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Vedlagt fremsendes til udvalgets orientering Lægemiddelindustriforeningens svar til EU-Kommissionen på den foreløbige rapport om kommissionens sektorundersøgelse af lægemiddelindustrien, som blev indledt i januar 2008.

Undersøgelsen blev indledt, da Kommissionen havde observeret, at der skete fald i antallet af nye lægemidler. Dette fald gav anledning til mistanke om, at lægemiddelindustrien begrænser introduktionen af nye lægemidler ved hjælp af patentsystemet, og at den forskende lægemiddelindustri samtidig skaber en række barrierer for introduktionen af kopimedicin (generiske lægemidler), efter at patentet/patenterne er udløbet.

I november 2008 offentliggjorde EU-Kommissionen en foreløbig rapport om sektorundersøgelsen. Vedhæftet er det svar, som Lægemiddelindustriforeningen i dag har sendt til Kommissionen som reaktion på den foreløbige rapport.

Desværre bygger Kommissionens rapport på en række misforståelser vedrørende patentsystemet. Blandt andet synes Kommissionen ikke at være opmærksom på, hvorledes patentsystemet generelt anvendes af virksomheder inden for brancher med fortløbende innovation, sådan som det kendes fra ikke bare lægemiddelindustrien, men også fra it-branchen. Den fortløbende forskning og udvikling sikrer, at de forskningsmæssige fremskridt løbende kommer forbrugerne, virksomhederne og samfundet til gode.

I foreningens høringssvar har vi derfor indledningsvist understreget, at effektiv patentbeskyttelse er fundamentet for fortsat forskning og udvikling i den farmaceutiske industri. Samtidig gælder det, at såvel myndighedernes som virksomhedernes evne og vilje til effektivt at beskytte – og om nødvendigt forsvare – patenter er en forudsætning for at bevare lægemiddelforskningen samt en konkurrencedygtig industri i Danmark og i Europa.

Ydermere gør vi i vort svar til Kommissionen opmærksom på, at det danske marked er anderledes end lægemiddelmarkederne i de lande, vi normalt sammenligner os med. Således er ibrugtagningen af moderne innovative lægemidler yderst langsom i Danmark. Forsinkelsen af ibrugtagningen skyldes en kombination af en generel prioritering af ældre produkter i bl.a. regionernes rekommandationslister, visse myndigheders bagatellisering af nye lægemidlers værdi og ikke mindst en udbredt grad af kassetænkning i det offentlige system. På den baggrund opfordrer Lif EU-Kommissionen til, i perioden frem til offentliggørelsen af den endelige rapport, at rette fokus mod de barrierer, der måtte føl-

ge af de nationale reguleringer mv. Omdrejningspunktet bør være at sikre alle patienter adgang til forebyggelse og sygdomsbehandling efter de mest moderne principper.

Giver ovenstående anledning til spørgsmål eller kommentarer, står jeg naturligvis til rådighed for yderligere oplysninger.

Med venlig hilsen

Henrik Vestergaard
Viceadministrerende direktør

Bilag: Lifs brev til EU-kommissionen af 30. januar 2009

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Response by the Danish Association of the Pharmaceutical Industry (Lif) to the EU Commission's Pharmaceutical Sector Inquiry – Preliminary Report

Summary

This response to the Commission gives the views of the Danish Association of the Pharmaceutical Industry (Lif) on the Pharmaceutical Sector Inquiry – Preliminary Report. Lif's comments generally fall into two parts.

The first part addresses those parts of the Commission's preliminary report that deal with patent rules, etc., in Europe, and hence the fundamental regulation of companies with the large intellectual property assets that characterize the pharmaceutical industry. The Commission's preliminary report is based, however, on a series of misunderstandings about the patent system. This part of the response supports the comments submitted in parallel to the Commission by the European Federation of Pharmaceutical Industries and Associations (EFPIA).

The second part of this response addresses the realities of the Danish market facing the innovative pharmaceuticals industry. This applies especially to the fact that the take-up of modern innovative medicinal products in Denmark is slow. Delayed take-up is due to priority generally being given to older products in the recommendation lists, the value of new products being downplayed and especially widespread "silo thinking". Accordingly, in the period up to publication of the final report, Lif would urge the Commission to direct its focus on the barriers arising as a result of national regulation, etc. The core point should be to ensure that all patients in Europe have access to prevention and treatment of disease according to the most modern principles.

Introduction

Lif thanks the Commission for the opportunity to submit the Association's comments on the interim conclusions of the Pharmaceutical Sector Inquiry - Preliminary Report. The preliminary report was published on November 28, 2008 and gives the interim results of

the extensive investigation of the pharmaceutical industry initiated by the Commission on January 15, 2008. Lif represents the researching pharmaceutical industry that markets medicinal products on the Danish medicines market.

In January, 2008, the Commission instituted an investigation on the pharmaceutical industry on the basis of having observed that there had been a decline in the number of applications for marketing authorisation for novel medicinal products, and that market penetration by generics was not going as rapidly as the Commission had originally expected. The conclusions of the Pharmaceutical Sector Inquiry - Preliminary Report are based on overall European considerations which may be summarized in that companies in the pharmaceutical industry apparently use the patent system to restrict the introduction of new products and that the researching pharmaceutical industry thereby creates a range of barriers to the introduction of generic drugs irrespective of the expiry of patents.

Joint European response to criticism of the use of patents

By way of introduction, it should be noted that Lif supports the points raised in the response submitted to the Commission by EFPIA, including the three points raised below relating to the European patent system.

Strong patent protection is the bedrock of R&D: There is no evidence that patents hinder innovation

This report's central thesis is overly simplistic and unfounded and reveals a lack of understanding of how the patent system works. Without a strong system of intellectual property rights and an ability to enforce and defend patents, it would be even more difficult to fund high-risk pharmaceutical research.

Taking the number of new molecular entities as the sole indicator of innovation is a narrow approach that fails to reflect the value of advances in biomedical science, vaccines, new salts and other incremental improvements. Notwithstanding this qualification, the pharmaceutical industry itself has expressed concerns about a certain productivity decline in research. The well-documented reasons for this productivity decline are many, including: more complex scientific targets, increased costs and higher attrition rates in late stage development due to a greater risk aversion by health authorities, and negative signals for reimbursement authorities unwilling to pay for incremental innovation.

Lif strongly supports the proposal formulated by EFPIA stating that the Final Report should contain policy recommendations on how the current patent system can be improved to reduce costs and increase legal and commercial certainty for all parties. These should include: a mechanism to resolve patent disputes before generic launch, adoption of the European Community Patent and the creation of a unified, specialised litigation system in Europe, and a streamlining of the opposition procedure of the European Patent Office.

Delays to generic entry are overstated and wrongly attributed

The research presented in the Preliminary Report confirms that generic entry has accelerated over time and is especially fast in relation to high value blockbuster medicines. It also notes the relevance of regulatory factors – market approval and reimbursement decisions – in delaying market access of generic drugs. Nevertheless, the press announcements on the release of the Preliminary Report focused predominantly on the estimate that in the period 2000 to 2007, approximately €3 billion across the 17 countries sampled could have been saved, had generics entered the market immediately upon the expiry of the innovator's exclusive rights. The inference that much of this expenditure was unduly pocketed by the innovative companies through recourse to a so-called toolbox of tactics to unfairly impede generic market entry is unfounded. The quicker entry in relation to high value products and the variations across countries and time suggest that the commercial attractiveness of the product and the prevailing regulatory systems are the principal factors influencing the timing of generic entry.

The European Courts have established that intrusion into intellectual property rights can only be justified in the most "exceptional circumstances" and any attempt to expand this notion to challenge common commercial practices will have a chilling effect on innovation. The Final Report should rather address what many stakeholders see as the most significant market entry barrier, namely, the sheer complexity and diversity of the applicable national regulatory regimes. Whereas the Preliminary Report has focused on alleged access delays of generic medicines, such delays are much more significant for innovative medicines. Streamlining processes to provide faster access to therapeutic advances is in the interest of patients and Europe's competitiveness.

The Potential for savings from more generic competition is largely ignored

The industry has long advocated a competitive off-patent market in Europe as the corollary to strong patent protection and reward for innovation. It is paradoxical that Europe pays significantly more for generics but less for innovative drugs that the United States. There is an increasing body of independent literature attesting to the potential savings to be gained from more efficient generics markets. The Preliminary Report cites the Dutch reference policy favouring the lowest price generics with a limited period of exclusivity which resulted in immediate price reductions in the region of 80%. If repercuted across Europe, such mechanisms would result in savings that would vastly exceed the estimated benefits of immediate generic entry.

Stimulating price competition amongst generics and ensuring that those savings are in large part passed on to the ultimate payors should be the major focus of the Final Report.

Scope of the preliminary report

The conclusions of the preliminary report should be regarded in the light of the objective at the European level of ensuring access by patients to novel, effective medicinal products, thus also creating the requisite basis for increased use of generics. Lif fully shares the fundamental objective of European citizens always having access to new innovative medicinal products and that access to these should, *inter alia,* be ensured by way of properly functioning generic markets for products where patents have expired, hence implicitly ensuring due economic use of medicines in individual national markets.

The Pharmaceutical Sector Inquiry - Preliminary Report shows that the generics market in Denmark works well with rapid access for generic suppliers, with low prices as a result. This is unfortunately not sufficient to ensure that Danish patients also gain the desired access to new, innovative medicinal products since there are various internal barriers to this in the Danish health service. These obstacles are reviewed below.

Pharmaceutical industry research effort in Denmark

Considering its population, Denmark is one of countries with the most intensive research on drugs. Another factor is that relatively speaking, Danish medicine exports place Denmark amongst the countries' with the greatest exports, with approximately seven percent of all Danish exports to other countries attributable to pharmaceutical products.

The pharmaceutical industry accounts for almost 30 per cent of total commercial research investment in Denmark. This means that out of all the sectors, the pharmaceutical industry does the most research. The pharmaceutical industry invested more than DKK 7.8bn in research in 2006, corresponding to approximately 0.5 percent of the Danish gross national product. The pharmaceutical industry contribution accounts for a quarter of the Barcelona target of total commercial investment in research and development to account for two percent of GNP in 2010. The pharmaceutical industry is the only sector that has been able to increase the share of GNP used for research throughout the 1990s and right up to 2006.

In other words, the pharmaceutical industry plays a significant part in the Danish national economy. The interim conclusions in the Preliminary Report could have an unfortunate impact on the Danish pharmaceutical industry, since the general suspicions cast on the pharmaceutical industry in the Preliminary Report are incorrectly based which could undermine the companies' credibility, and thus the Preliminary Report could significantly change companies' trading conditions and the basis for their business.

Competition in the Danish pharmaceuticals market

Lif is aware that the Commission's initiative is intended to investigate competitive conduct amongst researching pharmaceutical companies, and is not therefore considering these issues with respect to the widespread range of regulation that naturally greatly impacts on the functioning, organisation and effectiveness of the market. This may con-

stitute a natural delimitation, but it also increases the potential for an extensive series of errors since competition in the pharmaceutical markets is widely affected by specific regulation of the market. Similarly, the preliminary report makes no assessment of the conduct of generic companies in the market or the problems arising from parallel imports.

With respect to generic competition, Lif's view is that the generics market in Denmark works exceptionally well with significant, rapid competition on pricing in consequence despite the limited market. And indeed a market that works well without the direct official regulation of prices found in other countries. This means that the development of the generics market in Denmark runs counter to the Commission's conclusions of the corporate "toolkit" of barriers to access.

Lif also feels that the Danish generic market is unreasonably favoured at the expense of new innovative drugs since the regulatory authorities are increasingly using the reimbursement system as well as the recommendation lists to treat the various options for treatment differently. This involves a unilateral focus on pricing which does not allow (or if so only to a limited extent) for an assessment of whether there would be better treatment outcomes or fewer adverse effects by opting for treatment with medication that is not subject to generic competition.

Fewer new medicinal products?

One of the core conclusions of the Pharmaceutical Sector Inquiry - Preliminary Report is that the pharmaceutical companies use the patent system to block access to new, innovative medicinal products and thus reduce access by patients to improved potential treatments.

Lif feels that the general trend in the pharmaceutical industry over the past decade, with many patents expiring, will contribute to changing the research profile of several pharmaceutical companies. We are currently seeing extensive generic competition in several major therapeutic areas which can make it difficult to introduce medicinal products at higher prices, unless companies can demonstrate considerable added value. And while the regulatory authorities continue to play down added value, or ascribe it insignificant value, this naturally provides less incentive to bring new products to market in a given therapeutic area.

Focus on barriers to access to medicinal products by patients

It is Lif's view that many of the new drugs generally reaching the market by way of the common European approvals system face a series of internal barriers in the health service. This unfortunately helps delay take-up of the new products.

Since the overall objective is to ensure that European patients have access to new, innovative medicinal products, also by way of effective generics markets, Lif would point to the distortions that arise from the regulatory authorities not wishing to use the reim-

bursement system to promote the use of new drugs, irrespective of the valuable enhancement of indications or new active agents which make for better efficacy than the active agents actually used for treating or preventing a given condition.

Lif would urge the Commission to direct its focus on the barriers arising from national regulation, etc., since the core issue is access by patients to new, innovative medicinal products. Lif's fundamental assessment is that the general priority given to older products in the recommendation lists, minimizing the value of new products and especially widespread "silo thinking" makes the dissemination of new innovative medicinal products more difficult.

Yours sincerely,

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