Intellectual Property Rights in Medicines

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Discussions on pharmaceutical incentives

- due to debate on the sustainability of healthcare systems and pharmaceutical prices.
- connected to different topics of interest, including:
    - Pricing strategies,
    - Innovation,
    - Availability
    - Accessibility.

Incentives

The creation of appropriate incentives is key to driving investment in innovation, particularly for R&D-intensive industries such as those operating in the pharmaceutical sector.

Intellectual property

is among the **pharmaceutical incentives** to innovation, availability, accessibility, along with:

- the SPC framework
- data exclusivity
- market protection
- market exclusivity for orphan MPs
- pediatric patent extension and rewards

Different approaches (USA and Japan – CaChIn); 2001 TRIPs, Doha

Incentives

- positively influence product development and that predictability and certainty play a key role in driving investment in innovation;
- can **contribute to maintaining the attractiveness of the EU as an investment area**:;
- have a positive impact on pharmaceutical R&D and allow the development of innovative products for the benefit of patients.

An investment in a friendly environment can also **contribute to supporting European competitiveness and growth**.

The **unitary patent system** has the potential to foster innovation by offering a patent with a European dimension, more affordable protection and greater legal certainty through the provision of an exclusive specialized jurisdiction

Policies

Policies providing major certainty can allow to **orient private investments towards areas which represent priorities in the Health Sector**, contributing to addressing (unmet) public health needs.

Incentives versus pricing strategies

- product development and innovation
- **pricing strategies** do not seem to be affected, with impacts on sustainability of Health care systems.

Orphan drugs

- unaffordable price for National Health System
- limited negotiation or no power to negotiate
- great pressure from Patients' Association and Media
- not available as not launched in small markets
- centrally authorized sometimes with a very low level of evidence, persisting uncertainties on the efficacy and long-term safety
- a number of succeeding indication(s) after the first registered

In Italy the expenditure for orphan drugs accounts for about 6%

Roles played by different actors

- Academia
- Independent Research
- Company

i.e. Part of the initial research has been already payed by NHS.

Incentives

Paediatric Regulation (protocol assistance, fees reduction, supplementary patent period etc),

It is generally agreed that again incentives can have an impact on innovation, on development of new indications, new dedicated formulations but not on pricing
(eg. Kalydeco, extension to paediatric population)

Incentives are not

- **the only factors that influence pricing strategies, innovation, availability and accessibility**.

There are other elements:

- the number of patients intended to be treated directly connected to the dimension of the Member State,
- the level of education and
- the economic development of the country.

Case

- **Gene therapies** intended to treat **ultra-rare diseases** developed with public-private funding and regularly registered and available for eligible patients in the EU.

- **Treatment of patients with experimental drugs, if an approved product is available, should be avoided**.

- EU Resources for research and development should be addressed towards treatments intended for unmet medical needs.

eg. STRIMVELIS®: EMA authorised product, also assessed by HTA bodies such as AIFA (Italy) and NICE (UK).

Even though such a case does not represent an infringement of intellectual property rights, it certainly exposes patients to medicines for which the benefits and risks have not been assessed and constitutes inappropriate use of resources.

For the **benefit of the European patients**, there is still a need to improve on working together, in order to manage that innovative, high-value and costly medicines will not threaten **the sustainability of National HSs**.

Thank You!