Opinion  D277 CD

DRAFT PI & RMP

Submission of application

Evaluation of benefit/risk

Assessment of Risk Management Plan

Patient input

Patient input

Decision on need for post safety/efficacy studies

Preparation of RMP summary

Final Product Information / conditions / RMP

Decision on frequency of safety update reports

Patient input

Patient input

Patient input
**POST AUTHORISATION**

- Submission of application to change authorisation
- Revised PI & RMP
- Timelines dependent on specific procedure/medicine
- Signal detection
- Re-evaluation of benefit/risk
- Decision on need for new post safety studies
- Update of Product Information
- Update of RMP summary
- Regular submission/assessment of safety update reports
- Annual re-assessment/conditional renewal
- Safety variations
- Safety Referrals
- 5 yr - Renewal
- EMA - CHMP - PRAC
- Patient input
Acronyms

- CHMP = Committee for Medicinal Products for Human Use
- PRAC = Pharmacovigilance Risk Assessment Committee
- RMP = Risk Management Plan
- PSUR = Periodic Safety Update Report
- PASS = Post Authorisation Safety Study
- PI = product information
- D1, D80, etc = Day 1, Day 80, (procedural timeline)
- AR = Assessment Report
- LoQ = List of Questions
- LoOIs = List of Outstanding Issues
- OE = Oral explanation
- CD = Commission Decision