

Amsterdam, 31st January 2009

This response has been prepared by Health Action International (HAI) Europe. HAI Europe is a non-profit, growing, European network of consumers, public interest NGOs, health care providers, academics, media and individuals with over 25 years experience in representing the voice of civil society, and poor and marginalised people in medicines policy debates.

Our authority rests on our integrity and independence from commercial and political party interests, our research excellence and evidence-based advocacy.

- HAI Europe promotes increased access to essential medicines, the essential medicines concept and the rational use of medicines.
- HAI advocates for greater transparency in all aspects of decision making around pharmaceuticals, for example, by reducing industry secrecy and control over important clinical data.
- HAI promotes the rational use of medicines; that all medicines marketed should meet real medical needs; have therapeutic advantages; be acceptably safe and offer value for money.
- HAI works for better controls on drug promotion and the provision of unbiased and independent information for prescribers and consumers.

Summary

HAI Europe welcomes the preliminary report from DG Competition that has highlighted disturbing trends in the pharmaceutical sector linked to the delay of market access for more affordable generic medicines within the European Union.

The presentation of facts gathered from the ten month investigation confirmed the concerns of many civil society organisations that more affordable generic medicines were being stopped from reaching patients and consumers in Europe. The report's findings indicate that the current incentive system for pharmaceutical companies is deeply flawed. For originator companies, it is more attractive and rewarding to invest in marketing and litigation practices than to put money into research and development. These practices are a reflection of the monopolistic tactics utilised by the originator companies in pharmaceutical industry.

Though recognising the institutional limitations of EU policy making, HAI Europe calls upon the European Commission to take into account the wider context of such activities and to consider how the consequences of these affect other components in the pharmaceutical sector. These practices are complemented and facilitated by many factors. If not adequately addressed as a whole, any attempt to tackle the problems will have limited impact. A response that fails to significantly promote consumers' interests, fails to fulfil the ultimate goal of sound competition policies.

Competition Policy and Patent rules

HAI Europe recommends the strict application of competition policy in the area of pharmaceuticals. Patent rules should be applied more rigorously and the granting of patents should be more stringent. Patents were developed as tools to foster innovation by providing a temporary exemption from open market competition that can only work if it is, indeed, temporal. The high premium for patented brand name products is tolerated for the simple reason that it should stimulate research and development into new pharmaceutical products. Patent lengths should thus reflect the innovation life cycle of an industry. The longer the patent life, the more the monopolistic dangers of patents increase and the less their innovation benefits are manifested.

The European Patent Office (EPO) was established by an international treaty (Munich Convention, 1973). It is not a European institution but rather an independent organisation, as it is not integrated into the European Commission. It is, therefore, not accountable to any political institution other than the conference of the parties of the Munich Convention.

HAI Europe joins the call to create a single community patent and unified patent judiciary. This would mean removing the sole responsibility of administering patents from EPO. While it is not financially dependent on any EU institution, the EPO is dependent on its customers and its policies are therefore, biased towards the automatic granting of patents. This situation provides an incentive to grant patents less stringently, which in turn leads to low patentability standards. The competition among national patent offices to attract new patent submissions corroborates the ‘soft’ patent criteria applied throughout Europe. Therefore, HAI Europe calls for an institutional reform of the EPO that would ensure this institution is politically and socially accountable.

The report described evidence of various tools being used separately and in conjunction to weaken the ability of generic manufacturers to produce affordable medicines for consumers and patients in Europe. However, the response from the many representatives of originator companies is to reiterate their ‘right’ to protect their investments in any way deemed necessary and with no concern for the impact that this has on the quality of public health and the cost of public health expenditure for EU Member States.

To dismiss health when discussing medicines’ patents is disturbing, not least for its lack of consideration for the consumer and patient perspective, but also for the fact that it disregards the effect on public health expenditure for Member States. At a time when fiscal discipline has never been more important, promoting practices that artificially inflate the cost of medicines for health care funders is an irresponsible approach.

Concrete proposals

- Set up a single community patent and a unified patent judiciary;
- Reform the EPO, making it politically and socially accountable;
- Make a register of all patents per product and their expiration date publicly available to increase transparency and prevent delays of generic entry to the market;

- Request that originator companies refund national social insurance systems when legal cases against generic manufacturers are lost and manufacture is upheld as legitimate;
- Prohibit settlements with generic companies (i.e. payments to delay generic entry to the market).
- Encourage Member States to simplify the entry of generic medicines to the market and promote their use.

Promotion and marketing practices under the guise of ‘patient information’

DG Competition’s report describes a number of measures taken to boost product loyalty, such as criticising a competitor’s products and undermining public confidence in the efficacy and quality of generic products.ⁱ Additional tools such as disease management initiatives driven by pharmaceutical companies (i.e. patient education programmes, risk management plans, compliance programmes) have also been recognised as strategies aimed at building patient brand loyalty.ⁱⁱ

‘Innovator’ companies spend 23% of turnover on marketing, while only 17% is allocated to research and development. While that may be common practice in other business areas, pharmaceuticals are not simply consumer goods or commodities.

The choice of a specific medicine involves an overarching decision that weighs the treatment benefits against the treatment harms. That decision must be taken based on independent and relevant information devoid of commercial interest.

It is important to bear in mind the recent proposal for a directive on information to patients put forward by the Commission.ⁱⁱⁱ This new directive would allow the pharmaceutical industry to deliver direct information on prescription medicines to EU citizens. Quite clearly, such a regulatory framework would provide the legal basis for a relaxation of the current ban on advertising of prescription medicines, and lead to the provision of biased information of promotional nature, from producers to consumers. Originator companies would take advantage of such a mechanism, to promote brand-name drugs to the detriment of generics.

Were the proposal to be adopted, then the unethical marketing practices accounted for in the report would not only increase in number but also in severity. Opening the door to such a system, which would reward marketing tactics rather than providing incentives to meet real therapeutic needs, would have grave implications for public health and for the sustainability of EU health systems.

Concrete proposals

- Prohibit at EU level, both directly and indirectly, any communication on prescription medicines to the public by pharmaceutical companies;
- Withdraw the Commission's proposal on information to patients;
- Create or increase mandatory taxes on marketing and promotional expenditures in order to provide incentives for pharmaceutical companies to invest more in neglected research areas;

- Establish a permanent body to monitor marketing strategies, invested with the authority to refer cases of malpractice to the courts, and consider various unethical practices;
- Mandate prescribing using the international non-proprietary name (INN) of the drug across EU, as it avoids preventable medication errors and their public health consequences (i.e. serious adverse effects leading to hospitalisations).

Regulatory aspects: Marketing Authorisations, Pricing and Reimbursement

While both generic and originator companies have been keen to identify “bottlenecks” and regulatory hindrances, DG Competition must assess whether these are real barriers or just the result of dutiful implementation of marketing authorisation procedures. Promoting competitiveness by speeding up marketing authorisation should not be at the expense of public health or the protection of European citizens.

The role of the regulatory agencies is to act as firm gatekeepers of public health. This role should include a duty to publicly disclose all data related to the efficacy and safety of medicines, which is of clear public interest. It should be a priority to ensure that all information on drug safety and effectiveness submitted to regulatory authorities is publicly available, including all pre-market laboratory and clinical data and post-marketing studies.

Pharmaceutical companies are asking for “incremental progress” rewards, namely, the speedy consideration of even the slightest evidence likely to enhance a medicine’s attractiveness to patients, consumers and healthcare professionals. This distorts the notion of rewards based on real innovation.

In reality, a fourth criteria: real therapeutic advantage, should be added to the current three evaluation criteria of efficacy, safety and quality when granting a marketing authorisation. The therapeutic advance would be appraised in comparison with existing treatments, and demonstrated by relevant clinical data collected from comparative clinical trials.^{iv}

‘Commercial confidentiality’ is not a legitimate reason to withhold data about medicines. Greater transparency of pricing, with centralised information available on the prices of medicines throughout the EU is also necessary. Unlike other products, medicine prices have fundamental implications for public health, since they determine access to necessary medical care. Decisions on pricing and reimbursement should remain with individual member states. However, the criteria through which a medicine’s effectiveness is appraised should be harmonised as not all member states require pharmaco-economic evaluations.

One way to increase affordability would be to generalise reference pricing schemes in order to comprehensively reward medicines and adopt a coherent pricing policy. The principle being that one 'reference drug' would be 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.^v

Additionally, the transparency of reimbursement decisions must be guaranteed. Currently, a major barrier to transparency is commercial confidentiality of drug safety, effectiveness, and

pricing data. Publicly available data on actual production costs would prevent citizens from being overburdened or denied potentially life-saving treatments by unreasonably high prices.

Moreover, health agencies should no longer be directly funded by pharmaceutical fees; the ‘scientific advisors’ should be carefully monitored to prevent agencies from becoming a service provider devoted to the pharmaceutical industry and diverted from their evaluative mission and the safeguarding of public health.

Concrete proposals

- Strengthen and enforce the independence of health authorities from pharmaceutical companies;
- Create a public-needs research and development agenda (Public health authorities);
- Adopt the comparative evaluation of therapeutic benefits (relative effectiveness) in order to reward real innovation (therapeutic progress);
- Enforce existing legislation and stop the proliferation of exemptions to standard procedures such as accelerated authorisations and conditional authorisations;
- Evaluate research and development costs in order to set fairer prices;
- Generalise reference pricing schemes in order to comprehensively reward medicines and adopt a coherent pricing policy.

Competition failure on a global scale

High prices and a lack of innovation are also at the core of global debates on Access and Innovation and on policies towards developing countries.^{vi} Perverse incentives leading to sub-optimal levels of innovation and high prices of medicines are clearly not a Europe-only problem. Policy decisions taken at EU level will have broader implications beyond the European market; they will also affect the design and implementation of policies in many developing countries. HAI Europe therefore urges DG Competition to take into account the current global dialogues, especially those taking place at the World Health Organization (WHO) on the scope of Intellectual Property Rights as drivers for innovation. These dialogues have led the WHO to look at alternative financing mechanisms to the patent system.^{vii}

Concrete proposals

- Take into account the “Global strategy and plan of action on public health, innovation and intellectual property”, which discusses the scope of IPR and negative effects for public health.

Health as a legitimate concern

During the presentation of the report in Brussels on the 28th November, the public health perspective was barely taken into account. The concerns were framed squarely in terms of competition and open market policy. Presenters were unable to make the link between the findings of the sector enquiry and the people being served by competition policy: the public. At one point in the meeting, one industry supporter dismissed ‘emotional’ appeals about health as inappropriate to the discussion of patents on medicines. There is still an

unquestioning acceptance of the validity of discussing the pharmaceutical sector without reference to public health. This highlights the need for a change in framework to bring about a larger role for DG SANCO. DG SANCO could and should have more prominence in the pharmaceuticals portfolio, currently dominated by DG Enterprise & Industry. Such a transfer of responsibilities should be fully supported by DG Competition, given the findings of their investigation.

Research & Development

The role of industry investment in R&D and the need for patents to protect innovation are structurally overstated. In fact, publicly funded research plays a key role in the development of new medicines. Worldwide, approximately 50% of R&D is paid for with public money.^{viii} Some studies suggest that as much as 84% of all funds for basic research– the research needed to discover important new drugs- comes from public sources.^{ix} This large public investment being made into the development of new medicines should be taken into account when considering the relevance and length and when granting patents.

Alternative mechanisms

As the report indicates, the patent system has provided perverse incentives. While regulation and the application of stricter competition policies can tone down or reduce some of these incentives, they are an inherent part of the system. A patent holder will always spend energy on extending the patent beyond the time granted in relation to the innovation and thus, beyond the benefit it will bring to society.

In addition to the obvious costs to society, there is also the cost of lost opportunities for investing in innovation. Prolonging patents is a guaranteed source of income, while investing in innovation entails risk.^x

It is rational to look at alternative mechanisms to spur innovation and ensure access to medicines. There are several proposals circulating globally. One is the prize mechanism. The basic idea is that governments would award money to innovators to stimulate investment in medical innovation rather than giving drug developers exclusive rights over the sale of their products.^{xi, xii} Large monetary prizes would be tied to the actual impact of the invention, measured by the advancements in health care outcomes being provided by the successful products. A bill on this mechanism was introduced in the US Congress in 2005 under the title of the Medical Innovation Prize Fund Act.^{xiii}

Concrete proposals

- Take account of the role of publicly funded (basic) research when granting patent rights.
- Consider alternative financing mechanisms for innovation.

KEY RECOMMENDATIONS

- **DG Competition should treat health as a legitimate priority in pharmaceutical policy**
- **Pharmaceutical policy should be transferred from DG Enterprise to DG SANCO**

RECOMMENDATIONS

Competition Policy and Patent rules

- Apply competition policy more rigorously and enforce strict criteria in the granting of patents;
- Set up a single community patent and a unified patent judiciary;
- Reform the EPO, making it politically and socially accountable;
- Make a register of all patents per product and their expiration date publicly available to increase transparency and prevent delays of generic entry to the market;
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Promotion and marketing practices under the guise of 'patient information'

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Regulatory aspects: Marketing Authorisations, Pricing and Reimbursement

- Strengthen and enforce the independence of health authorities from pharmaceutical companies;
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- Enforce existing legislation and stop the proliferation of exemptions to standard procedures such as accelerated authorisations and conditional authorisations;
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Competition failure on a global scale

- Take into account the "Global strategy and plan of action on public health, innovation and intellectual property", which discusses the scope of IPR and negative effect for public health.

Research and Development

- Take account of the role of publicly funded (basic) research when granting patent rights;
- Consider alternative financing mechanisms for innovation.

ENDNOTES

ⁱ 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.

ⁱⁱ 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.

ⁱⁱⁱ www.europa.eu/enterprise/pharmaceuticals/pharmacos/pharmpack_12_2008/patients/citizens_summary_info_to_patients.pdf.

^{iv} 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.

^v 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.

^{vi} Report of the Commission on Intellectual Property Rights, Innovation and Public Health, WHO 2006.

^{vii} Global Strategy and Plan of Action on Public Health, Innovation and Intellectual Property. WHA 62.21 2008.

^{viii} Global Forum for Health Research: Monitoring Financial Flows for Health Research , 2006.

^{ix} Light, Donald. 2006, Basic research funds to discover important new drugs: who contributes how much? Global Forum for Health Research.

^x Michel Boldrine and David Levine, *Against Intellectual Monopoly*, Cambridge university Press, 2008.

^{xi} Love & Hubbard, The Big Idea, *Chicago-Kent Law Review*, 1519-1534, Nov 28, 2007.

^{xii} Stiglitz, Give Prizes not Patents, *New Scientist*, Sept 2006.

^{xiii} H.R. 417, 109th Congress, Representative Bernard Sanders.