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UPIP – VAPI

THE NEW LEGAL FRAMEWORK FOR HEALTHCARE PROFESSIONALS IN BELGIUM

Revision of Royal Decree n° 78 – Impact Industry & Pharmacists

IMPACT FOR 'PHARMACISTS'
IN LIFE SCIENCES INDUSTRY

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HISTORICAL VIEW ON THE INDUSTRIAL PHARMACIST

- After World War II, first penicillin and later other antibiotics became available in Belgium.
  - Almost NO QUALITY REQUIREMENTS existed
  - Lack of control (inspection) resulted in ABUSE
- As the use of antibiotics without prior control can be hazardous for public health, the government was prompted to organise controls
- Monographs were drawn by the Pharmacopoeia-commission and a system of batch control is set up by the RD of July 12, 1953
  - Each batch is ANALYSED in an APPROVED LABORATORY prior to sales
  - Each VIAL IS LABELED with a corresponding batch number
- The pharmaceutical inspection mandated for supervision and inspection of the pharmaceutical industry
  - a lot of irregularities (installations, cleanliness, organisation,...) were recorded

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HISTORICAL VIEW ON THE INDUSTRIAL PHARMACIST

- This situation resulted in the first RD on drug manufacturing: the Royal Decree of August 20, 1955 about trade, manufacturing and large scale preparation of medicinal products
  - The industrial pharmacist appears for the 1st time, mainly charged with analytical tasks on starting materials and finished products

- An improved version, the RD of June 6, 1960 finetunes the manufacturing, wholesale and delivery of medicinal products

- More attention was paid to the entire manufacturing process with a shift from analysis to Quality Assurance, incl. Quality Control

- Good Manufacturing Practices were included or added as an attachment of the RD of June 6, 1960
  - References to the WHO, the European Directive, strongly inspired by EFTA GMP originating from the famous Orange Guide of the British Government

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HISTORICAL VIEW ON THE INDUSTRIAL PHARMACIST

- Industrial pharmacists were, by means of accreditation, registered on a list kept by the Ministry of Health (Pharmaceutical Inspectorate)
  - No other obligations
  - Many industrial pharmacists voluntarily registered with the Order of pharmacists

- Industrial pharmacists who completed 1 year training in a manufacturing department of a pharmaceutical company or in an accredited analysis laboratory were approved by and registered on the official list of the Pharmaceutical Inspectorate

- Later only training in industry was accepted. The period was reduced to 6 months for those who followed the newly established additional specialisation year for industrial pharmacy at the university
- Also pharmacists of other EU countries could be registered

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CURRENT VIEW ON THE INDUSTRIAL PHARMACIST

- The concept "industry pharmacist" not being formally recognised, the Belgian legislation needed to be adapted
- Belgium was the first European country to regulate the industrial pharmacy
- In May 2006 the "Medicinal Products Act" of March 25,1964 has been revised, being the legal basis for a fundamental revision, the so-called Mammoth Decree of December 14, 2006.
- The Mammoth Decree covers medicinal products for both human and veterinary use
  - Provisions for registration & manufacturing of drugs were combined
  - The RD of June 6, 1960 and many other decrees were abolished

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CURRENT VIEW ON THE INDUSTRIAL PHARMACIST

- For the first time it is stated that a qualified person is responsible for GMP, controls and release for the products with MA
- This way, the "industry pharmacist" disappeared after 50 years from the legislation. Remains the university curriculum & diploma (Master in geneesmiddelenontwikkeling & Master in industriële pharmacie als ManaMa)
- The qualified person has no contact with patients, does not make ex-tempore preparations. RD 78 is not applicable here and registration with the "Order of Pharmacists" is not mandatory,
- The 'industrial pharmacist' is not listed as a health care professional

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CURRENT VIEW ON THE INDUSTRIAL PHARMACIST

- Qualified Person
  - EU Guidelines for GMP for Medicinal Products for human and veterinary use holding a Market Authorisation or made for export
  - Guidance on the Certification by a Qualified Person (QP) and on batch release, principles also apply to IMP for human use
  - Eudralex, Volume 4, Annex 16

- MIA
  - Manufacturing and Importation Authorisation
  - Manufacture of medicinal products in the EU or import from 3th country is subject to the holding of a MIA
  - National CA issues these authorisation
  - EudraGMPD

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CURRENT VIEW ON THE INDUSTRIAL PHARMACIST

- QP – Academic degree
  - Master in Development of Medicines
  - Master in Industrial Pharmacy (ManaMa)

- Industrial Pharmacist – broader than concept of QP
  - Analysis related competences, Quality Control, QA
  - pharmaceutical technology, optimalization, data analysis
  - regulatory affairs, R&D, clinical research
  - biotechnology
  - strategic management

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CURRENT VIEW ON THE INDUSTRIAL PHARMACIST

- Industrial Pharmacist – profile of competences

  - knowledge competences

  - scientific competences

  - intellectual competences

  - cooperation and communication comptences

  - societal competences

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CURRENT VIEW ON THE INDUSTRIAL PHARMACIST

- Industrial Pharmacist – Role as Qualified Person
  - Control and responsibility for medicinal products manufactured in Belgium according to MA
  - Full qualitative and quantitative analysis of at least all Active Pharmaceutical Ingredients as well as all tests and controls to guarantee the quality of the imported products according to MA
  - To be registered at the list of QP's at the FAMPH

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CURRENT VIEW ON THE INDUSTRIAL PHARMACIST

- In Hospital Environment
  - (Academic) Hospitals :
    - Procedures according to MIA with respect of GMP regulation under control and responsibility of a QP, including PhVig
    - Circular letter FAMPH nr 596
  - For IMP
    - 2-step approach
    - Sponsor according to CTA
    - Hospital release by QP
  - For IIS
    - Same procedure in Academic hospitals
    - Circular letter FAMPH nr 596
- Special attention
  - ATMP
  - Cells and tissues (e.g. Tissue graft in burns unit)
  - RD 31/5/1885 – PICS
  - GMP regulation for MA products – for IMP

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CURRENT VIEW ON THE INDUSTRIAL PHARMACIST

THANK YOU

FOR YOUR ATTENTION