

REGULATION AS AN ENABLER FOR EMERGING INDUSTRIES (A UK-EU PERSPECTIVE)

Connect Research 2009

OECD Conference Centre, Paris, 12-13 November 09

Laure Brévignon-Dodin
ld308@cam.ac.uk



Overview

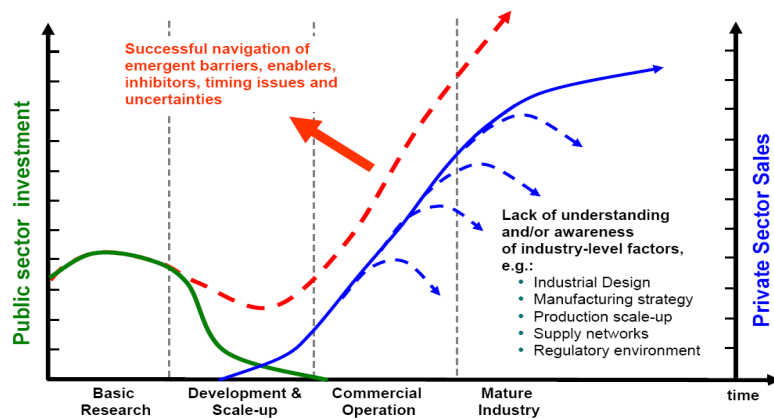
- Context of research
- Case study # 1: regulatory enablers for the regenerative medicine industry
- Case study # 2: regulatory enablers for the photovoltaic industry
- Initial findings and insights

Research project

3

Emerging Industries Programme

- What are the drivers and dynamics which support the emergence of science-based industries?



Research questions

- Is there such a thing as a level of regulatory readiness for emergence?
- Identification of patterns
- Evidence-based project:
 - Case study #1: the regenerative medicine industry
 - Case study #2: the photovoltaic industry

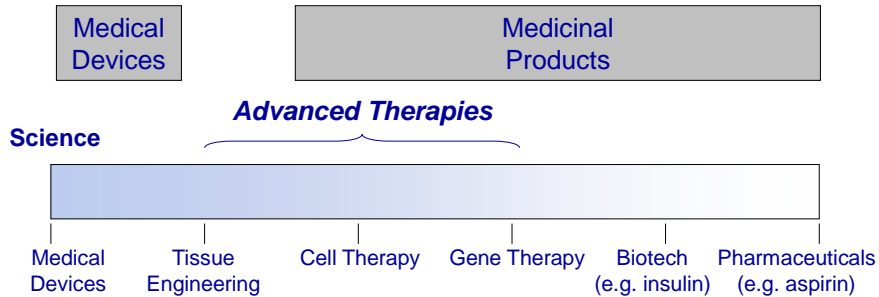
5

Regulatory enablers for the regenerative medicine industry

6

Background

EU Legislation (up to December 2007)



- Lack of a harmonised and tailored regulatory environment
- Divergent national approaches and market fragmentation
- Uneven access to treatments

7

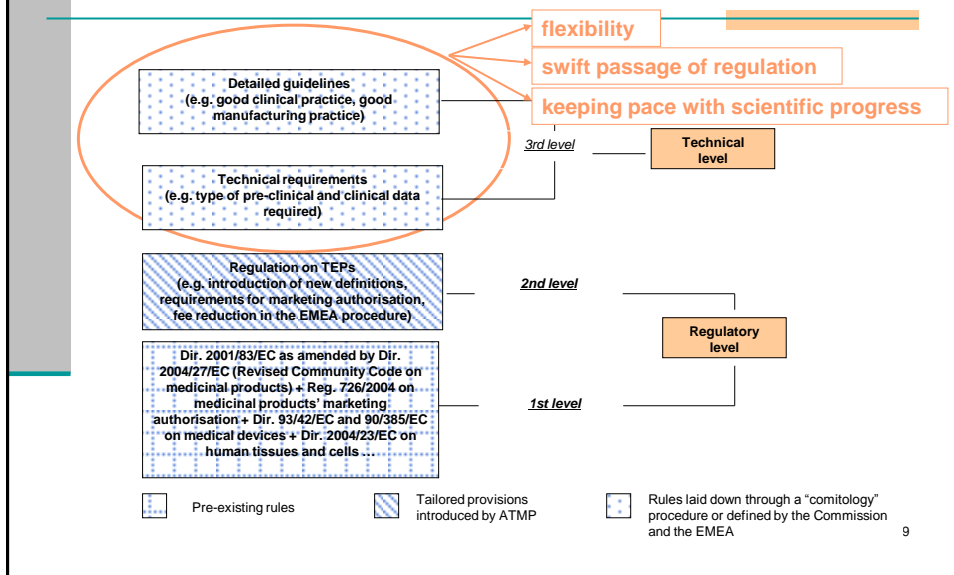
Source: EU Commission (2005), Proposal for a Regulation on Advanced Therapy Medicinal Product, Impact Assessment

Involvement of 3rd parties

- Collaboration regulators/ product developers:
 - UK Code of practice for human derived therapeutic products (2002)
 - Practical guidance for manufacturers
- Consultation of stakeholders in the EU regulatory process:
 - During the preparation phase: public consultations launched by the EU Commission in 2002, 2004 and 2005
 - During the implementation phase: e.g. workshop on cell-based medicinal products in Lisbon (2007)

8

3-tier regulatory strategy



9

Key provisions of the new EU regulation

- Bridging a regulatory gap
 - Harmonised and tailored regulatory requirements
 - EU marketing autorisation
- Pooling of expertise
 - Creation of a Committee for Advanced Therapies



London, 26 June 2009
Doc. Ref. EMEA/CHMP/394741/2009

PRESS RELEASE
European Medicines Agency recommends first marketing authorisation for an advanced therapy medicinal product

The European Medicines Agency has recommended the first marketing authorisation for an advanced therapy medicinal product, following a positive opinion from the Agency's Committee for Advanced Therapies (CAT) and the Committee for Medicinal Products for Human Use (CHMP).

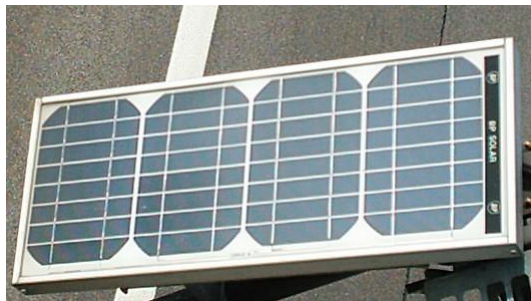
10

Regulatory enablers for the photovoltaic industry

11

Photovoltaic modules

- Generation of electric power by using solar cells to convert energy from the sun into electricity
- PV industry informed by the regulatory experience gained in the semi-conductor industry
- 1st and 2nd generation of solar panels are commercially available



Crystalline-silicon PV
module composed of
individual PV cells

Source: Wikipedia

12

Addressing standards gaps

- Commercialisation issues
 - Inconsistencies in the quality of PV modules and installations commercially available
 - Potentially damaging for the whole sector
- Global Approval Program for PV (PV Gap)
 - Bridging of standards gaps and creation of interim standards
 - PV quality mark to label products

13

Setting a Trade association

- Representative trade association
 - European Photovoltaic Industry Association (EPIA) created in 1984
 - Representative of the overall PV sector in Europe
- Adoption of a proactive stance
 - provision of data
 - commission of studies
- Advisory role towards EU regulators

14

Recast of regulation

- The case of the WEEE Directive
 - Collection and recycling of electrical and electronic equipment
 - Art 17.5 and potential recast of the Directive

L 37/24

EN

Official Journal of the European Union

13.2.2003

DIRECTIVE 2002/96/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 27 January 2003
on waste electrical and electronic equipment (WEEE)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE
EUROPEAN UNION,

(4) The Council in its Resolution of 24 February 1997 on a
Community strategy for waste management (*) insisted
on the need for promoting waste recovery with a view

Public/private partnership

- Industry driven initiative
 - partnership EPIA-PV Cycle
 - voluntary take-back system for end-of-life PV modules
- 30/09/2009: signature of an Environmental Agreement with the EU Commission
- Addressing consumers' concerns
 - « Double green » image of the PV industry

Conclusion

17

Initial findings and insights

- Regulatory readiness for emergence?
 - Content
 - Process
 - Structure
- From traditional command and control regulation to alternative approaches
- What would be a « super » regulatory enabler for emergence?

18

Thanks to ...

EPSRCEngineering and Physical Sciences
Research Council

This work was supported by the **UK Engineering and Physical Sciences Research Council (EPSRC)** and is based on research carried out as part of the **Innovative Manufacturing Research Centre (IMRC)** run by the **Institute for Manufacturing** at the University of Cambridge.



Institute for Manufacturing
Department of Engineering
17 Charles Babbage Road
Cambridge
CB3 0FS, UK

**UNIVERSITY OF
CAMBRIDGE****IfM****Institute for Manufacturing**