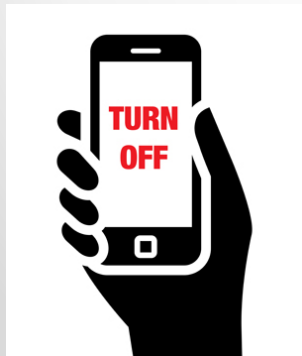


# Seminar KB78 – AR78



20 February 2017  
Hotel Van der Valck  
Diegem



- **U**nion des **P**harmaciens de l'**I**ndustrie **P**harmaceutique
- **V**ereniging van **A**pothekers van de **P**harmaceutische **I**ndustrie
- Founded in 1953
  - From an association of "Industry Pharmacists" (QP's)
  - To an association of Pharmacists working in the Life Sciences Industries
- Royal Association since Sep 2016
- Member of the EIPG: European Industrial Pharmacist Group
  - *E.I.P.G. is a European association representing the national, professional organizations of pharmacists employed in the pharmaceutical or allied industries of the Member States of the European Union*



- Very active association
- **P**harmacist = **P**rofessional
- Our Activities and Goals:
  - Train - Inform
  - Network – Socialize
  - Bridge with
    - The industry
    - The Belgian authorities
    - The European level (EIPG – EU)
    - Our sister associations (pharmacists, industry)

# Revision of Royal Decree n°78

Did you know about this ?



# Revision of AR78 / KB 78

## Why this topic ?

- 10 Aug 2016: Information meeting with the Federal Public Service (FPS) Health, Food Chain Safety and Environment
  - Service Public Fédéral (SPF) Santé Publique, Sécurité de la Chaine Alimentaire et Environnement
  - Federale Overheidsdienst (FOD) Volksgezondheid, Veiligheid van de Voedselketen en leefmilieu

### **Joëlle Pieters**

Chef de Cellule Organes d'avis et Réglementation  
Cellhoofd Adviesorganen en regelgeving

DG Soins de Santé/Gezondheidszorg  
Dienst Gezondheidsberoepen en Beroepsuitoefening

Place Victor Horta/Victor Hortaplein

### **Jeanne Riqué**

Internship 2nd Master Pharmacy



# Creation of a Council of Pharmacists

- The Minister wants to create a council of pharmacists in which all the professions of pharmacists are represented
    - Assist in obtaining credentials, proficiency profiles, determine the practice of professions
    - When these are multidisciplinary, provide opportunities to exchange information between them
    - Give advise on request of the cabinet
  - The minister would like to create this council without waiting for the new legislation
- *UPIP-VAPI could bridge between the pharmacists of the industry and the ministry*

28 Sep 2016



Minister van Sociale Zaken en Volksgezondheid

MAGGIE DE BLOCK

# Startconferentie Hervorming KB nr. 78

28 september 2016

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# Conférence de lancement Réforme de l'AR n° 78

28 septembre 2016

# Revision of Royal Decree n°78

## Impact for Pharmacists and the Industry



### So why this topic ?

- Because UPIP–VAPI is involved → Opportunity to bridge
- Because it is about healthcare professionals
- Because it seems there are still many questions relating to pharmacists:
  - *What is the impact on those working in the industry...?*
  - *Does this have an impact on the Qualified Persons ?*
  - ...
- Because it is happening soon...





# SPEAKERS



# The different stakeholders

- The minister of Social Affairs & Public Health
  - The cabinet of the minister (beleidscellen, cellules stratégiques)
  - It's administration (Secretariat)

- FSP – FPS – FOD



- Founded in 2001
- Authority comes from the ministry of Social Affairs & Public Health and from the ministry of Agriculture
- Health domain: organize the healthcare in Belgium
- Other domains: Food – Animals & Plants - Environment

- Partners (eg Federal Agencies):



- FAGG - AFMPS – FAMPH = competent authority for medicines and health products in Belgium
- FAVV – AFSCA = control of food safety
- FANC = nuclear control
- INAMI - RIZIV
- ...

# Besluitvorming over herziening KB 78

- **Kabinet minister De Block:** strategische beleidskeuzen en vertalen in een voorontwerp van wet – overleg in ministerraad
- **Raad van State:** advies over het voorontwerp
- **Kabinet en FOD Volksgezondheid:** vaststellen van definitieve wetsontwerp
- Bespreking in bevoegde **Kamercommissie**; verslag van de bespreking en goedkeuring ervan
- Vervolgens naar de **Kamer van Volksvertegenwoordigers**
- Publicatie in het **Belgisch Staatsblad**; in werking treding van wet
- Eventueel: procedure voor het **Grondwettelijk Hof** (bevoegdheidsoverschrijding; schending gelijkheidsbeginsel)



*“The new legal framework for healthcare professionals in Belgium :  
Revision of Royal Decree n°78 - Impact on the Industry and Pharmacists”*

14h45: Introduction by UPIP-VAPI:

**Frank Peeters**

*President UPIP-VAPI*

15h00: The view from the government:

**Maggie de Block**

*Public Health and Social Affairs Federal Minister*

15h30: The legal aspects:

**Herman Nys**

*Emeritus Professor Medical Law, K.U.Leuven*

15h50: The view from the industry (Manufacturing and Distribution):

**Johan Van Calster**

*Clivan bvba, Policy and Government Affairs Office  
for Medicinal Products*

16h15: Coffee break

16h30: The view from the pharmacist and the patient:

**Jan Depoorter**

*Secretary General at APB (Community Pharmacists)*

**Thomas De Rijdt**

*Vice President ABPH-BVZA (Hospital Pharmacists)*

17h15: **Questions & Discussion**

17h45: Afternoon closing

18h00: Networking & Cocktail Reception



# Maggie De Block

## Arts

- Stagemeeester voor artsen in opleiding VUB
- Erkend huisarts 1991
- Dr Genees- Heel en Verloskunde VUB 1988 (Huisarts)

## Politiek

- 2014 - ... Minister van Sociale Zaken en Volksgezondheid
- 2014 Minister van Justitie
- 2012 Ondervoorzitter VLD
- 2011 - 2014 Staatssecretaris voor Asiel en Migratie, Maatschappelijke Integratie en Armoedebestrijding
- Verschillende functies in de Kamer:
  - Voorzitter, ondervoorzitter, vast en plaatsvervangend lid in verscheidene commissies:
    - 2010-2011 Voorzitter commissie Infrastructuur
    - Sociale zaken, Emancipatie...
  - 2003-2007 Secretaris Kamer Volksvertegenwoordigers
- 1999-2011 Federaal volksvertegenwoordiger BHV



# Herman Nys

## Studies Rechten - KUL

- Emeritus Gewoon Hoogleraar Medisch Recht aan de faculteiten Geneeskunde en Rechtsgeleerdheid
- Specialisatie medisch recht aan buitenlandse universiteiten
- 1980 Doctor in de rechten
- 1974 Licentiaat in de rechten

## Gerelateerde Functies

- Voorzitter AZ Nikolaas en van LUCAS (kennis centrum voor Zorgonderzoek en Consultancy)
- Sinds 2011 adviseur Bio-ethiek van de voorzitter van de Europese Commissie
- Tot 2015 Directeur van het Centrum voor Biomedische Ethiek en Recht



# Johan Van Calster

## The “early” years

- 2003 - 2007 Director-General for Medicinal Products at the Federal Public Service for Public Health
- 2003 – 2006 Member of Management Board EMEA and Heads of Agencies EU
- 1999 – 2003 Chair PPTA Belgium
- 1988 - 2003 Managing Director Biotest Seralc Benelux (Biotest AG)
- 1986 -1988 General Manager KAVA
- 1984 - 1986 Manager Oncology line & Regulatory Affairs Manager of Farmitalia Carco Erba Benelux
- 1980 -1984 RA & Quality Systems Manager at Baxter Travenol International Services
- 1973 - 1980 Medical science Liaison & Head Sterile Mfg Upjohn Puurs

## Managing Director Clivan bvba

Policy and Government Affairs  
Office for Medicinal Products

- Founded 2007
- Offering professional services for stakeholders in the Health Care environment (Industry, Government and Professional Associations)
- Focus on innovative products, orphan drugs, biopharmaceuticals, blood & plasma products, cell tissues & invasive products
- 2000 – 2014 President Farmaleuven
- 1972 Pharmacist KUL - 1973 Industrial Pharmacist
- 1977 Postgraduate Business Administration KUL
- 1983 Pharmaceutical Engineering UCL

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## Jan Depoorter

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- 2014 - ...      RIZIV – INAMI      Member Insurance Committee
  - 2010 - ...      FAGG - AFMPS      Member Transparency Committee
  - 2006 - ...      APB (Belgian Pharmacist Organisation)      Secretary General 2010- ...  
Member Federal Board 2006 – 2010
  - 2003 - 2010      OFFICINALL (Pharmacist Software Developer)      President
  - 2001 - ...      KOVAG (Pharmacist Organisation East-Flanders)      President 2006-2010  
Member ExCo - Vice-President
  - 1987 - ...      Pharmacy Depoorter      Owner
  - 1981      RUG (University Gent)      Pharmacist
-

# Thomas De Rijdt



## Education & Training

- Doctoral research (KUL)
- 2012 Certificate Lean Management in Hospital Pharmacy (Amelior)
- 2007 Management for Hospital Pharmacists (Vlerick)
- 2006 Certificate Hospital Management (KUL)
- 1994 Hospital Pharmacist (KUL)
- 1993 Pharmacist (KUL)

## Work Experience

- 2016 - ... Head of the Pharmacy Department of the University Hospitals Leuven
- 2014 - ... Member Scientific Committee of the European Association of Hospital Pharmacists
- 2011 - ... President of the Belgian Association of Hospital Pharmacists
- 2009-... Board Member Flemish Association of Hospital Pharmacists
- 2000 - ... FarmaLeuven Post University Education
- 1997 - ... Training of Pharmacists at the KUL
- 1994 - 2016 Assistant-head Pharmacy Department University Hospitals Leuven

Certificates yearly post-university courses:

- VZA (Flemish Association of Hospital Pharmacists)
- FarmaLeuven (KUL Alumni Association)

Thank you !

