# PATIENTS AND EU HEALTH POLICY: SETTING THE SCENE

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# Overview

- **Part 1 – EU main institutions and where EPF fits in the structure**
- **Part 2 – EU legislative framework**
- **Part 3 – some examples of patient advocacy**

# EU main institutions

European Advocacy Goups

**European Commission**

**28 Commissioners**

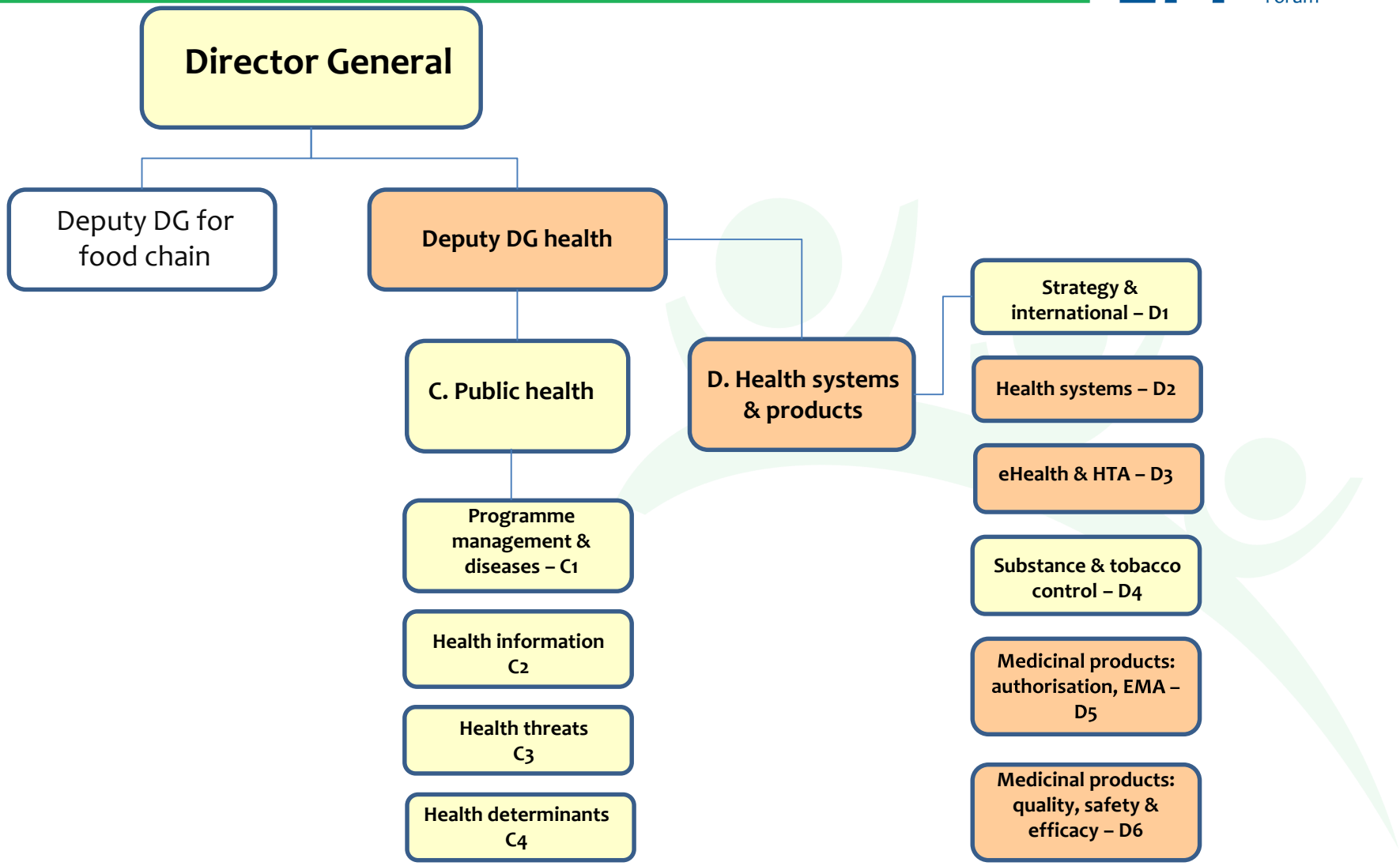
**European Parliament**

**751 MEPs**

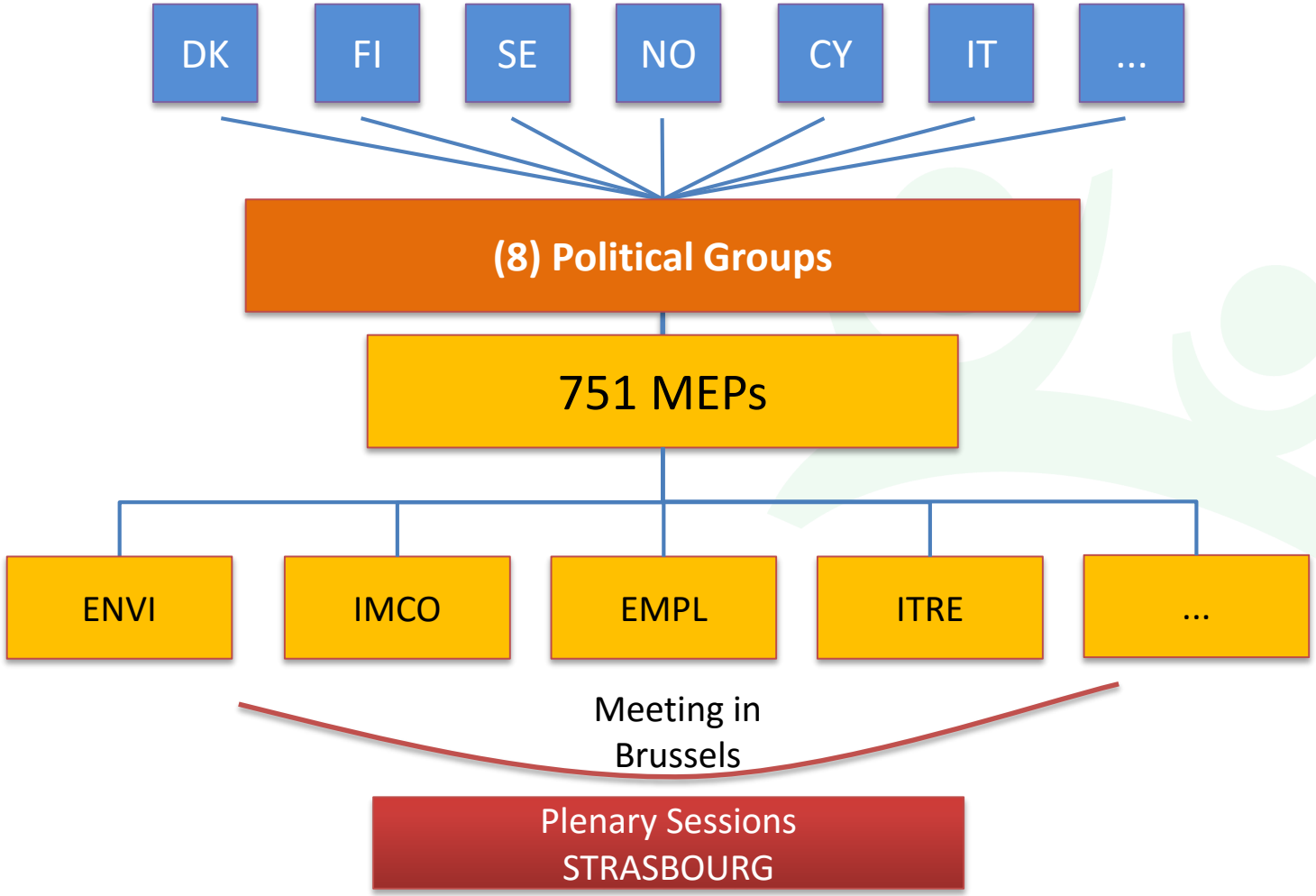
**Council of the EU**

**28 Member States**

# DG SANTE – key units



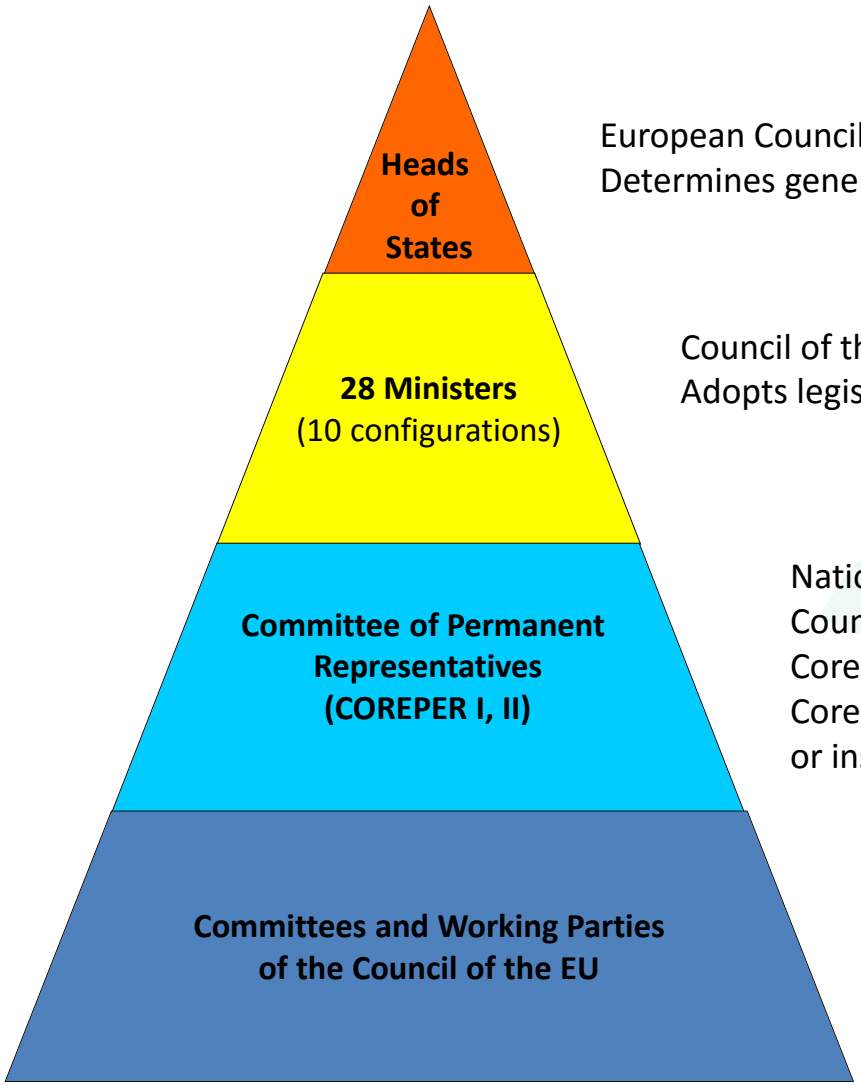
# European Parliament




**Political groups**

- Group of the European People's Party (Christian Democrats)
- Group of the Progressive Alliance of Socialists and Democrats in the European Parliament
- European Conservatives and Reformists
- Alliance of Liberals and Democrats for Europe
- European United Left - Nordic Green Left
- The Greens/European Free Alliance
- Europe of Freedom and Direct Democracy Group
- Europe of Nations and Freedom

# The EU Council




European Council – Heads of state + President EC
Determines general political directions of EU

Council of the European Union – Ministers
Adopts legislative and non-legislative proposals

National representations – prepares work and tasks for the Council of Ministers
Coreper I – deputy permanent reps, technical matters
Coreper II – ambassadors, political, commercial, economic or institutional matters

Expert level – articulation of interests and demands (positions) of Member States

# The EU Presidency (of the Council)

- Rotates every 6 months
- 18 months joint programmes (since 2007) – each “trio” has common agenda
- Administrative and political role (organise work of the Council + deal with political situation, leads policy dossiers in Council)
- Current & upcoming:
  - 2015: Latvia / Luxembourg
  - 2016: Netherlands / Slovakia
  - 2017: Malta / United Kingdom

# Part 2

# EU legislative framework

# EU Competences in Health

1

**Article 168 TFEU Limited Competence**

- Responsibility for organisation of health systems and delivery of healthcare is with the Member States
- Principles of subsidiarity & proportionality
- Union action shall complement national policies

2

**Binding legislation (regulations & directives) to harmonise MS laws in some areas defined in Art. 168**

3

**Health Programme since 2003**

# EU Competences in Health

- In most areas, including public health, **ordinary legislative procedure** used (formerly “co-decision”)
- European Parliament and Council – co-legislators
  - Commission initiates: a proposal
  - Proposal considered in EP committee –> report
  - Adopted in plenary (first reading)
  - Council position prepared in parallel
  - Often second reading and informal negotiations (“trilogue”) between EP, Council and Com → agreement on final legislation
  - Sometimes no agreement in Council (“Information directive”) or it takes a long time (cross-border healthcare)

# Non-legislative collaboration

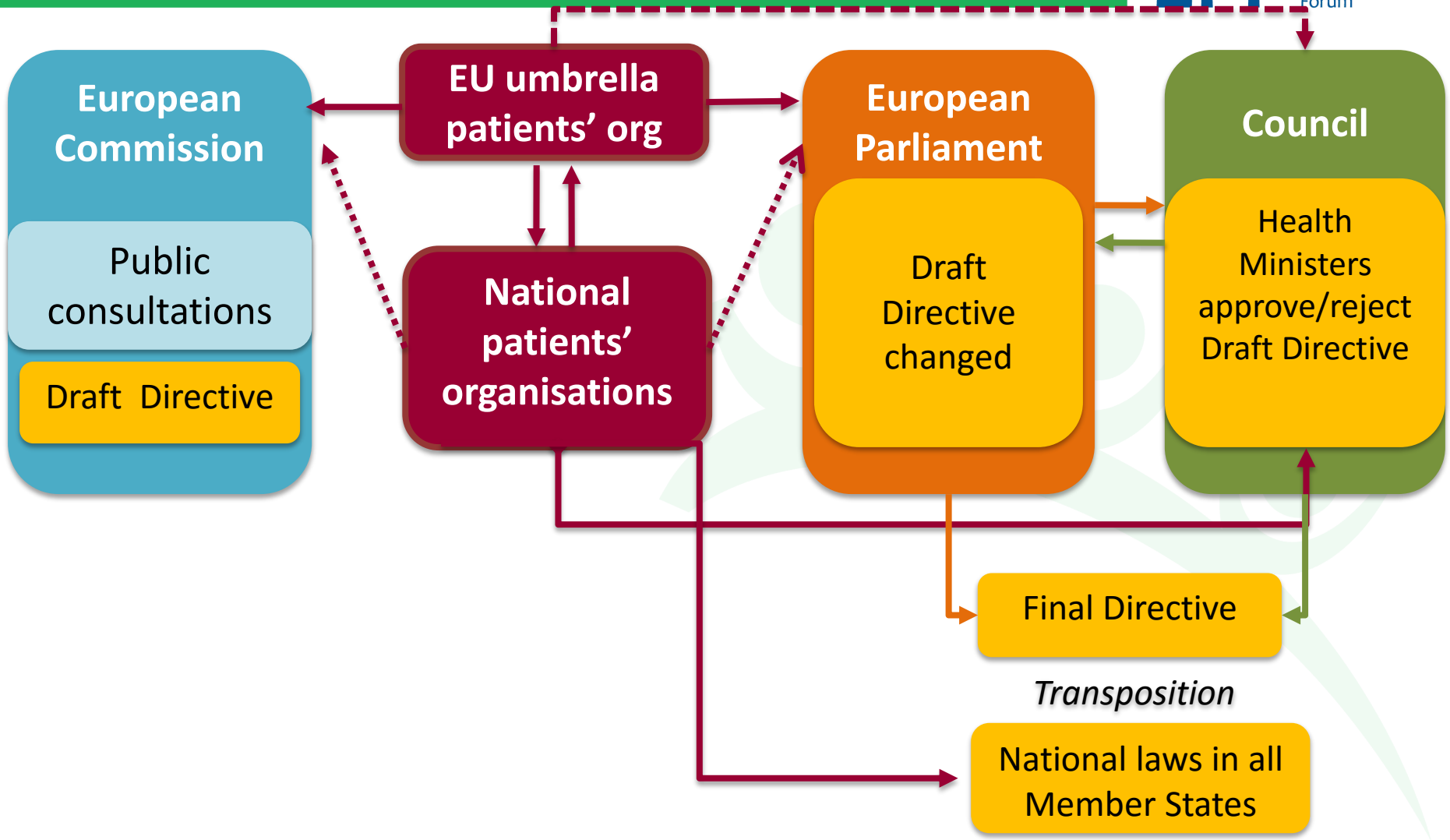
Many forums for stakeholders:

- EU Health Policy Forum
- EC Expert Groups – patient safety, health workforce…
- Initiatives, e.g. “Corporate responsibility in the field of pharmaceuticals” (2010-2012)
- European Innovation Partnership Active & Healthy Ageing (2011-- )
- EU-funded projects, joint actions, tenders – e.g. ChRODIS (chronic disease), PASQ, tender on patient empowerment, self-care…

# Part 3

# Examples of patient advocacy

# Our place in the EU legislative process



# Example 1 – CBHC Directive

## How did we engage our members?

**Consultation** during the legislative process

**Guidance for POs**+ Template **Recommendations** to send to ministries

**Regional conferences** to raise awareness + define the role of POs in ensuring the directive is well implemented

An informal network of **patient leaders on CBHC** across Europe:
for peer support and to report on how it is working locally

# Example 1 – CBHC Directive

EPF European Patients Forum

**SOME OF THE KEY BENEFITS FOR PATIENTS ARE:**

- Recognition for the first time in EU law that patients have a right to cross-border healthcare and are entitled to be reimbursed for it;
- Right to information on cross-border healthcare, and the creation of National Contact Points in each Member State to provide this;
- Right of patients to obtain a copy of their medical record and to get appropriate medical follow-up in the home country;
- Recognition of prescriptions made abroad ;
- Transparency on the quality and safety standards for healthcare that apply in each Member State;
- Legal basis for European co-operation on eHealth and Health Technology Assessment;
- Better cooperation between Member States in rare diseases, including establishing a legal basis for European Reference Networks and centres of excellence.

"Upfront payment is a barrier to equitable access"

"We have a lot of work to do in terms of basic information to patients about their rights"

"The Directive has highlighted that our countries are not as similar as we would like to think: for example, we have been talking about quality and safety standards as if every Member State has them…"

**Key role for Patient Organisations to unlock the potential of this Directive!**

# Example 2: Clinical Trials legislation

2009: EC impact assessment on CTD (EC)

2011: EC consultation on revision of CTD (EC, EP)

2012: Legislative proposal published on 17/7 (EC, EP, Council)

2012-2014: Legislative process in EP, Council – EPF letters

- 7 June 2013: Willmott report
- 20 Dec 2013: COREPER agrees after 4 trilogies
- 22 Jan 2014: ENVI vote
- 10 Mar 2014: Plenary vote
- 27 May 2014: Regulation (EC) 536/2014 published in EU OJ

2016/17: Date of foreseen adoption (EC, MS, EMA)

→ Implementation in Member States

→ Implementation by EMA

→ Engagement of EPF members & disease specific groups

# Example 2: Clinical Trials legislation

Same fundamental positions since 2009:

- Meaningful patient involvement
- Access to quality information and meaningful informed consent
- Transparency of results of trials
- Access to treatments

- Important provisions adopted, e.g.
  - Transparency
  - informed consent specifics
- …but also gaps and uncertainties:
  - No guidelines for information to patients/informed consent
  - Patient involvement in ethics committees
- Lay summary: EPF position → development of EU guideline


"I'm here about the details."

# Example: Patient Safety

EPF European Patients Forum

## EC Patient Safety & Quality Working Group

- Communication (2008) and Recommendation (2009)
- Reflection paper on quality

Council of the European Union

## Advocacy:

- Directive on patients' rights in cross-border healthcare
- Pharmacovigilance, Falsified medicines
- Self-care, antimicrobial resistance….
- Patient empowerment
- Council conclusions 2014

EUNetPaS European Union Network for Patient Safety

PaSQ European Union Network for Patient Safety and Quality of Care

## EU Projects on patient safety

- EUNetPas (2008-2011), Joint Action PaSQ (2012-2015)

***Building partnerships and collaboration*** **with WHO, health professionals, other stakeholders**

# Council Recommendation (2009)

"**2. Empower and inform citizens and patients by:**

- (a) **involving** patient organisations and representatives in the development of policies and programmes on patient safety at all appropriate levels;

  (b) **disseminating information** to patients on:

  (i) patient safety standards which are in place;

  (ii) risk, safety measures which are in place to reduce or prevent errors and harm, including best practices, and the right to informed consent to treatment, to facilitate patient choice and decision-making;

  (iii) complaints procedures and available remedies and redress and the terms and conditions applicable;

(c) considering the possibilities of development of **core competencies** in patient safety namely, the core knowledge, attitudes and skills required to achieve safer care, for patients."

# Complementary levels of action!

## European POs

- Closer to European decision-makers (better access to the European Commission, European Parliament's Committees)
- In a better place to monitor the legislation at EU level
- Have a better "overview", able to compare situations and transfer best practices whenever possible

**Influence**

**Knowledge**

## National Alliances

- Closer to national decision-makers (including Council of the EU)
- Have a greater influence on MEPs from their country (they are voters!)
- Know about national-specific situations, realities
- Know about national legislation
- Closer to patients

# Conclusions

1. EU competences in health are limited but being “stretched”
2. EU legislation has an impact on policies in Member States
3. Patient organisations can play a role in the EU decision-making process
4. This role is different according to the nature of the PO (EU vs. national)
5. Dialogue and exchange of information are the KEY to complementarity actions

# THANK YOU FOR YOUR ATTENTION!

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"A STRONG PATIENTS' VOICE TO DRIVE BETTER HEALTH IN EUROPE"

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