

30 January 2009

European Commission
DG Competition
Jozef II straat 70
1000 Brussel
BELGIË

Att: Mr Philip Lowe

Sent via e-mail: COMP-SECTOR-PHARMA@ec.europa.eu.

Re: European Commission - Pharmaceutical Sector Inquiry Report

Dear Sir / Madam,

The National Association of Pharmaceutical Manufacturers (NAPM) welcomes the sector inquiry into the EU pharmaceutical market and the publication of the findings of the preliminary report by the European Commission.

1. EU Findings

The findings, notwithstanding their focus on the European market, are most relevant to the South African pharmaceutical sector and hence supported by the NAPM. Inefficiencies in the market and obstacles to access to affordable generics medicines brought on by the strategies observed by the European Commission namely interventions in national regulatory procedures for approval of generic medicines, life-cycle strategies for follow-on products, strategic patenting and to a lesser extent patent litigation and patent settlements are also present and evident locally.

2. South African Generic industry

The biggest challenges facing the generic industry in South Africa are the disparaging of generic medicines by originator companies and the delays in the registration approval process. The biggest threat is the increasing trend of multinational companies launching their own generics at least three to four years before patent expiry.

Disparaging of generics

Multinational companies deliberately mislead healthcare professionals and the general public regarding the safety, quality and efficacy of generic medicines by questioning the theory and science behind bioequivalence, the registration process and substitutability.

Delays and interventions in the generic regulatory process

In terms of the approval process for generic medicines, multinational companies hold the Medicines regulatory authority ransom by claiming patent infringement, copyright issues and data protection, consequently creating a barrier to rapid access to affordable generic medicines and at the same time securing longer marketing exclusivity and revenue streams for their medicines.

Life-cycle Strategies for follow-on products

In the last few years, an increasing number of multinational companies have launched their own generics, pre-patent expiry, by either the creation of a generic arm or the use of an existing generic subsidiary of another multinational company. The aim is to switch patients to the “new” version before the ‘real’ generic becomes available. This now becomes the first to market generic, capturing major market share. Consequently, ‘real’ generic companies are reluctant or prevented from entering the market, jeopardising the long-term sustainability of the generic industry and hampering long term competition.

3. Conclusion

These practices delay or block the entry of generic medicines resulting in healthcare systems and consumers paying more for their medication, impacting to a greater extent on poor communities and developing countries. There is still tremendous potential for even greater generic uptake in South Africa and effective ways to speed up both the registration and the uptake of generic medicines should be investigated, as a means of making healthcare more affordable and accessible to patients worldwide.

In conclusion, the NAPM would like to emphasise the need for urgent reform in the pharmaceutical sector that will deal with the loop holes that perpetuate such strategies while opening up the market to authentic generic medicines competition.

Such measures include improving patent quality, patent assessment procedures, education of patients and medical professional as well as the implementation of measures to promote the prescribing, dispensing, and the use of generic medicines.

Thank you

Yours faithfully

Raseela Inderlall
Executive Director: **NAPM**

Notes:

NAPM is a Section 21 Trade Association consisting of South African Pharmaceutical and Generics based manufacturers and distributors. NAPM, a voluntary non-profit organisation, was established in 1977 and is the longest standing Association for the Pharmaceutical Manufacturing Industry in South Africa.

The NAPM is focused on the supply of generic medicines, taking into account the environmental needs of the country and its members. By increasing the supply of generics and promoting the market as a whole, the NAPM will also assist the government in its policy of making medicines more affordable and more accessible to all South Africans.

Some of the NAPM's functions are to ensure that the Pharmaceutical sector plays a constructive role in our country's economic growth, development and transformation and thereby create an environment in which the sector can thrive, expand, be competitive and enhance access of medicines to all of our country's citizens. The NAPM's members are manufacturers and suppliers of drugs, mainly generics in South Africa. The NAPM represents these members in interaction with various stakeholders including Health, Trade & Industry and others.