Erasmus School of Law

EU Pharmaceutical law

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Outline

- EU Pharmaceutical law: regulating the pharmaceutical chain
- What is a medicine?
- Clinical Trials
- Marketing Authorization
- Distribution of medicines
- Information and Advertising
- Recent developments & Conclusions

EU Pharmaceutical law: Regulating the pharmaceutical chain

- Thalidomide drama
- Pharmaceutical strategy (Directive 65/65/EEC)
- From R&D towards using medicines: R&D, clinical trials, patents, registration, distribution, wholesale, packaging and labelling, advertising, and privacy

What is a medicinal product?

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What is a medical product?

- Definition: Directive 2001/83/EC, art.1(2)
- EUCJ case law: case-by-case approach
- Differences in classification
- Relevance: placing on the market
- Market authorization

R&D: CT Directive 2001/20/EC, repealed by Reg. 536/2014/EU

- Rationale CTs
- Ethics Committee: pre-trials approval
- Good clinical practices (2005/28/EC)
- Declaration of Helsinki
- Role of Sponsor
- EU Portal (EUdraCT: trial identification number and Transparency)
- Notification adverse reactions
- New regulation: more uniform approval process

Clinical trial disaster in France: One of Them Brain-Dead

- Biotrial was testing a compound called BIA 10-2474, developed by Portuguese pharma company Bial as a candidate drug for a range of diseases. The study started in July 2015, and initial administrations of the drug produced no severe side effects; things went wrong in a group of eight people who entered the study on 6 January and received multiple, high doses. Six of them were scheduled to receive 10 daily doses of BIA 10-2474, two others a daily placebo. On 10 January, a subject identified as "volunteer 2508" complained of headaches and blurry vision; he was taken to the hospital in the early evening and stayed there overnight

Obtaining a Marketing Authorization (MA)

- Rules on MA:

  - Directive 2001/83/EC
  - Regulation 726/2004/EC

- Art. 6: MA required to place a medicinal product on the market, UNLESS..
  - Compassionate use supply

- Renewal of MA

- Refusal of MA

MA procedures

- National procedure (2001/83/EC):
  - application national authority
  - procedure governed by national law
  - first step towards MR procedure

- Mutual recognition/decentralised procedure:
  - Application to reference member state (RMS)
  - Based on trust
  - Grounds for refusing to recognise RMS approval
  - EMA commission referral for arbitration

- Centralised procedure (Reg. 726/2004)
  - high-tech med. products
  - EMA application

Orphan Drug Products Regulation (EC) No. 141/2000 (ODR)

- Regulation (EC) No 141/2000 (ODR)
- Purpose
- Defining Orphan Drugs (art 3)
- Community marketing authorisation
- Market exclusivity (art 8)
- ‘breaking’ market exclusivity
- Other incentives
- Criticism ODR

Distribution: Wholesale (Art. 76 Dir. 2001/83)

- International distribution chain
- Wholesale distribution
- Subject of licensing
- Key obligation: GDP compliance

Distribution: Retail sale

- No harmonised rules
- Pharmacies and hospitals
- Diversity ownership laws, free movement, and public health exception (e.g., *Blanco Pérez* case)

Information and Advertising (arts. 86-100, Dir. 2001/83)

- Complete harmonisation
- General/specific conditions advertising
- Latest regulatory proposal: information to patients about prescription medicines (repealed)

Gifts & Inducement: GSK Viox training course at Lighthouse Golf Resort Varna

EU Pharma law: Recent developments

- Tackle counterfeiting life-saving medicines: Directive 2011/62/EU
- Distance selling and European Logo (Art. 85c)

Recent developments (2): shortages of medicines

Press release. Towards improving the availability of medicines in the EU. EU-wide task force publishes work programme 2019/20 and prepares multi-stakeholder workshop (29 August 2018)

Key strategies, Options?

Recent developments (3): Commission unveils EU vaccines strategy (COM(2020) 245 final)

- Adapting EU regulatory framemwork to accelerate the development, manufacturing and deployment of vaccines against COVID-19 (regulatory flexibilities)
- Securing the production of vaccines in the EU (Purchase Agreements)
- Mobilising resources for global solidarity

Recent developments (4): MA Pfizer's vaccin

EMA recommends first COVID-19 vaccine for authorisation in the EU

Share

News 21/12/2020

Comirnaty is now authorised across the EU. This follows the granting of a conditional marketing authorisation by the European Commission on 21 December 2020.

EMA has recommended granting a conditional marketing authorisation for the vaccine Comirnaty, developed by BioNTech and Pfizer, to prevent coronavirus disease 2019 (COVID-19) in people from 16 years of age. EMA's scientific opinion paves the way for the first marketing authorisation of a COVID-19 vaccine in the EU by the European Commission, with all the safeguards, controls and obligations this entails.

EMA's human medicines committee (CHMP) has completed its rigorous evaluation of Comirnaty, concluding by consensus that sufficiently robust data on the quality, safety and efficacy of the vaccine are now available to recommend a formal conditional marketing authorisation. This will provide a controlled and robust framework to underpin EU-wide vaccination campaigns and protect EU citizens.

Conclusions

- Pharmaceuticals highly regulated field
- Internal market, public health, human rights driven
- Incomplete area as pricing/reimbursement remains national affair
- Attempts failed so far (updating Transparency Directive)

Discussion

Case study

Outsourcing clinical trials in Burundi. What are the (legal) risks and how does EU law cope with it?