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OBSERVATIONS ON THE PRELIMINARY REPORT IN THE PHARMACEUTICAL SECTOR INQUIRY

Pharma Industry Finland (PIF) is the interest organisation of the research-based pharmaceutical industry operating in Finland, currently with 60 member companies. We welcome the opportunity to submit our country specific comments about the preliminary report in the pharmaceutical sector inquiry. In all other aspects, we fully support the observations submitted by EFPIA, the European Federation of Pharmaceutical Industries and Associations.

General comments

The Commission acknowledges that the pharmaceutical industry is vital to the health of Europe's citizens and that patents are key to providing reward for innovation and incentives for future research. The Preliminary Report (PR) deals with topics that are of great importance to the future of the research-based industry in Europe, but we are disappointed that the report does not adequately recognize the complex and highly regulated nature of the pharmaceutical market in Europe. It also misses the opportunity to address the real issues impeding innovation and access to innovative medicines and ignores the real inefficiencies of the generic market.

Savings attainable via generic competition have been neglected in the Preliminary Report

Savings that can be achieved due to well functioning generic competition have been neglected in the PR. In Finland generic competition starts very rapidly, even before expiry of the product patent, due to weak patent protection and short regulatory data protection for nationally authorised products. Therefore access of generic products into the reimbursement scheme is rapid and the Finnish generic substitution scheme is very competitive.

In Finland analogous process patents are still very common. Until 1995 patent protection for pharmaceuticals was limited to process patents. Applications for product patents have only been allowed since 1st of January 1995 and at that time companies were not able to extend their pending applications to cover the product itself. Therefore only regulatory data exclusivity is available to protect the original products and especially for centrally authorized products it often plays much more important role for access to



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market by generic manufacturers than patent protection. On the other hand, for products authorized via national or mutual recognition procedures, only 6 years of data exclusivity was available for originators. Therefore generic products may enter the Finnish market faster than in other EU countries, sometimes well before expiry of the product patent.

Access of generic products to the Finnish reimbursement scheme is very fast, sometimes only a couple of days. This is also demonstrated in the figure 14 of the PR. Generics must enter the reimbursed market at 40 % discount (or more). This is well established practice and even if it is not written in the law, it can be found for example from the governmental motivations of the latest amendments to the Health Insurance Act. While this, together with the limited size of the market, can reduce the commercial opportunities of generic companies in Finland and discourage generic entry, if the generic companies choose to launch in Finland, the competition in the generic market is working well.

In Finland, generic substitution scheme has been in use since 2003. Annual savings of the reimbursement costs due to price competition and substitutions by the pharmacies has varied from 4 to 6 percent (Source: Report of the reference price working group, 2007). It has decreased prices more than the 40 percent rule set by the pricing authorities. In addition to that, prices of some major product groups have decreased by 80-90 percent.

Due to the weak patent protection and heavy competition between generics and between generics and the original products, data on the PR¹ covering market share of generics in Finland is incorrect. Based on national statistics, the market share (value and volume) of generics in Finland is far beyond 16 % (value) or 41 % (volume) that are the figures of the PR based in IMS data. This is due to different definitions of "generics". The IMS data refers only 20 generic companies. In Finland, there are two large companies (Orion and Leiras Finland) that have innovative products but also very strong generic portfolios. In IMS figures, these companies are counted fully as "originators" even if they are actually bigger players in the generics field in our national market. Therefore the EC figures do not represent the real situation on the market in Finland. Latest figures for 2006 were 21 % (value) and 49 % (volume), and for 2007 22 % (value) and 52 % (volume).

It should also be clear that citing only the value figure, as has been done in the executive summary of the PR, without putting it in context to the volume figures, can give a biased picture. From the competition point of view, we find that high volumes but low values of generic market shares would mean optimal competition within that sector. High values alone can just be a sign of over-priced generics.

Patent portfolios, patent litigation, patent settlements and marketing and development of second generation products

As explained above, in Finland the patent protection for pharmaceuticals was, for a very long time, limited to process patents. Applications for product patents have only been allowed since 1st of January 1995 and at that time companies were not able to extend their pending applications to cover the product itself. Therefore until recently patents

¹ Executive summary on page 7 and paras. 147-148



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have had limited impact on access to market by generic companies in Finland. Analysis made in the PR that the delayed market entry by generic medicines is linked to "delaying tactics" by innovator companies are not supported by this fact.

For R&D-based pharmaceutical industry, availability of patent protection for new inventions fulfilling the criteria of patentability and access to justice in cases when patents are violated is essential prerequisites for economically sound business in the field of pharmaceuticals. This is also demonstrated by the evolution of R&D-based pharmaceutical industry in Finland, where pharmaceutical R&D activities expanded only after introduction of TRIPs level IPR protection.

Patent portfolios reflect the level of innovation in the pharmaceutical industry as in any high technology sector. The much quoted figure of 1,300 patents or patent applications misleadingly inflates, up to 27 times, the number of parallel patent "families" needed to obtain protection in each of the EU 27 states. According to our understanding, medicines are protected by relatively few patent families compared to the amounts of patents protecting other high technology products. It should also be clear that no later patent can extend an earlier patent's term but any subsequent application must cover a new invention. It should remain up to the patent authorities to decide if the criteria of patentability are met and if the validity of any IPR is put into question such case should be handled by the court competent to deal with IPRs. It is not the role of competition authorities to start questioning the decisions made by them.

The apparent criticism of the patenting of improvements to a product late in the original patent term disregards the importance of incremental improvements as a source of innovation. Such improvements provide real benefits to doctors and patients in terms of potency, reduced side effects and simpler dosing regimens. It would be antithetical for the competition rules to prevent or inhibit an innovator from using its superior knowledge of its own products to devise and protect new and valuable improvements.

Marketing and development of second generation products are the essence of competition, particularly in high tech industries and certainly not just in the pharmaceutical field. It would be absurd to suggest that companies should not introduce next generation products because to do so unfairly disadvantages generics who can copy only old technologies. If next generation products are successful then they will add to the range and choice of products available to doctors and patients, including generic versions of the old products. If they are not, then the cheaper generic versions of the old technology will prevail. If no additional benefit is provided by the second generation product, it is highly unlikely that reimbursement authorities would be ready to prefer it over generics.

Patent litigation is essential for intellectual property protection. To extrapolate from a handful of decided cases to brand the pharmaceutical sector as characterised by what the report calls weak secondary patents is, again, without support. It commits the "self-selection error" of choosing the most contentious cases – the tiny minority of patents that litigated – to generalise about the rest. The reality is that once the primary patent has expired, imitators are free to copy it. If weak patents are identified, generic companies have demonstrated their ability and willingness to challenge or design around them. Suggesting that certain types of patent litigation may be suspect creates damaging legal uncertainty for innovators who rely on patent enforcement as the only effective means of protecting their investments.



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Patent settlements are also an essential business tool to draw a line under protracted and expensive litigation and move on, allowing the parties to invest in conditions of business certainty. The public interest in facilitating settlement of litigation, both for litigants and overworked courts, is generally recognised. There can be no presumptively good or bad settlements.

The use of patents, their effective enforcement through patent litigation, patent settlements and development and marketing of next generation products are legitimate and essential standard practices in many R&D driven high technology industries. It is of great importance that the legality of these practices is not called into question by over-interpretation of competition law or simplistic and one-sided interpretations of causal relations between use of IPRs and generic entry.

The Regulatory Framework for innovative medicines

Another major deficiency of the PR is lack of discussion on and impact of the Regulatory Framework on competition between innovative companies. In Finland, that is the main reason for delays in access to market by innovative medicines. Particularly access to the reimbursement scheme is often delayed, which has huge impact on the competition between original products. The marketing authorisation procedures on the other hand currently follow the EU timelines quite well, even if this has always been the case.

In Finland we have a two-step reimbursement system. The health insurance will subsidize the patients the medicines prescribed by a physician. The normal reimbursement rate is 42% of the medicine price (basic reimbursement category). In certain severe and chronic diseases, the patient will receive a 72% or 100% reimbursement of the medicine price (lower or upper special reimbursement category). A company has to apply for the basic reimbursement and a reimbursable price first. Only after a couple of years after approval into the basic reimbursement group, the company may apply for access to the special reimbursement class.

Access of a new active substance into the reimbursement scheme is very slow. (By new active substance we mean a product including an active substance which has not been approved earlier to the reimbursement system.) The delays have been especially long for the 1st in class products, 3-5 years from the marketing authorization. Please find enclosed a couple of examples.

Trade name	Active substance	Company	Marketing Authorization in Finland	Access to the final reimbursement class (special reimbursement 100% in all of these cases)
Zyprexa	Olanzapine	Eli Lilly	27 Sept. 1996	1 Apr. 2000
Lantus	Insulin glarginine	sanofi-aventis	09 June 2000	1 Nov. 2003
Avandia	Rosglitazone	GlaxoSmithKline	11 July 2000	1 Aug 2004
Cellcept	Mycophenolate mofetil	Roche	14 Feb. 1996	1 July 2001



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This practice seriously undermines the efforts of innovative companies to bring new treatments available for patients, as due to the slow access to reimbursement system they can not benefit from the competitive advantage of being the 1st in class on the market.

Summary

Many of the allegations made in the PR are not supported by the data that has been collected by the Commission. Significant factors having major effect on competition in the pharmaceutical field have been either omitted or misinterpreted. Any antitrust analysis needs to be based on sound, objective and comprehensive evaluation of the market situation. In the case of this sector inquiry, this still remains to be done.

We thank you for taking into account these views. In all other aspects and details of the PR we fully endorse the more detailed submission of EFPIA.

Yours sincerely,

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