Pharmaceutical Sector Inquiry – Preliminary Report

Fact Sheet
"Regulatory Framework"

The pharmaceutical industry must comply with three main sets of rules, covering:

1) patent law and enforcement,
2) marketing authorisation, and
3) pricing and reimbursement.

Companies sent a large number of comments on the shortcomings they perceive in these three areas.

1) Patent Law and Enforcement

Patent protection grants companies exclusivity to commercially exploit their invention over a certain period of time in order to reward their efforts. Pharmaceutical companies rely heavily on patents to protect their inventions. Today, it is still not possible to obtain a single patent which is valid and enforceable in the whole EU. The European Patent Office grants European patents that need to be validated in each Member State and can only be enforced before the national court concerned under national procedural rules.

The sector inquiry found that both generic and originator companies support the creation of a single Community patent to amend the current system consisting of a bundle of national patents.

Originator and generic companies also support the creation of a unified and specialised patent judiciary in Europe replacing the existing national patent litigation system, which is fragmented and costly. Three findings of the sector inquiry suggest this would result in significant cost and efficiency improvements:

- First, obtaining a Community patent which is immediately enforceable throughout the Community will be much cheaper than the current alternatives of obtaining a European patent and then validating it in 27 Member States or of obtaining 27 national patents.
- Second, litigation about the same medicine was often initiated in many different Member States, thus multiplying costs. The total cost of patent litigation in the EU - relating to the 68 medicines on which litigation was reported for the period 2000 to 2007 - is estimated to exceed € 420 million. A unified patent judiciary would allow one court decision to resolve the patent issue for all Member States.
- Third, in 11% of the final judgements reported, two or more different courts in different EU Member States gave conflicting final judgements on the same issue. A unified patent judiciary would instead ensure Europe-wide judicial consistency and legal certainty.

Many generic and some originator companies also called upon the European Patent Office to ensure that patents granted are of high quality and to effectively counter patent strategies that may result in unnecessary delays.

2) Marketing Authorisation

Pharmaceutical companies need to obtain a marketing authorisation for each new medicine, proving that it is safe, effective and of good quality, before it can be sold on the market. Marketing authorisation procedures have been harmonised in Europe.

Many companies reported administrative obstacles in marketing authorisation procedures, generally blaming the lack of adequate resources in certain marketing authorisation bodies. Generic companies especially point to discrepancies in the assessment criteria and to the disclosure of information to competitors. Moreover, they point to the fact that some regulatory bodies consider whether the generic product may infringe the originator company's patents (so-called "patent linkage" is considered unlawful under Regulation (EC) No 726/2004 and Directive (EC) No 2001/83).

Certain originator companies also expressed their support for further international harmonisation of marketing authorisation procedures, especially between the EU and the United States.

3) Pricing and Reimbursement

Generally, pharmaceutical companies need to obtain a decision by national authorities on the pricing and reimbursement level of each new medicine. Each Member State has its own pricing and reimbursement rules and procedures.

Originator companies argued that national pricing and reimbursement procedures cause delays and uncertainty and could shorten the period during which they enjoy exclusivity and consequently reduce their expected reward. They mainly attribute delays and uncertainties to the fragmentation of the national decision making-process, the increasing use of health technology assessments and the wide-spread use of cross-border reference pricing (which e.g. uses a basket of reference prices in other Member States).

Generic companies also complained about delays resulting from national decision-making procedures and often also from the additional requirements for obtaining pricing and reimbursement status for generic medicines (e.g. information on the patent status or on the complete equivalence between the originator and generic product). These additional requirements would give opportunities for originator companies to intervene before national authorities in order to delay generic entry.

For further information on the Pharmaceutical Sector Inquiry, please consult:
http://ec.europa.eu/comm/competition/sectors/pharmaceuticals/inquiry/index.html