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Antitrust: preliminary report of sector inquiry into pharmaceuticals

Opening remarks at press conference

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Ladies and gentlemen,

Today the Commission publishes its preliminary report on the competition sector inquiry into the pharmaceutical sector – and we find that competition in this industry **does not** work as well as it should.

Our focus has been on whether Europe is maximising innovation and affordability in this sector. This matters greatly because more innovation and more affordable medicines would mean better lives and savings for patients, including all of us here today, and governments.

The preliminary report provides an in-depth description of the sector. It really gets to the heart of how companies behave in the patent and other regulatory systems and the mechanisms by which medicines reach consumers.

Several of the most damaging practices which delayed or blocked market entry of competitors include:

1. **Patent clustering**, where a company forms a dense network of patents around a medicine. The worst example we found of this method was 1300 separate patent filings, across the EU, for a single medicine.
2. A **large number of litigation cases** over patents, which originator companies invoked against generic companies. On average, these cases took three years to resolve, and originator companies lost a clear majority of cases.
3. **Patent settlements** which constrain market entry of generic companies, and sometimes involve direct payments from originator companies to generic companies. In total, these payments amounted to more than € 200 million

Interventions before regulatory bodies, which have to approve generic products and decide on their pricing and reimbursement status. These interventions slow down the approval process by 4 months on average.

Where successful, these practices result in significant additional costs for public health budgets – and ultimately consumers – and reduce incentives to innovate.

In contrast we have found that one year following entry by generic medicines, prices are almost 20% lower, and 25% lower after two years. In a rare number of cases prices can drop as much as **80-90%.**

To bring these various issues into an even clearer perspective let me explain the scale of the market and the problems

There are tens of thousands of prescription and non-prescription medicines on the market, and more people are taking more medicines as our population ages. Medicines account for annual sales of over €214 billion at retail prices – approximately €430 per EU citizen in 2007.

Using a sample of medicines across 17 Member States that faced loss of exclusivity in the period 2000 to 2007 we found €14 billion in savings after generic entry, and that delays to entry cost consumers around € 3 billion on that sample. You can already see the savings available from good generic competition.

We also found that originator companies engage in so called defensive patenting strategies to block or delay competition from other originator companies. What could summarise our concerns better than the internal strategy document of a large originator company. It reads: "We identify options to obtain or acquire patents for the **sole** purpose of limiting the freedom of operation by our competitors."

Is that really the outcome we want from a strong intellectual property rights system? I don't think so.

While our initial observations about competition in the sector are confirmed, I stress that the preliminary report does not seek to identify wrongdoing by individual companies. Nor does it advocate regulatory solutions to any problems. That may come at a later stage.

This report is simply a progress report that offers new opportunities for your feedback and views. Indeed we are launching a public consultation today that will remain open until 31 January, before we go on to publish the final report in spring 2009.

I should also specifically mention a point of strong agreement between the key stakeholders and the Commission.

Stakeholders, including both generic companies and originator companies, have called for a single Community patent and the creation of a unified and specialised patent judiciary in Europe. These calls are supported by the findings of the report.

Let me conclude saying we now have a solid view of what is happening in the sector and why. We will continue to consult and analyse our findings. You will not be surprised if I tell you that the Commission will not hesitate to open antitrust cases against companies where there are indications that the antitrust rules may have been breached.

I hope the strong spirit of cooperation we have enjoyed so far in this inquiry continues.