WETENSCHAPPELIJK INSTITUUT VOLKSGEZONDHEID
INSTITUT SCIENTIFIQUE DE SANTÉ PUBLIQUE

European Directorate for the Quality of Medicines & HealthCare | Direction européenne de la qualité du médicament & soins de santé

federal agency for medicines and health products

Medicines, Public Health & the Media

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Biological Standardisation (OMCL)

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Belgian Chairmanship
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Biological Standardisation Unit

- Scientific unit in the Operational Direction "Expertise, Service Provision and Client Relations"

- Official Medicines Control Laboratory (OMCL) for Biologicals,
  - active member of the Official Control Authority Batch Release network for human Vaccines and Plasma Derived Medicinal Products,
  - part of the General European OMCL network

- Regulatory framework

Core Activities

- Batch Release of Biological Medicinal Products

Vaccines: legal basis

Belgium: Royal Decree 14/12/06 Art. 89 ***(Official Control Authority Batch Release Certificate after testing)***

EU: Art. 114 in Dir. 2001/83/EC as amended by Dir. 2004/27/EC

Plasma derivatives: legal basis

Belgium: Law 05/07/1994; Royal Decrees 04/04/1996, 05/09/2001 and 14/12/2006 Art.88

EU: Art. 114 in Dir. 2001/83/EC as amended by Dir. 2004/27/EC

Core Activities

- **Advising during licensing**

request received from the FAMHP

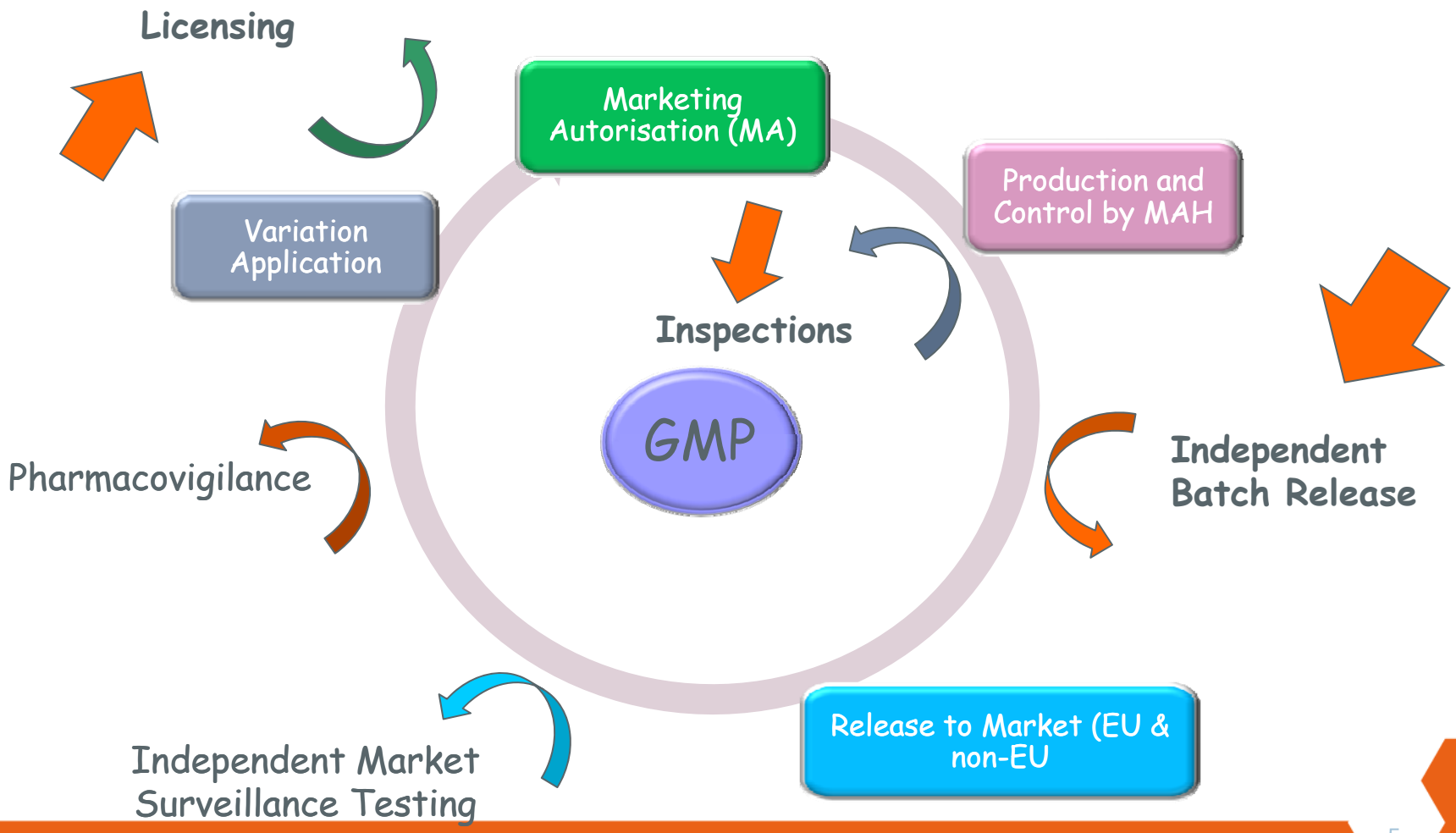
  - Vaccines
  - Plasma derivatives
  - rDNA Biological Medicinal Products

- **Advising during GMP Inspections**
  - Vaccines
  - Plasma Derivatives
  - rDNA Biological Medicinal Products

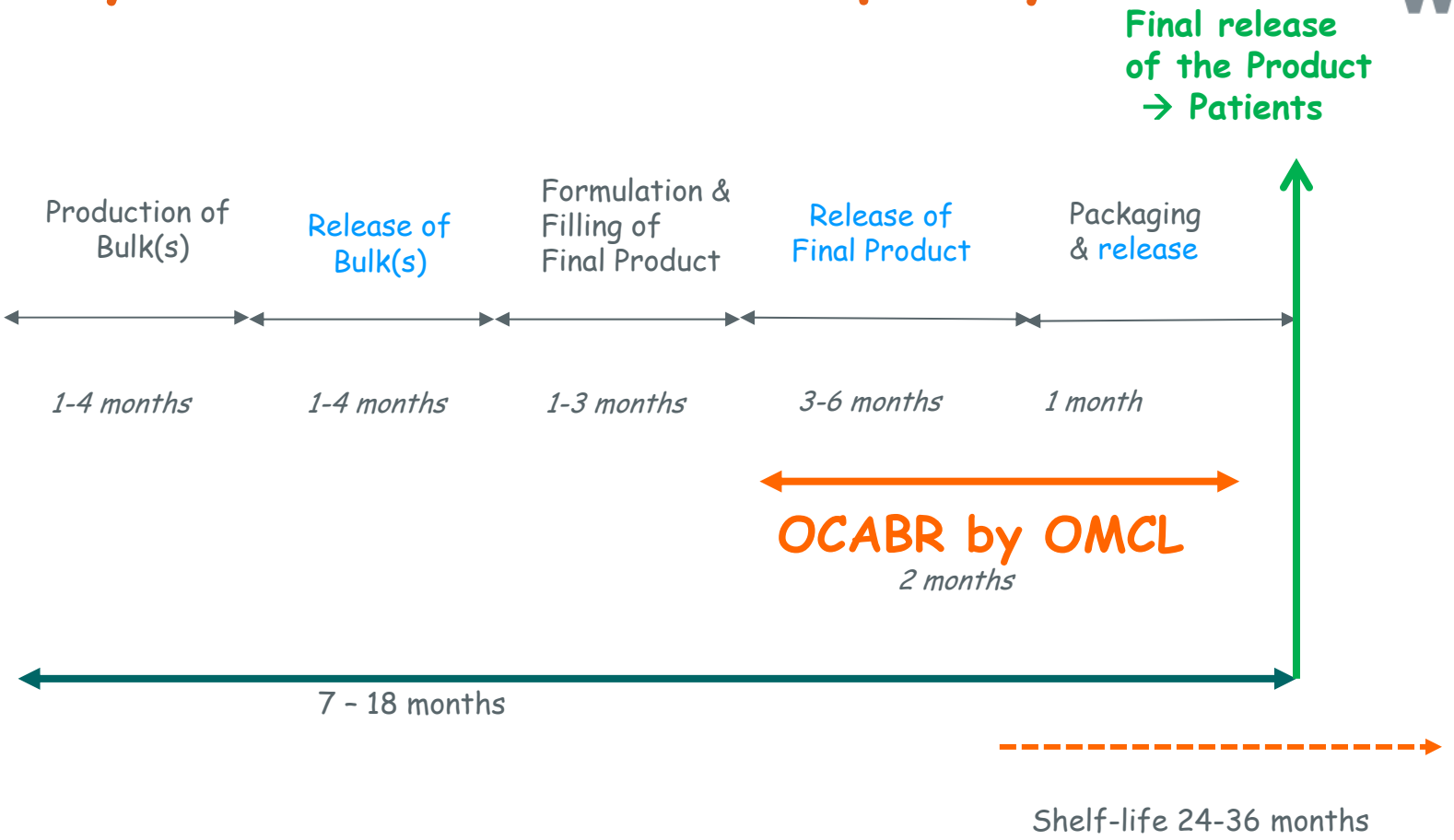
Royal Decree 14/12/2006, Art. 82: participation of Expert from WIV-ISP

- **R&D projects (regulatory framework)**
  - PhD, Master thesis
  - Participation in international projects

Our activities within the EU system of Vaccine & Plasma Derivatives Quality Surveillance



From the production to the Patients, only batches of assured quality



The Batch Release procedure

PRODUCER-INDEPENDENT OMCL & PRE-MARKETING

- RE-testing and/or RE-evaluation of production & control protocol (according to an agreed list of tests and model protocol by the OCABR network)
- To verify & monitor conformity with Marketing Authorisation, Ph.Eur. Monographs & WHO recommendations
- To follow production consistency (e.g. after manufacturing process changes, …) and to detect inconsistency

The Batch Release & Expertise

- In Europe
  - Mutual recognition system based on mutual confidence
  - Lab activities under Quality Assurance system (external audits by BELAC & EDQM)
  - Development & validation of analytical methods
  - Participation in Proficiency Testing Studies & Collaborative studies
  - Exchange of confidential information/data
  - Rapid information system (Network – National Competent Authorities – WHO)
  - Annual reports & Annual OMCL meetings

Batch Release & Expertise

In Europe

- Blood Products (4): ± 305 certificates /year
- Vaccines (28): ± 1250 EU & 1650 non-EU certificates/year
  - Knowledge of products (quality aspects)
  - Active in the OCABR Advisory group, Vaccine drafting group, Ph.Eur. Expert group "Human vaccines" (Be), Mutual Joint Audit as technical auditor
  - EMA biologicals related meetings & guidelines writing

World Health Organisation

- Pre-qualification procedure : assessment of quality data, GMP inspections, lot testing, National Regulatory Authorities assessment
- Participation in ad hoc meetings (e.g. writing of recommendations for vaccines) & research projects

Expertise activities

This global overview of the lifecycle of the biological products from their manufacturing process until their final release performed by the manufacturer has led to an important know-how and a high level of expertise, in constant expansion (new products, new techniques).

This expertise is appreciated during our participation in advisory groups and the writing of regulatory documents (e.g Ph.Eur. Monographs, WHO Recommendations, European Medicines Agency guidelines, Belgian Superior Health Council advices).

Thank you !

More info on www.wiv-isp.be