

Erasmus  
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# EU global health law

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# Introduction: EU global health law

- Occasion: globalisation and global health threats
- National and European responsibilities
- EU as a global actor in health
- Conceptualising EU global health law: Health law; International or global law; European law
- External dimension of EU law in health issues

# EU GHL: the quest for a legal framework

- Communication 'The EU role in Global Health' COM(2010)128 final
- Several pillars:
  - International trade
  - Professional mobility/migration
  - Global health security
  - Development aid
  - External relations and health
  - EU-WHO relationship
  - CSR

# EU GHL: External trade and global health

- Common commercial policy (CCP), Art. 207 TFEU
- Updated proposals: TTIP; CETA; ...
- Relevance to health (medicinal products, services, IPRs, etc.)
- Including public health, and patent-related flexibilities
- New-generation EU free trade agreements: risks of unilateral trade pressure (EU/Mercosur free trade agreement, draft text)
- Association Agreements (Art. 217 TFEU): change of focus & compliance with EU legislation, rules and standards

# EU GHL: Migration

- ILO: Global workforce mobility of health professionals unequally devided
- EC: programme for action to tackle the critical shortage of health workers in developing countries (2005), e.g. *internal* EU action; ethical recruitment clause under the “Blue Card Directive”
- Effectiveness global immigration policy actions?

# EU Health Law and external relations

- Communicable diseases: EU-neighbouring countries-WHO 'early warning and response network'
- Medicines: international convergence of regulatory requirements, sharing of information and addressing common challenges:
  - marketing authorisation and good clinical practice (GMP), inspection findings – preventing 'clinical trials dumping' & incorporating EU 'ethical equivalence standards'
  - mutual recognition agreements (MRAs) with 3<sup>rd</sup> countries (conformity assessment of medicinal products) (EMA-FDA-TGA)
- 'foster international collaboration and information-sharing and to reduce unnecessary duplication' (Art 168 TFEU)

*Ezra*

# EU-WHO relationship

- Increased interaction: WHO Brussel Representation
- Technical/ financial cooperation
- EU Membership?
- ‘Duty of cooperation’ MS and European Commission, art 10 TEC

## EU-WHO relationship (2)

- EU's involvement in WHO decision-making:
  - IHR “give rise to the need for strong Community involvement and action in a coherent and effective way”
  - FCTC 2005
  - Towards a framework convention on global health?



# Global health security

- direct connection between health issues and security concerns (e.g., Ebola, bioterrorist threats)
- ‘to strengthen health preparedness and respond globally to threats of biological, chemical, radio-nuclear terrorism and pandemic influenza’ (GHSI)
- EU level: Health Security Committee (HSC) by Decision 1082/2013/EU
- EWRS and exchange good practice
- ECDC: cooperation with 3<sup>rd</sup> countries which *‘have adopted and apply legislation of equivalent effect to Community legislation’*

# Global health security challenges

- To contribute to global and 3rd countries' national capacities of early prediction, detection and response to global health threats under International Health Regulations 2005
- Proliferation of antimicrobial resistance (AMR) and vaccine shortages may also constitute a public health emergency of international concern
- Health situation of migrants and refugees

# EU and (Big Pharma's) CSR

- Corporate Social Responsibilities (CSR)
  - Strategies and mechanisms for Pharma's CSR (seminar)
  - Monitoring Pharma's CSR efforts (seminar)
- EU legitimacy to act:
  - founded on common values (Art 2); EU CFR
  - “In its relation to the wider world, the Union shall uphold its values ...It shall contribute to eradication of poverty and human rights protection” in line with international HR obligations (respect, *protect* and fulfil) (Art. 3(5) TEU)
  - EU: trade/development policy promoting CSR (207/8 TFEU)
  - EU CSR Communication 2011 based on UN's Business & HR Principles
  - Disclosure non-financial information (Dir 2014/95): improving corporate transparency

# Remaining questions

- Implementing Directive in national law: status?
  - annual monitoring
- What does new reporting mechanism in Europe mean for companies?
- Pharma's *accountability* social issues
- Other EU activities encouraging CSR disclosure

# Conclusions

- Increased involvement EU global health issues
- Health as a multisectoral policy issue
- Extended to EU-WHO-WTO relationship and beyond
- Fear of 'creeping expansion'?