Dutch competition authority ACM publishes a sector report on the impact of biosimilars on competition between TNF-alfa inhibitors

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Introduction

The Dutch competition authority, ACM, initiated a market study in 2018 into the effect of the introduction of biosimilars on the competition between TNF alfa inhibitors. TNF-alfa inhibitors are biological medicines that are mainly used by rheumatoid arthritis patients, but also by patients with other autoimmune diseases. The ACM decided to conduct a sector study into this group of medicines because TNF-alfa inhibitors are an important medicines group with a high turnover, high numbers of patients and persistently high prices, while there are relatively many therapeutic alternatives available. By investigating the functioning of the market in this segment, the ACM also wanted to learn lessons for comparable markets of pharmaceutical products.

The ACM did not find any clear violations of competition law during its market study but does not rule out the possibility that conditional discounts for originator medicines could be found restrictive of competition. In the report, ACM concludes that there is no single comprehensive solution to strengthen the functioning of the pharmaceutical markets. According to the ACM, effective market forces and competition based on a healthier market structure must be achieved in the interplay between hospitals, health insurers and regulation; by disseminating the best practices of hospitals and health insurance companies, by creating a more effective market environment and by a regulatory framework contributing to reducing the gap between manufacturers' list prices and net purchase prices.

Significance of TNF-alfa inhibitors

Generally, hospitals buy TNF-alfa inhibitors for their patients. In the period prior to the expiry of the patent, TNF-alfa inhibitors were the biggest burden on the hospitals' medicines budgets. With some 50,000 patients, the total expenditure on TNF-alfa inhibitors in the Netherlands amounted to almost € 550 million in 2016. In recent years, the patents for three of the five originator TNF-alfa inhibitors have expired. As a result, competitors were able to introduce generic variants of these medicines, so-called biosimilars.

ACM considers competition from biosimilars not only important for the affordability of TNF-alfa inhibitors, but also for other biological medicines for which patents will expire in the future. Hence, the ACM decided to conduct a sector inquiry into the market developments of TNF-alfa inhibitors before and after the expiration of patents.

Competition following market entry of biosimilars

The ACM reports that the expiry of originators' patents has led to strong price competition between the originators and the biosimilars. The expiration of patents and the entry of biosimilars have led to decreases in the net purchase prices of three important TN- alfa inhibitors. As a result, hospitals have been able to make substantial savings on the purchases of these medicines.

However, the ACM identifies a number of risks for the sustainability of this competition in the long run. It has found that biosimilars are not always able to gain sufficient market share. This applies in particular to products that patients administer themselves with a subcutaneous injection. Hospitals incur switching costs because they have to spend time and effort on internal coordination and informing patients. They also often have a residual group of patients who are unable or unwilling to make the switch to a biosimilar (5-20% on average). For this residual patient group, there is a risk that hospitals will no longer be able to purchase the original drug at a favourable price if they also purchase biosimilars, given the fact that discounts will also be less if lower volumes are being purchased. This can be a reason for hospitals to continue to buy only the original drug.

In the case of infusion medication, these barriers to switching are less pronounced because the hospitals have more control over the changeover. ACM expects that if the market shares of the biosimilars remain limited in the longer term, there is a risk that biosimilars manufacturers will withdraw from the Dutch market, which in the end will lead to price increases.

Promoting competition

The ACM concludes in its report that hospitals, health insurers and the government can contribute to promote competition in this market:

- The Ministry of Health, Welfare and Sport can contribute by adjusting the price regulation in such a way that the suppliers of the original medicines cannot demand a much higher price for the residual group of tied patients.
- Health insurers can take into account the switching costs associated with choosing a biosimilar in their reimbursements.
- Hospitals can contribute by tendering on the basis of fair opportunities for all providers and a clear procedure that is not deviated from in the interim.

The ACM will contribute to promoting competition in the pharmaceutical sector by, among other things, investigating signs of foreclosure through the use of conditional rebates and, where appropriate, by enforcing competition rules. Hospital purchasers are invited to report to ACM if they are faced with discount structures that impede the entry of generic products.

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The report is published in Dutch at the ACM's website: https://www.acm.nl/sites/default/files/documents/2019-09/sectoronderzoek-tnf-alfaremmers.pdf. Please contact the authors at Pauline.Kuipers@twobirds.com or Janneke.Kohlen@twobirds.com if you would like to receive an informal English translation.