



AIM

ASSOCIATION INTERNATIONALE DE LA MUTUALITE

**Pharmaceutical Sector Inquiry
Preliminary Report – 28 November 2008**

**AIM Response
2 February 2009**

AIM would like to thank DG Competition for having taken the initiative to analyse the competition in the pharmaceutical sector.

AIM welcomes the preliminary report which provides an impressive set of data, facts and figures. The report gives a solid global as well as detailed overview of the situation of competition in the pharmaceutical sector. This report represents a very valuable tool to understand the strategy underlying the pharmaceutical industry's behaviour during the whole life-cycle process of a medicine.

The findings noted in the report confirm certain of our own ideas on competition problems in the pharmaceutical sector and abuse of the current patent system.

AIM wants to encourage DG Competition to pursue the analysis of the data accumulated in the report, to have the courage to draw the right conclusions about the misbehaviours and to propose a set of actions to remedy the non-acceptable situations.

AIM comments focus on the two key aspects which motivated this sector inquiry: how to boost real innovation and how to promote generic competition.

Executive summary of AIM proposals:

AIM welcomes the preliminary report which provides an impressive set of data, facts and figures. It represents a very valuable tool to understand the strategy underlying the pharmaceutical industry's behaviour during the whole life-cycle process of a medicine. The facts describe general misbehaviour which requires urgent action to remedy to a non-acceptable situation. That situation has very costly implications for European patients, taxpayers and health systems, and must ultimately be detrimental to the pharmaceutical industry itself.

To boost R&D, AIM calls on originator companies to invest more in R&D instead of in marketing and to support diversified R&D areas. AIM invites the European Commission to consider the evolution over time of pharmaceutical industry investments in R&D as well as in marketing/promotion and to report on this in the annual European Innovation scoreboard. AIM calls on the Commission to investigate why SMEs are more successful in R&D compared to big pharma.

Public authorities and social health insurance organisations need a more rational basis to decide on fair prices. AIM calls for more transparency of the components underlying the final price which is of utmost importance for economic optimisation between supplier, payer and patient across Europe.

Urgent initiatives and measures need to be taken to put an end to the abuse of the current patent system, especially of secondary patents enabling a strategy of patent clusters and patent evergreening. Patent rules must be applied much more strictly with regard to novelty and inventivity. The European Patent Office and national agencies need to emphasise high quality of the granted pharmaceutical patents. A pre-condition for this is to ensure that the EPO is a completely independent office, does not rely on commercial funding and is fully financed by public money. EPO staff and experts must be fully independent and be without any conflict of interest.

We recommend putting in place a publicly accessible database including a register of the number of patents per product as well as the patent expiration dates.

To put an end to the strategy of delaying generic competition through long and costly litigation processes, the originator industry should be obliged, in any case where they lose their litigation process, to compensate health systems as well as the generic companies for their respective losses.

We invite the Commission together with the national authorities to investigate where public research would be the most worthwhile and to encourage networking among public research institutes to enable the creation of synergies and economies of scale. AIM encourages public health authorities to set up a public-needs R&D agenda.

There must be full transparency in the use of public money. It must be ensured from the beginning that outcomes from R&D, partly or fully financed by public money, have to be made available at affordable prices for all those who need them.

AIM calls on the European Commission and the Member States to support fully the implementation of the “Global strategy and plan of action on public health, innovation and intellectual property” giving the WHO a central role in research on diseases which disproportionately affect developing countries.

AIM calls for the addition of a fourth condition for the marketing authorisation: the provision of information on the added therapeutic value of the new product compared to alternative treatments. AIM strongly calls for the consistent use of comparative trials and of post-marketing studies.

AIM encourages the European Commission and Member States to impose an INN prescription system.

AIM encourages Member States to put in place independent vocational training courses for health professionals to update their knowledge of new drugs and generics.

AIM encourages reinforcing of collaboration among national bodies involved in issuing independent patient information. AIM calls on the Commission to withdraw its recent legal proposal on information to patients.

AIM calls for a switch of competence for pharmaceutical policy from DG ENTR to DG SANCO.

To create full transparency of pharmaceutical industry marketing strategies and respect for competition law, AIM calls on DG Competition to set up a permanent observatory.

I. How to boost innovation

Need to boost R&D, not marketing

Research is the basis for innovation. However, over the past several years it has become widely recognised, as has been confirmed by the preliminary report, that the productivity of R&D expenditure has been declining while R&D expenses have been steadily increasing¹. The facts and data revealed by the preliminary report begin to illustrate the underlying reasons for, and depth of, the innovation crisis.

In our opinion a prime reason is to be found in the **strategy of originator companies’ investing more in marketing than in R&D**. The data found in the inquiry speak for themselves: on average, 17 % of turnover from prescription medicines is spent on R&D - of which only 1,5% is dedicated to fundamental research - known as the most risky - whereas 23% of turnover is spent on marketing and promotional activities². The

¹ According to the United States Government Accountability Office report on New Drug Development (November 2006), although the US pharmaceutical industry has reported substantial increases in annual R&D costs, the number of New Drug Applications (NDA) submitted to, and approved by the FDA has not been commensurate with these investments. From 1993 to 2004, the industry reported that annual R&D expenses steadily increased from nearly \$16 billion to nearly \$40 billion - a 147 % increase. In contrast, the number of New Drug Applications (NDAs) submitted annually increased at a lower rate – 38 % over this period - and even declined generally over recent years.

² European Commission Preliminary Report on Pharmaceutical sector Inquiry, 28 November 2008.

number of employees in marketing and sales departments is twice the number of those working in R&D.
This trend needs to be reversed.

The report also indicates that originator companies rely to a large degree on innovations acquired from third parties: 1 out of 4 molecules in clinical development have been acquired from others, mainly from SMEs. Recent years have also been characterised by mergers between originator companies and/or acquisitions (also, of generic companies), with view to diversifying the product and risk portfolio. Even if these trends sustain the profit margins in the short term, we are of the opinion that this does not advance originator companies' fundamental purpose in discovering and developing newly innovative products: on the contrary.

Why are SMEs more successful in R&D compared to big pharma? We encourage DG Competition to investigate this in much more detail. We are also of the opinion that the trend of mergers/acquisitions will have, in the long run, a negative effect on R&D. Very often it leads to suppression of R&D units and to a concentration on R&D areas which appear to be the most lucrative and commercially promising.

AIM would like to invite the European Commission to consider the evolution over time of pharmaceutical industry investments in R&D as well as in marketing/promotion and to report on this in the European Innovation scoreboard.

Need for diversity³, not dependency on blockbusters

The originator companies have focused R&D too much on the development of blockbuster products. This has led to a decline of novel molecular entities (NMEs) entering the market: on average a decline from 40 NMEs (from 1995 to 1999) to 27 for the period 2000 to 2007. Furthermore, the originator companies' product portfolios have become far too dependent on their blockbuster products: 19% of turnover of the 9 largest originator companies relies on one of their blockbuster products. For three companies the "far blockbuster product" generates 30% or even more of their respective turnovers. As a significant number of blockbuster products will lose patent protection in the next few years, the innovation crisis for originator companies will actually amplify. We therefore expect originator companies to make maximal use of the strategies described in the preliminary report⁴ to prolong the monopolistic market situation for their respective products on the market over the next few years.

Rewards for added therapeutic value – not for me-too products

Compared with the decline in the number of new products reaching the market, these new products are mainly only 'Me-too' products with little or no added therapeutic value in comparison to what exists already⁵. According to the US FDA, only one out of four new drugs produces some kind of therapeutic progress. According to AIM, this so-called "incremental innovation" should not benefit from incentives for R&D which have been established to reward real innovation. **Strong quality criteria, based on proof of added therapeutic value of new medicines, are the best way to demonstrate progress in medical therapy and would ultimately strengthen sound competition in the pharmaceutical sector.** The added therapeutic value can only be demonstrated through comparative analysis. **AIM therefore calls for the addition of a fourth condition for the marketing authorisation.** Further to safety, efficacy and quality, the manufacturer should also, **whenever possible, provide information on the added therapeutic value of the new product compared to already existing alternative treatments. AIM strongly calls for the consistent use of comparative trials and of post-marketing studies.**

³ Broad scope of treatment areas.

⁴ The preliminary report describes the different originator companies' strategies (a tool-box of instruments) to restrict or distort competition, aiming to ensure continued revenue streams for their own medicines: patent clusters, patent litigation, settlement agreements, etc.

⁵ Only 15% of new drugs approved by the US's FDA from 1989-2000 were highly innovative drugs. (*NIHCM Foundation*, 2002).

Only 5.9% out of 1,147 newly patented drugs appraised by the Canadian Patented Medicine Prices Review Board, between 1990 and 2003, met the regulatory criterion of being a breakthrough drug. (Morgan et al, *BMJ* 2005)

According to the analyses made by the journal 'revue Prescrire' during the last 15 years (1992- 2006) 55% of new products brought "nothing new or were even not acceptable", 25% were possibly helpful, 11 % offered an advantage and only 3% presented a real advantage (*Prescrire International*, 2007).

Urgent measures need to be taken to put an end to the abuse of the current patent system, especially through secondary patents which are the basis for “patent-cluster” strategy.

Transparency of real costs of developing a new medicine: a condition for fair prices and sustainable solidarity-based health systems

AIM calls on DG Competition to further investigate the real costs of developing a new medicine and of bringing it on the market. Today, the amount of US\$ 1 billion is commonly reported by pharmaceutical industry. Others contest this amount which seems much exaggerated. We would also like to invite DG Competition to investigate in much more detail who is paying for research⁶.

In Europe the growth rate of drug expenditure exceeds the growth rate of total health expenditure. This trend is exacerbated by increasing prices. Pharmaceutical industry justifies the high prices during the patent protection period as recovering the high R&D costs. But the high prices serve also to recoup the marketing costs which are significantly higher than R&D expenses. Drug prices are often simply based on what the market will bear. And to maintain health, every citizen is ready to pay all that he has. **Public authorities and social health insurance organisations need a more rational basis to decide on fair prices** - even the best new medicine is of no use if it is unaffordable.

Transparent, fair prices and improved competition are the basis for financial affordability. For AIM a fair negotiated price is the decisive principle. **For AIM, improving the transparency of the components underlying the final price is of utmost importance for economic optimisation between supplier, payer and patient across Europe.** A fair price should reflect a balance between: supplier-investment (requiring ethical profit), the therapeutic benefit (clinical necessity) for the patient, and the capacity of third-party payers to pay for the product. We need a price based on benefit: ‘value for money’. AIM members request companies to disclose key elements of their cost components, in order to have a rational basis for price negotiations.

We invite the Commission together with the national public health authorities to investigate where public research would be the most worthwhile and to encourage networking among public research institutes to enable the creation of synergies and economies of scale. In case of use of public money to support private research or PPP, it must be ensured that the priority for public money is the investigation of public health needs rather than own-company strategic plans. **There must be full transparency in the use of public money.** For social health insurance schemes represented in AIM it is not acceptable to have R&D financed by public money while private for-profit companies on the other hand take all the profit on resulting pharmaceuticals. **It must be ensured from the beginning that outcomes from R&D, especially those which are partly or fully financed by public money, have to be made available at rational prices** (duly considering the input of public money, the cost of R&D and a fair revenue) **for all those who need them.** The Drugs for Neglected Diseases Initiative⁷ is a good example of a new way of developing drugs, where the partnership model is effective and where at the end the price of the drugs can also be affordable for patients and for society.

For a ‘needs-driven’ R&D agenda – alternative mechanisms to fund R&D

In our market economy, R&D does not necessarily focus on ‘public health’-defined priorities but rather on commercially-promising and lucrative markets.

“Priority Medicines for the Citizens of Europe and the World” was a key priority of the Dutch EU Presidency (2004) and a first attempt at European level **to set a public-needs R&D agenda.** AIM fully supported this initiative and we hope that grants provided by the 7 Research Framework programme will be of benefit for R&D on the identified public health priorities.

Under the auspices of the WHO, an intergovernmental working group on Public health, Innovation and Intellectual Property analysed the question of appropriate funding and incentive mechanisms, for the creation of new medicines against diseases that disproportionately affect developing countries. The aim was to

⁶ According to the US’s NIH report (“Contributions to pharmaceutical development”, National Institute for Health, February 2000), taxpayers and public research funds contribute heavily to pharmaceutical research, up to 85 %. Only 14 % of the drug industry’s total R&D spending goes to basic research, considered as the riskiest and most costly, while 38% goes to applied research and 48% goes to product development.

⁷ DNID, www.dndi.org

provide a framework for an enhanced and sustainable basis for needs-driven essential research relevant to neglected diseases in developing countries⁸. This led to the adoption of a Resolution of the World Health Assembly in May 2008 on a “**Global strategy and plan of action on public health, innovation and intellectual property⁹” giving the WHO a central role in research on diseases which disproportionately affect developing countries.** The main idea is to boost research on neglected diseases through alternative mechanisms to fund R&D, in particular by de-linking research and development costs from drug prices. This could be done through prize funds, patent pools, PPP, open-access drug discovery entities, etc. **We invite the European Commission to collaborate actively with the WHO to implement this global strategy.**

Current Patent and intellectual property rights system: inhibiting or rewarding innovation ?

Patents aim to reward companies for their innovative efforts and to allow them to recoup their considerable investments in developing new products, as well as being an incentive for future research.

Recent experiences and the facts described in the intermediate report confirm to us the idea that originator companies abuse and misuse the current patent and intellectual property rights system. As a consequence the patent system inhibits and hampers R&D efforts instead of promoting innovation.

The US GAO identified **intellectual property rights and the focus on developing blockbuster drugs as being among the factors contributing to declining productivity¹⁰.**

To improve this situation and to find more innovative drugs the GAO report suggested focusing on reducing the costs and considering provision of financial incentives or disincentives by extending or reducing the period of patent protections and intellectual property rights.

The Commission’s preliminary report explains the important difference between primary patents (provided for active molecules) and secondary patents mostly granted during the development phase of a product for dosage forms (tablets, capsules or solutions for injections) or formulations.

For the 219 INNs under scrutiny, about 40.000 patents had been granted or patent applications were still pending. 87% of these patents were classified by the companies as secondary patents, giving a primary:secondary ratio of approximately 1:7. One single blockbuster product was protected by as many as 1.300 patents EU-wide. The majority of granted patents concern a small proportion of the INNs. The top 20% of INNs under scrutiny account for 60% of all patents, whilst the top 50% account for 90% of all patents. The number of granted patents (and pending applications) increases with the value of the INN, in particular for the top-selling INNs (blockbusters). It was also very surprising to see that patent portfolios of originator companies for blockbuster INNs showed a steady rise in patent applications, especially at the end of the protection period of the first patent.

This clearly shows the abuse by originator companies of the current patent system in prolonging the monopolistic market place, especially for their best-selling and blockbuster products. **Solutions must be found to put an end to the strategy of patent clusters and patent evergreening. Patent rules must be applied much more strictly than before, especially for secondary patents, and only be granted for real innovation with regard to novelty and inventivity. We recommend putting in place a publicly accessible database including a register of the number of patents per product.**

A stricter application of the patent rules would lead to less litigation¹¹, opposition, appeals or use of the settlements and agreements procedure.

⁸ The reality is that diseases that affect people in developing countries do not get adequate attention and investment in research, compared with diseases that have more lucrative markets. The statistics speak for themselves: only one per cent of the drugs reaching the market between 1975 and 2006 were developed for neglected diseases.

⁹ http://www.who.int/gb/ebwha/pdf_files/A61/A61_R21-en.pdf

¹⁰ United States Government Accountability Office report to Congressional Requesters, November 2006, GAO-07-49, “Science, business, regulatory, and intellectual property issues cited as hampering drug development efforts”.

¹¹ The intermediate report indicates that the total litigation cost for cases analysed for 2000-2007 is over €420 million.

II. How to promote generic competition

Generic medicines play an important role in providing affordable medicinal products. The development of generics needs to be encouraged: financial savings made through generics would allow health systems to help fund new innovative medicines, thereby further promoting the development of the research-based pharmaceutical sector.

The preliminary report indicates that policies for generics differ greatly among Member States. According to the preliminary report, **there is still plenty of room for manoeuvre in improving generic penetration**, which contributes to enormous cost savings for health systems, payer organisations, tax payers and patients:

- Faster take up of generics: on average it takes 7 months; for most valuable medicines it takes still four months.
- Competitive prices: at market entry, on average the generic product is sold at 25% lower price than the originator's medicine; two years after entry, a price difference of about 40 %.
- Market share (volume); in the first year about 30 % and after two years 45%.

Different national practices have shown that price reductions of up to 80% are possible.

Different procedures reflect different priorities within Member States. Pricing and reimbursement decisions are within the competence of Member States. AIM is in favour of exchange on best practices on access to generic products.

To keep health budgets under control, **we support therapeutic reference price systems as a tool to strengthen competition**. Therapeutic Reference price systems include equivalent therapeutic products in one price group. This procedure makes equivalences and differences between products transparent and thus improves competition between originators and generic companies. To improve competition within the generic market, some countries also involve the patient in the decision making process (e.g. no co-payments on cheaper products, as is the practice in Germany).

AIM calls on the Member States to put an end to the misuse of and uncertainties created by the patent system. AIM suggests making easily and publicly available the patent expiration dates, notably through the establishment of a public database.

The preliminary report describes strategies of originator companies in steering the prescribing behaviour of health professionals to enhance brand product loyalty (medical visitors, disparaging the quality and efficacy of generic products, etc.). **We encourage the European Commission and Member States to impose the INN prescription system** (prescription of an active substance rather than a brand) which allows dispensing pharmacists and ultimately the patient to choose the product preferred. **We would like to encourage Member States to put in place independent vocational training courses for health professionals to update their knowledge of new drugs and generics.**

The legislative proposal on "information to patients" adopted on 10 December 2008 represents yet another tactic to delay generic competition, by enabling the pharmaceutical companies to communicate directly to the public on their respective prescription-only medicines, thereby building "brand loyalty" and market share for their own originator products at the expense of affordable medicines for the public. If this legislative proposal were to be implemented as adopted, it would have an adverse impact on public health - especially on perceptions, requests for specific drugs, medication prescribing and compliance, as well as on healthcare expenditure and drug prices generally. **We call on the Commission to withdraw the legal proposal on information to patients.**

AIM invites the Commission and Member States to support the empowerment of EU-citizens - patients as well as health professionals - through better access to comparative, unbiased high-quality information generated by official independent bodies within a validated process. Many examples of such information and good practice exist already and should be benchmarked throughout the Member States. We are convinced that high added value for all Member States, EU citizens and patients is best achieved by developing synergies at EU-level and reinforcing collaboration among existing national bodies involved in issuing independent patient information.

III. Regulatory framework

Community patent

We understand the reasons why the pharmaceutical sector calls for a Community patent (reduction of costs). However we would like to stress that a Community patent would not at all remedy to the problems (anti-competitive strategies) described in the report. We cannot therefore agree with the pharmaceutical industry statement that "...the current fragmented patent system is seen as a **major impediment to innovation in Europe and to its global competitiveness**".

Patent litigation

We agree however that the multiplication of national Court procedures and absence of any possibility of a uniform binding ruling on validity of a patent throughout Europe is a major weakness which leads to legal uncertainty. In parallel with a **European patent, European jurisdiction should contribute to setting up a more efficient patent litigation system in Europe**. In the current framework, and in order to put an end to the strategy of delaying generic competition through long and costly litigation processes¹², **we propose that the originator industry should be obliged, in any case where they lose their litigation process, to compensate health systems as well as the generic companies for their respective losses**.

Better application of patent law

We fully support that **the priority for the European Patent Office¹³ should be an emphasis on quality over quantity in the granting of European patents**. A pre-condition for this is to ensure that the EPO is a **completely independent office, does not rely on commercial funding and is fully financed by public money**. EPO staff and experts must be fully independent and be without any conflict of interest.

Public Health Competence

In order to tackle European pharmaceutical policy primarily from a public health perspective, **AIM calls for a switch of competence for pharmaceutical policy from DG ENTR to DG SANCO**.

We furthermore suggest that DG Competition **sets up a permanent observatory of marketing strategies of the pharmaceutical industry and of respect for competition law**. In order to create full transparency on pharmaceutical industry competitive behaviour, which has important consequences for patients, tax payers and European health systems, the observatory should make a report every two years.

Brussels, 2 February 2009

About AIM

The 'Association Internationale de la Mutualité' (International Association of Mutual benefit societies) (AIM), created in 1950, brings together 40 national federations of autonomous health insurance and social protection bodies in 26 countries, all operating according to the principles of solidarity and not-for-profit orientation. They provide coverage against sickness and other social welfare risks to more than 210 million people, either by participating directly in the management of compulsory health insurance, by providing voluntary health insurance or by delivering directly health care and social services through own facilities.

AIM's goal is to defend and promote, at international and European level, the social values and basic principles shared by its members: access to health care as a fundamental right, solidarity and non-exclusion as essential means to ensure this access to quality health care for all, irrespective of health status or financial capacity to pay; finally, autonomous management and non profit orientation as guiding principles for health insurance based upon the needs of citizens.

AIM endeavours to voice concerns and ideas raised within the sphere of non-profit health insurance institutions in the EU. AIM positions, requiring validation through its own statutory decision-making process, do not commit its individual member organisations. Therefore, AIM involvement does not detract from its member organisations taking dissentient views.

¹² According to the preliminary report, a great majority of opposition cases were won by generic companies.

¹³ Preliminary report, p. 376