EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Test Data Protection

The European Medicines Agency Perspective*

Prof. Vincenzo Salvatore
Head of Legal Service

** The views expressed here in are those of the author and do not necessarily reflect the views of the European Medicines Agency*

A networking Agency

27 EU + 3 EEA-EFTA countries

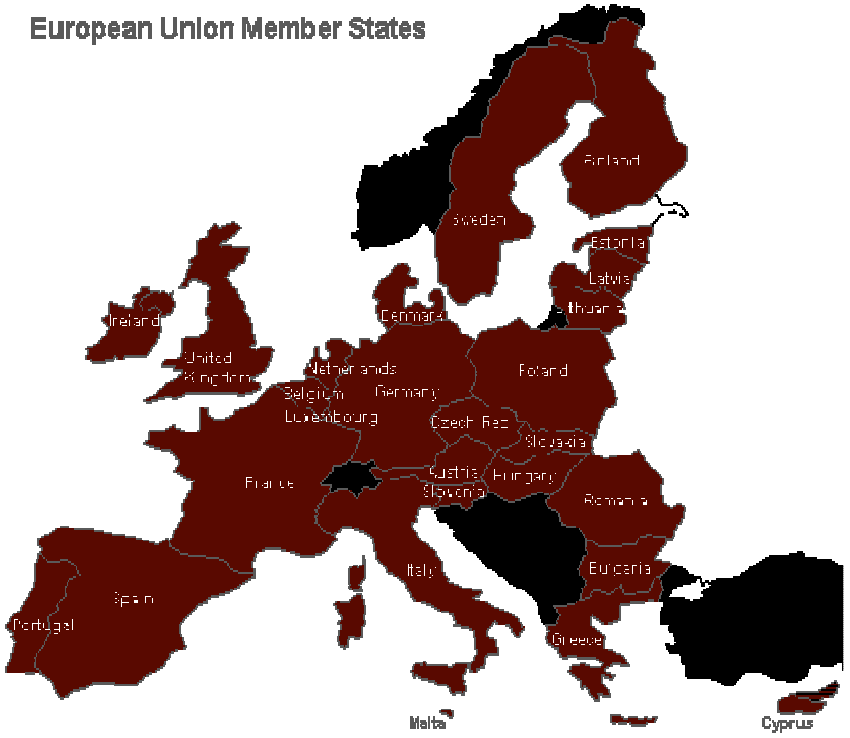
> 40 national competent authorities

1 European Medicines Agency

One system, two routes for approval

- Centralised (European route)
- Mutual recognition + decentralised national routes

One application, one evaluation, one rapid EU-wide authorisation



A MA can never represent a patent infringement

- Administrative act (it's a licence) issued by a public authority
- MA removes an obstacle and entitles the MAH to place the product on the market as it has been considered in compliance with the requirements set by relevant legislation
- It is granted once the benefit/risk *ratio* has proved to be positive further to the assessment of the quality, safety and efficacy of the concerned medicinal product
- MA doesn't empower MAH to infringe third parties' right (*e.g.* IPRs)

Test data protection: the legal framework

- Article 39(3) of the Trade-Related Aspects of IPRs Agreement (TRIPS)

  "*Members, when requiring, as a condition of approving the marketing of pharmaceutical … , the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against* ***unfair commercial use***"

- Article 14(11) of Regulation (EC) No 726/2004

- Article 10(1) of Directive 2001/83/EC, as amended

- Chapter 1 (section 6) NTA, Volume 2A

The "8+2 + 1" formula

Regulatory data protection/exclusivity 8 years

+ 2 years market exclusivity

+ 1 additional year market exclusivity

- if new indication approved during the first 8 years of authorisation

and

- if significant clinical benefit compared to existing therapies

Applicable only for RMPs to MAAs submitted as of 20 November 2005

Data protection

A tool for compensating the innovator of the investment in R/D

Prevent competitors from entering the market

It doesn't affect IPRs as results of PCT and CT are not eligible for patent protection

Data protection is available whether or not the product subject to regulatory approval is protected by patent

Data protection ≠ Patent protection

Patent protection and SPC

Registration of patents at national level

Registration provides a patentee the right to prevent anyone making, using, selling, or importing the invention for 20 years.

+ possibility for "patent extensions" of up to 5 years for pharmaceuticals

providing as much as 25 years of patent life for originator medicines

+ possibility for further patents (eg. new uses, indications, dosages and changes in formulation, colour or markings, etc.)

Intellectual property and access to medicines

IPRs stimulate research and innovation

Can patent deter innovation? (Bolar *v* Roche case)

Before the Hatch Waxman Act (1984) the experimental use of a medicinal product for the purpose of obtaining regulatory approval of a patented medicinal product was considered an infringement if such use occurred before the expiry of the patent expiry date

The EU Bolar clause

Where to strike the right balance between (conflicting) interests of:

- Brand leader (commercial – Patent protection)
- Generic industry (commercial – Rules of competition)
- Improve access to innovative medicines (Public health policy)

"Conducting the necessary tests and trials with a view to application of the paragraphs 1,2, 3 and 4 and the consequential practical requirements shall not be regarded as contrary to patent related rights or to supplementary protection certificates for those medicinal products" (Art. 10.6 Directive 2001/83/EC)

Positive impact of the EU Bolar provision

- Avoid duplication of unnecessary (and unethical) Clinical Trials
- Foster competition for generics and biosimilars
- Increase availability of innovative medicines on the market

Do we need test data protection?

What if not?

- Remove a drive for investing in R/D of new active substances
- Lack of provision of alternative sources of compensation of the costs incurred for producing the data
- Higher prices (and public health related costs)
- There may be no compensation at all in case of not patented medicinal products or compulsory licence

Test data protection and CCI

- Different magnitude:
  - CCI embraces more than RDP
- Different life cycle:
  - CCI may vary depending on different steps of regulatory procedure
  - Data protection is fixed in time
- CCI may be protected for ever
- Overriding public health interest may be relied upon as an exception to sacrifice CCI (at any time) but not to sacrifice test data protection

The openness challenge

Increased demand for transparency

High risk of disputes taking into account different interests involved

No definition of CCI in the EU legal system

Different notions from different stakeholders

Need to minimise the risk of information shopping and ensure consistency across Europe

Moving forward: new transparency initiative, new access to documents policy

Thank you!

For further information on the Agency activities

www.ema.europa.eu

vincenzo.salvatore@ema.europa.eu