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The EU-Ukraine Association Agreement and its Relevance to Health Care

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Outline

- Occasion
- Content Agreement
- Relevance to the Health Care Sector
- Conclusions

Occasion: EU-Ukraine Association Agreement

- The European Parliament gave its consent to the EU-Ukraine Association agreement, which includes a Deep and Comprehensive Free Trade Agreement (DCFTA), on Tuesday in Strasbourg. At the same time, the Agreement was also ratified by the Ukrainian Parliament in Kiev. The deal will establish a deep political association and economic integration between the EU and Ukraine and provide for mutual free market access.



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Content AA: General

- What is in the Association Agreement?
 - key parts focus on support to core reforms, economic recovery and sector cooperation, including social development and protection, equal rights, consumer protection, and public health
 - values and principles: democracy and the rule of law, respect for human rights, good governance, a market economy and sustainable development
 - Covers about 1200 pages, including Annexes and Protocols
 - Towards gradual EU integration
 - Timeline: 2-10 years

1. European Union Health Law: Public Health

- EU: no competence in health *care*
- Focus on Public Health (Art. 168 TFEU): limited powers "towards improving public health and preventing diseases"
- Complementary role
- Legal competences: standards blood(products), organs, tissues and medicines
- Encourage cooperation between MS and with third countries
- Respecting the Member States' responsibilities for the organisation, financing and delivery of medical care.

2. Indirect effect: Internal Market and Competition law

- Underlying notion: free movement principles
- Free movement and Health care:
 - health professionals
 - patients
 - medicines
- EU Competition law
- Reservations!



a. Mobility of Health Professionals

- Mutual recognition of diplomas (Directive 2005/36/EC)
- Mutual trust
- Minimum standards of professional qualifications
- Challenges:
 - Disciplinary misconduct and exchange of information
 - Introduction revalidation mechanisms
 - Third country diplomas
- Right to Establish and Public policy/health restrictions: EU Court Justice case law



b. Patient Mobility

- Patient Mobility Directive (Directive 2012/24/EU)
- Prior to Directive: reimbursement health care restricted to 'home Member State'
- Cross-border health care: Prior authorization (PA) needed
- EUCJ extended right to cross-border health care (out-patient care); PA: justified in case of *in*-patient care and highly expensive out-patient treatments

Current and Future Challenges PM:

- Demand for Clarity:
 - Differences in health care services covered social security
 - Differences in tariffs
 - Differences in quality
 - Differences in professional ethics
- New issues: eHealth and HTA
- Contractual arrangements planned care/Bilateral agreements in border regions



c. Free movement of Medicines

- Thalidomide drama
- Pharmaceutical strategy: towards an internal pharmaceutical market
- Scope: entire pharmaceutical chain (R&D, Clinical Trials, Patents, Registration, Production and Distribution, Packaging and Labelling, Advertising)
- Excluded: Price-setting and reimbursement medicines

Challenges

- Outsourcing and offshoring clinical trials
- No harmonized rules pharmacies (ownership)
- Internet sale
- Counterfeit medicines
- Direct to consumer advertising
- Rare diseases and Orphan medicines
- Classification Medical Devices and Safety rules (PIP crisis)

3. European Competition Law and Health Care

- Aim: restore free competition (cartel, abuse dominant position)
- Applicable to health care?
- Examples: Pharmaceutical companies
 - dual pricing system (GSK)
 - supply quota
- Challenges:
 - Pharmaceutical sector inquiry (blocking genetics market entree)
 - Parallel trade of medicines

Conclusions

- EU-Ukraine AA: Towards gradual integration
- Health Impact and concerns:
 - Collaboration border crossing health threats (e.g., counterfeits, pandemic diseases)
 - Cross-border health care
 - (Inter)national 'brain drain' health professionals
 - Future medicines (pharmacogenetics, nanomedicines)
 - Equal access to health care & market competition
- Health lawyers: new focus

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