The protection of test data for pharmaceuticals

Karin Timmermans

WHO

The author is a staff member of the World Health Organization. The author alone is responsible for the views expressed in this presentation and they do not necessarily represent the decisions, policy or views of the World Health Organization.

Symposium on Intellectual Property and Life Sciences Regulation

Geneva
16 Nov. 2007

Outline:

- what is data exclusivity?
- does TRIPS require it?
- recent developments
- policy options

Medicines are subject to two sets of rules:

Intellectual property rights

The right to exclude

But not the right to market or to use

Registration requirements

Authorization to put a medicine on the market

Medicines are among the most regulated products on the market

There are good reasons for the extensive regulatory intervention in pharmaceutical markets

Reasons for regulating medicines:

- Market failure, especially information imbalance between manufacturers, prescribers and consumers;
- Ineffective or dangerous medicines may undermine confidence in the entire health care system;
- Money spent on ineffective or dangerous medicines is wasted;
- Misuse of certain medicines (such as antibiotics) can have serious implications for the individual and for public health.

Registration objective:

To protect public health by ensuring the quality safety and efficacy of medicines available on the market

Registration criteria:

Quality – Safety – Efficacy

Quality control
(testing samples)

Quality assurance:
(procedures, e.g. GMP)

Registration criteria:

Quality – Safety – Efficacy

Preclinical and clinical trials (original)

or

Bioequivalence (generics)

Data exclusivity:

During the data exclusivity period,

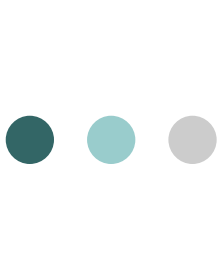
Authorities may not rely on those data to register generic equivalents.

As long as data exclusivity lasts:

Generic manufacturers will have to submit their own data to prove safety and efficacy

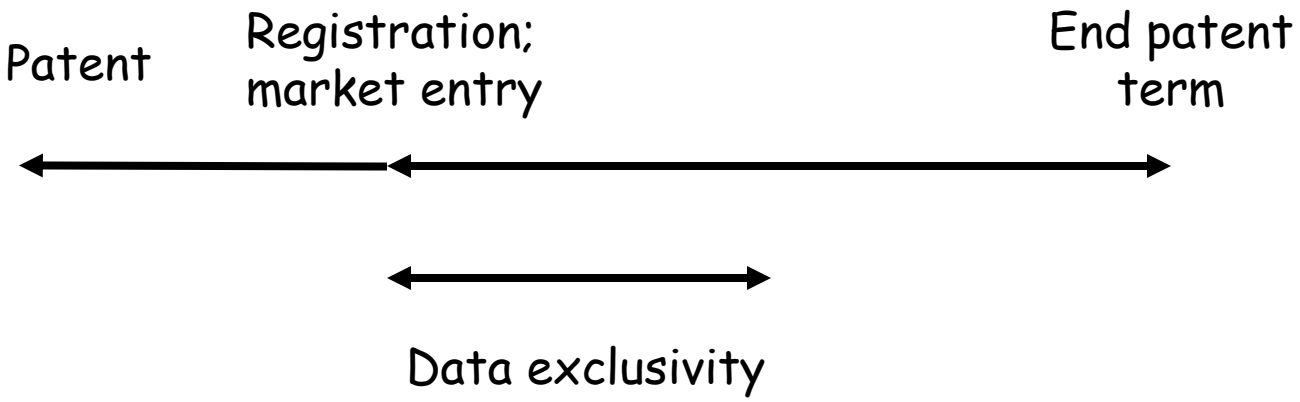
=> They will have to repeat the clinical trials and other tests

Alternatively, they can only enter the market after expiry of the data exclusivity period

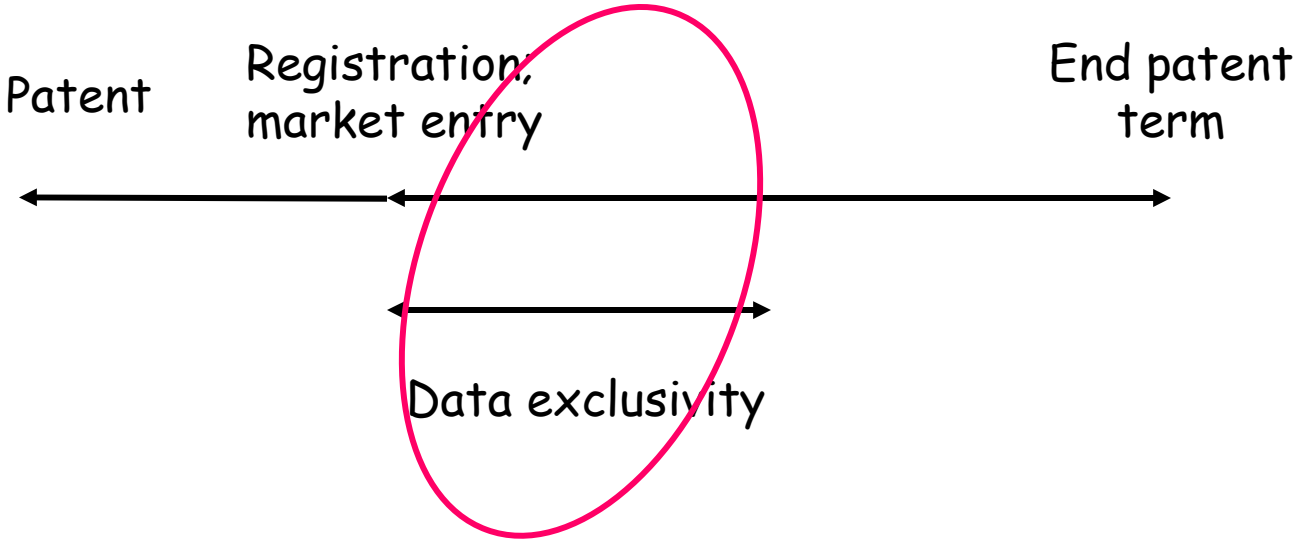


When is data exclusivity important?

"Standard" situation (NCE):



May interfere with TRIPS flexibilities:



?

During this period, generics may not be able to enter the market, even when a CL has been issued

Second indication:

If data exclusivity is allowed for 2nd or subsequent indications:

⇒ possible additional delay for generic market entry

⇒ may encourage research for new indications

When there is no patent:

- When the drug is not new
- No patent law, or patents not granted for pharmaceuticals
- No patent application

TRIPS - Article 39.3:

Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

TRIPS - Article 39.3:

Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

Undisclosed data about New Chemical Entities

should be protected:

- against unfair commercial use
- against disclosure

Thus:

- Publication of such data is not allowed,

  except when necessary to protect the public.

- Authorities are not to share these data (for instance with generic companies).

"Unfair commercial use"

Does the Drug Regulatory Authority actually use the data??

- Often not; the DRA may not even have the data;
- Even if the DRA does use the data, it is not commercial use.

WHO Commission on IP, Innovation and Public Health:

- Article 39.3 does not create property rights, nor a right to prevent others from relying on the data for the marketing approval of the same product by a third party, or from using the data except where unfair (dishonest) commercial practices are involved.

- The TRIPS agreement does not refer to any period of data protection, nor does it refer to data exclusivity.

WHO Commission on IP, Innovation and Public Health:

A public health justification should be required for data protection rules going beyond what is required by the TRIPS agreement.

There is unlikely to be such a justification in markets with a limited ability to pay and little innovative capacity.

Thus, developing countries should not impose restrictions for the use of or reliance on such data in ways that would exclude fair competition or impede the use of flexibilities built into TRIPS.

Data exclusivity and ‘linkage’

- Responsibility for implementation will fall on the health sector (Regulatory Authority),
- Yet the health sector is usually not consulted;
- Developing countries may not have the capacity to implement these provisions;
- Regulatory Authority should focus on ensuring quality, safety and efficacy;
- Policy coherence??

- Demands for data exclusivity (and other “TRIPS-plus” provisions) are made:
  - During WTO accession negotiations;
  - In the context of bilateral/regional free trade agreements (FTAs) with developed countries.

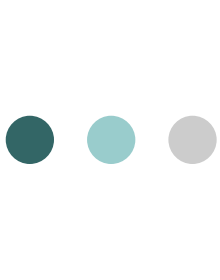
Overview recent US FTAs

	Vietnam	Laos	Chile	Singap.	Australia	Morocco	CAFTA	Bahrein
Exclusivity	V	V	V	V	V	V	V	V
New indications	(v)	(v)		(v)	V	V		V
Incl. foreign registration				V	V	V	V	V
Incl. disclosed data				V		V	(v)	V
Can surpass patent term				V	V			V
“local” definition NCE					V	V	V	V
“waiting period”							V	

- Demands for data exclusivity (and other “TRIPS-plus” provisions) are made:
  - During WTO accession negotiations;
  - In the context of bilateral/regional free trade agreements (FTAs) with developed countries.
- Provisions on data exclusivity have also been found in ‘model laws’.

Options for (developing) countries

- Avoid data exclusivity in WTO accession and FTAs (stick to TRIPS wording)
- Determine the duration of data exclusivity
- Decide the scope of exclusivity:
  - only for NCEs?
  - only for undisclosed data?
  - don't extend it to foreign registration?
- Create national exemption mechanisms
- Consider alternative ways to compensate for the use of the data



Thank you