

European Commission
Directorate-General for Competition
Antitrust Registry
1049 Brussels
BELGIË

Your reference: 39514
Our reference: MK/MK/2009/15558

Regarding: Preliminary report on the Pharma Sector Inquiry

Date: 30 January 2009

Dear mrs. Kroes,

Nefarma, the Dutch Association of Innovative Medicines, welcomes the opportunity to contribute to the examination of competition and innovation in the pharmaceutical sector, a sector vital to the health and welfare of Europeans and a leading player in Europe's innovative economy. The preliminary report by DG Competition unfortunately fails to address real issues impeding patient access to innovative medicines and the urgent need for a more efficient generic market in Europe. Therefore, Nefarma would like to express its opinion on the following issues:

1. Regulatory hurdles
2. Innovation and patent laws
3. Delay of generic entry
4. Prices of generics and the Dutch 'transition' agreement.

Regulatory hurdles

Nefarma would like to stress that the preliminary report does not take into account the vast set of regulatory rules for pharmaceuticals, sets that - to make matters worse - are different in basically every EU member state. Regulation regarding market access, prices & reimbursement and marketing strongly influence the development of the pharmaceutical market. We would therefore like to make a plea to DG competition to enhance the introduction of one set of comprehensive regulatory rules for the whole of the EU on this matter.

Innovation and patent laws

Nefarma welcomes the conclusion that patents are key to pharmaceutical innovation and should be protected. We are however surprised by the negative remarks regarding the right of the industry to use perfectly lawful practices – such as patent portfolios, patent litigation and the release of improved medicines. To our opinion these are essential for innovators to protect their huge investments in R&D. The present laws regarding competition are working as they should. We want to emphasise that whenever abuse or illegal agreements are established by the EC, national competition authorities or private parties, it is in the best interest of the pharmaceutical sector that these practices are dealt with in the appropriate manner.

Delay of generic entry

We can't find any evidential basis for the reports' statement of €3 billion cost due to the delay of generic entry. The findings in the report show generic entry is fast - a weighted average of 7 months, under 4 months for highest value medicines and even 2.5 months in some countries. Since the generic manufacturers themselves state that regulatory delays are a reason for not entering the market one day after a patent expires, we would once again like to stress the importance of one set of comprehensive regulatory rules.

Prices of generics

Regarding the prices of generics, analysis of competition in this market and its impact on healthcare budgets is *impossible* without considering the impact of state regulation or the inflated prices of generics, something which the preliminary report does not take into account.

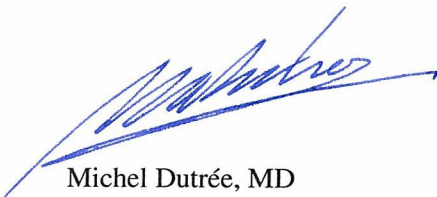
The report states that swifter generic entry could result in an amount saved of €3 billion (8 years, 17 countries), i.e. €375 million a year. The report fails to emphasise that in the Netherlands, we have achieved greater savings, almost €400 million in one year, on only 33 medicines, simply by promoting active price competition between generics.

Nefarma has been - and still is - closely working together with the other relevant parties to achieve this result. We therefore kindly offer to share our expertise with DG Competition in order to achieve a similar agreement for the European Union as a whole.

Nefarma would welcome a situation in which DG Competition takes these matters into account when further investigating the pharmaceutical sector.

Furthermore, we would also like to express that Nefarma shares the viewpoints on this subject expressed by EFPIA, the European Federation of Pharmaceutical Industry and Associations.

Yours sincerely,



Michel Dutrée, MD
Director general Nefarma