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Pharmaceutical sector enquiry: Preliminary report brings no surprises, Action needed to place public interests first

• Answer to the consultation on the Pharmaceutical sector enquiry - preliminary report ⁽¹⁾ (Addressed to: COMP-SECTOR-PHARMA@ec.europa.eu)

The *International Society of Drug Bulletins* (ISDB) would like to congratulate the DG Competition of the European Commission on holding this enquiry on the situation of competition in the pharmaceutical sector (1,2).

The report is well detailed and informative: it provides an impressive set of data, facts and figures. It provides a solid overview of the situation of competition in the pharmaceutical sector. It also gives citizens the opportunity to understand the financial reasons that lead to delay in generic competition: a decrease of the average price of the blockbuster trade-name drugs when their equivalent generics enter the market.

Moreover, it shows to what extent originator pharmaceutical companies have diverted the patent system to delay both generic competition and innovation from other originator companies.

First of all, ISDB would like to underline the fact that the victims of this condemnable behaviour are the patients, who not only have to pay too high prices for their medicines, but also have delayed access to the drugs they need due to anticompetitive practices from originator companies.

Originator companies strategies - ISDB's proposals for improvement

The life cycle management strategies described in detail in the report come as no surprise. They illustrate what is wrong in the pharmaceutical companies' model, which is based on the massive sale of blockbuster medicines.

The ISDB would like to add a few specific points, making the following proposals to improve the situation:

1- *"measures enhancing product loyalty (including criticising competitor's products)" and "putting into question the efficacy or quality of generic products"*

The sales representatives' job is to increase sales of the brand product they present. Discrediting competitor's and generic products is part of their portfolio (3).

Involvement in disease management initiatives driven by pharmaceutical companies (i.e. patient education programmes, risk management plans, compliance programmes) has been recognized as a new strategy aimed at building patient brand loyalty (4).

The current Commission's proposal on "information" to patients, which opens the door to a disguised form of "direct-to-consumer advertising" by pharmaceutical companies, is very worrying. It will lead to increased brand loyalty if adopted and will further exacerbate the deficiencies in the current system (5).

► **ISDB proposals:**

- Prohibition at EU level, both directly or indirectly, of any communication on prescription medicines to the public by pharmaceutical companies;
- Withdrawal of the Commission's proposal on information to patients.

2- *"reformulation and second-generation launch"* (i.e. "follow-on" and "me-too" products)

Pharmaceutical companies are asking for "incremental progress" rewards, namely the rapid consideration of the slightest evidence likely to enhance a drug's chances of being considered superior to existing alternatives (see the disappointing conclusions of the Pharmaceutical Forum on "relative effectiveness"), which perverts the notion of reward for real innovation.

► **ISDB proposals:**

- Add to the 3 current evaluation criteria (efficacy, safety and quality) when granting a marketing authorisation, a 4th criteria: **real therapeutic advance** in comparison with already existing treatments ("gold standard"), demonstrated by relevant clinical data collected from well-designed comparative clinical trials (6);
- Public health authorities should also set up a public-needs research and development agenda.

3- *"creation of patent clusters (in particular through secondary patents protecting a product)" and "defensive patenting against other originators"*

This unethical behaviour brings light into current research and development difficulties.

► **ISDB proposal:** enforce patent rules in a stricter way, namely as to novelty and inventivity.

4- *"litigation against originator companies; litigation against generic companies"*

This strategy is very costly to patients and society.

► **ISDB proposal:** The originator companies should have to pay back national social insurance systems, when a case is lost (a great majority of opposition cases were won by generics companies according to the report).

5- *"settlements with generic companies"*

These settlements (i.e. payments to generics companies to delay generic entry to the market for some blockbuster drugs) are unfair and costly. They should be forbidden and duly prosecuted. Member States should be encouraged both to simplify the entry of generic medicines to the market as well as promote their use.

► **ISDB proposals** (for point 3 to 5):

- The Commission should set up a permanent body to monitor marketing strategies, invested with the authority to refer cases of malpractice to the courts, and consider the various specific points made above;
- A register of all patents per product as well as their expiration date should be publicly available in order to increase transparency and prevent delays of generic entry to the market;
- In order to encourage generic use, international non proprietary name (INN) prescribing should be made mandatory at EU level. INN prescribing avoids preventable medication errors and their public health consequences (i.e. serious adverse effects leading to hospitalisations).

6- *"interventions at the level of marketing authorities and pricing and reimbursement bodies"*

(i.e. in order to discredit generics; to influence the regulatory authorities and health technology assessment bodies)

Despite their obvious conflicts of interests, pharmaceutical companies want to be involved in the assessment of the products they commercialise (7). Amendments to the draft report on the proposal for a directive on the application of patients' rights in cross-border healthcare propose that pharmaceutical companies be involved in the European network connecting the national authorities or bodies responsible for health technology assessment (8). This is an important component of the industry's strategy to negotiate increasingly higher prices for their products.

► ISDB proposals:

- Strengthen and enforce independence of health authorities and health technology assessment bodies from pharmaceutical companies: Regulatory Agencies should no longer be directly funded by pharmaceutical fees; the so called “scientific advisors” should be carefully monitored to exclude conflict of interests and to avoid that Agencies become a service provider exclusively devoted to pharmaceutical industry and diverted from their evaluation mission and safeguard of public health;
- Improve transparency of research and development expenses as to set up fair prices for reference drugs;
- Generalise reference pricing groups. The principle is that one 'reference drug' is chosen from a group of drugs that are equally effective and safe. The price for the reference drug is covered, but if a more expensive drug is chosen from that group, then patients would have to pay the difference in price. This incentive results in increased use of affordable reference medicines, in detriment of more expensive drugs (9).
- Create or increase mandatory taxes on marketing and promotional expenditures in order to generate funds for independent research.

Comments on the regulatory framework: public health protection provisions should be enforced, not weakened

Some of the facts contained in the report call for concrete actions: higher expenses for marketing (23% of companies' turn over) than for research (only 17 %), very limited basic research, waste of time and energy in meaningless patent disputes, etc.

The analysis of the data accumulated in the report should be pursued, in order to draw the right conclusions about the misbehaviours and the reasons for “less market entry of new originator medicines”.

The ISDB would like to outline specific points on the regulatory framework.

1- Patents. In a highly competitive environment, it is just common sense to consider that originator pharmaceutical companies would do anything to prolong the monopoly life of their drugs. It is an illusion to believe that they would stop this behaviour, if granted prolonged data and/or patent protection.

- See the suggestions above as to rewarding real innovation amounting to therapeutic progress.

2- Marketing authorisations. Accelerated drug approvals put public health at risk, as has been amply demonstrated by the experience of the US Food and Drug Administration (FDA) (10). International harmonisation according to the International Conference on Harmonisation (ICH) standards would amount to adopting a platform of minimal demands.

► ISDB proposals:

- Real therapeutic advance to be adopted as evaluation criteria when considering a marketing authorisation. This would re-orient pharmaceutical research to currently neglected but important areas;
- Enforce existing legislation and stop the multiplication of exemptions to the standard procedure (accelerated authorisation, conditional authorisations) currently being granted without a serious public health rationale (11);
- Reorganise the ICH process to make it participatory, more democratic and transparent (12).

3- Prices and reimbursement. The pharmaceutical industry's pricing strategies are artificial and unjustifiable.

► ISDB proposals:

- Comparative evaluation of therapeutic benefits (relative effectiveness) should be generalised in order to reward real innovation (therapeutic progress) (6);
- Evaluate research and development costs in order to set fair prices;
- Generalise reference pricing schemes in order to comprehensively reward medicines and adopt a coherent pricing policy (9);
- Refuse pharmaceutical companies' participation in health technology assessments (HTA) to avoid the possibility of exerting pressure on HTA bodies.

To conclude

Pharmaceutical companies spend enormous energy and money in their defensive strategies, at the detriment of public health and social security systems' sustainability. These anticompetitive strategies show that some companies have forgotten their main mission: to bring new medicines, with added therapeutic value, to the market.

The ISDB requests the European Commission to seize this opportunity and reconsider its overemphasis on industrial interests when outlining its medicines policy (symptomatically, the Directorate General Enterprise and Industry (DGE) is in charge of legislative proposals in the field of medicines not the DG Health and Consumers (DG Sanco)).

Medicines policy and practices in Europe should be reoriented in patients' interest.

► ISDB proposals:

- The responsibility for medicines policy in the EU should be transferred to the Directorate General for Health and Consumers (DG Sanco);
- The policy of DG Enterprise, to start biased consultation processes with heavy industry involvement and the creation of dubious advisory entities like the Pharmaceutical Forum, should be stopped immediately, and replaced by more transparent and balanced approaches (13).

The International Society of Drug Bulletins

Some references:

- 1- ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf (full report: 426 pages).
- 2- ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/exec_summary_en.pdf (Executive summary: 13 pages).
- 3- Prescrire Editorial Staff "15 years of monitoring and one simple conclusion: don't expect sales representatives to help improve healthcare quality" *Prescrire International* 2006 ; **15** (84) : 154-159. www.prescrire.org/aLaUne/dossierVMbilanEng.php.
- 4- Joint Position of Medicines in Europe Forum, International Society of Drug Bulletins, Health Action International Europe "Health Information - a clear division of roles is needed to protect public health" March 2007: 4 pages. Websites www.prescrire.org or www.isdbweb.org.
- 5- ec.europa.eu/enterprise/pharmaceuticals/pharmacos/pharmpack_12_2008/patients/citizens_summary_info_to_patients.pdf.
- 6- ISDB "Declaration on Therapeutic Advance in the Use of Medicines" Paris 15-16 November 2001. www.isdbweb.org/pag/documents/ISDB-decl-english.pdf: 12 pages.
- 7- Price Waterhouse Coopers "Pharma 2020: the vision: which path will you take?" 2008 : 52 pages.
- 8- "Draft report on the proposal for a directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare" <http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+COMPARL+PE-415.355+01+DOC+PDF+V0//EN&language=EN>
- 9- Aaserud M et coll. "Pharmaceutical policies: effects of reference pricing, other pricing, and purchasing policies" *Cochrane Database of Systematic Reviews* 2006, Issue 2. Art. No.: CD005979. DOI: 10.1002/14651858.CD005979.
- 10- Prescrire Rédaction "AMM prématurées = danger" *Rev Prescrire* 2008 ; **28** (297) : 535.
- 11- Prescrire Rédaction "Dérogations à l'AMM "classique" : accès plus rapide au marché, au détriment de l'évaluation des médicaments" *Rev Prescrire* 2008 ; **28** (299) : 696-701.
- 12- "About ICH – Structure of ICH" www.ich.org/cache/compo/276-254-1.html.
- 13- Joint open letter from 18 organisations "Patient information" by pharmaceutical companies comes up against almost unanimous opposition from civil society" www.isdbweb.org/pag/documents/1.pdf : 6 pages.



ISDB. *International Society of Drug Bulletins* (ISDB), founded in 1986, is a world wide Network of bulletins and journals on drugs and therapeutics that are financially and intellectually independent of pharmaceutical industry. Currently, their members include 57 members in 35 countries around the world. More info: www.isdbweb.org.
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