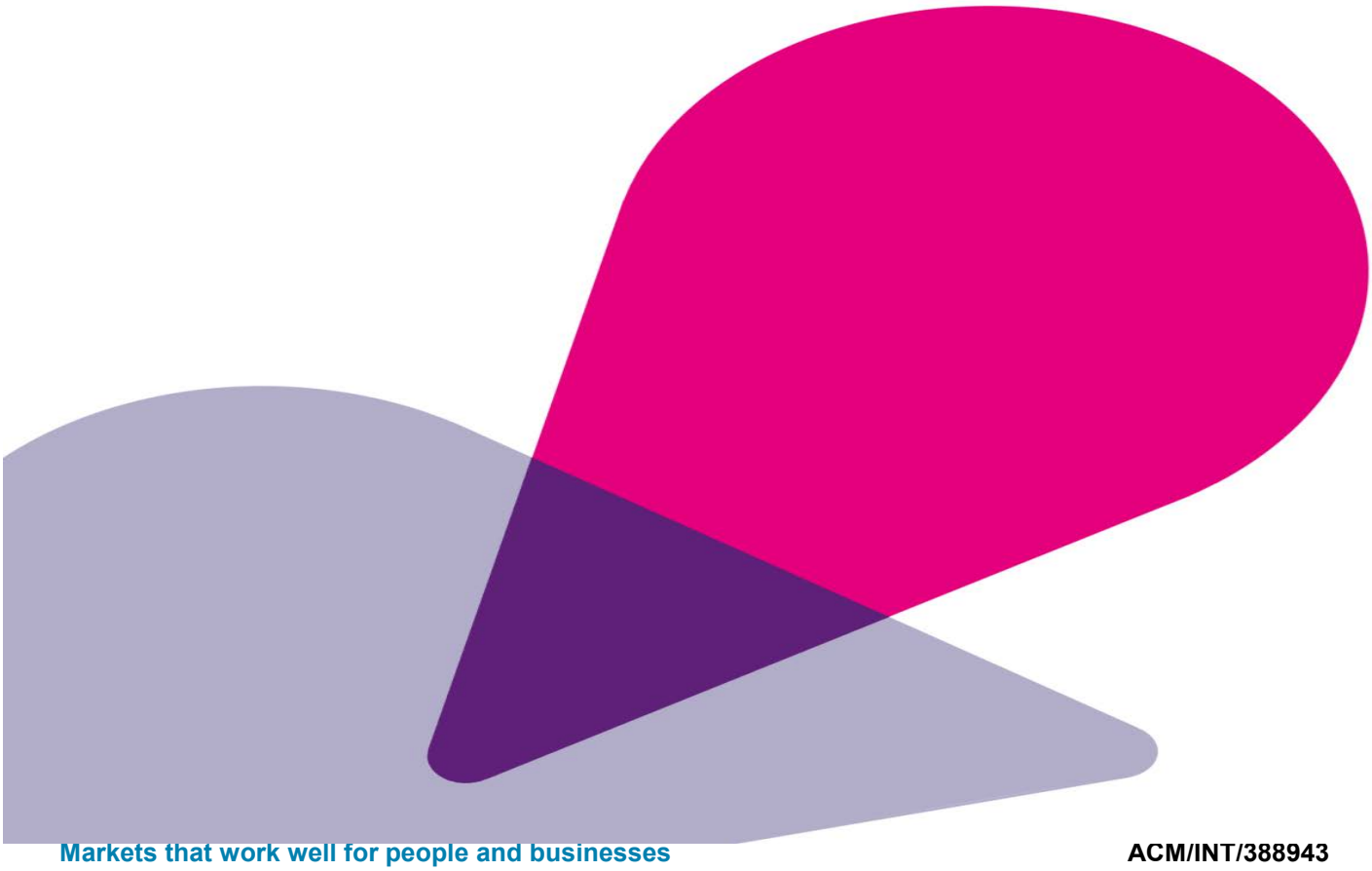
Authority for Consumers & Markets

Study

Sector inquiry into TNF-Alpha inhibitors

Competition before and after the entry of biosimilars

Executive Summary



0 Executive summary

Sector inquiry by ACM into competition in TNF-alpha inhibitors

In 2018 and 2019, ACM undertook an own-initiative sector inquiry into competition in TNF-alpha inhibitors. TNF-alpha inhibitors are biological prescription drugs that are mainly used by patients with rheumatic disorders, but also for psoriasis and Crohn's disease, among other conditions. They are the category of drugs with the largest budgetary impact in the Netherlands. In 2016, TNF-alpha inhibitors represented a total turnover of 517 million euros, and 50,000 patients in the Netherlands use them every year. The costs per patient per year amount to approximately 11,000 euros in the period under review.

At this moment, a total of five medicines and around thirteen brands of drugs based on those medicines, including the biosimilars (generic biological drugs), are involved. Between 2015 and 2018, the patents on the medicines for three TNF-alpha inhibitors expired, enabling biosimilars to enter the market. Secondary patents are still in place, for example on auxiliary agents.

Despite the number of medicines and the introduction of biosimilars, the list prices of TNF-alpha inhibitors remained relatively high for a long time, while the uptake of biosimilars remained low in comparison with biosimilars of oncological drugs, for example. This prompted ACM to study the competitive process in the drug group of TNF-alpha inhibitors before and after the expiry of patents on the original medicines. We distinguish two forms of competition in this inquiry:

I. Competition between different medicines
II. Competition between the original version and biosimilar versions of the same medicine

Competition among different versions of the same medicine is only possible after the expiry of the patent on the medicine. Competition between different active ingredients is possible both before and after the expiry of patents.

With this sector inquiry, ACM wishes to contribute to a market for TNF-alpha inhibitors that works well for people and businesses. In addition, the sector inquiry offers general lessons regarding the market dynamics in biological drugs that fall under the hospital budget. In this report, ACM presents its findings from the sector inquiry without any legal characterizations, such as, for example, regarding the market definition, economic dominance, or abuse of dominance. However, ACM may use the data from the sector inquiry as input for legal assessments in possible future cases.

Main conclusions of the sector inquiry

1. In the period before the entry of biosimilars, price competition between different active ingredients was limited.

ACM establishes that the net purchasing prices that hospitals pay for TNF-alpha inhibitors hardly fluctuated before the entry of biosimilars and that these net purchasing prices were generally only marginally below the list price. Limits on price competition are largely explained by the medical practice that existing patients are not switched to a different medicine without medical reasons. Given the often chronic use of TNF-alpha inhibitors, this practice significantly restricts any room for competition.

2. Competition of biosimilars ensures substantially lower net purchasing prices of TNF-alpha inhibitors

After the expiration of the patent on the three originator medicines and the market introduction of biosimilars, the discounts offered to hospitals rise to well over 70% of the list prices for each of the brands of the same medicine. However, the speed and steepness of the price drops differ per TNF-alpha inhibitor. When the first patent on a TNF-alpha inhibitor medicine expired in 2015 (infliximab), price reductions took off gradually at first, and eventually amounted to 60%. The medicine the patent of which expired most recently (adalimumab), showed a much steeper price drop almost immediately after the introduction of biosimilars.

The gradually growing price competition can be explained by the fact that the medical specialists involved in prescribing TNF-alpha inhibitors and their scientific associations initially were reluctant to switch existing patients from an originator to a biosimilar version of the same medicine. Results of medical studies contributed to the consensus that existing patients, too, can safely be switched.

3. The market share of biosimilars that have to be administered subcutaneously is lagging behind

Despite the price pressure exerted by biosimilars, the market share of biosimilars keeps lagging behind in some cases. In two out of three cases where medicine patents expired, manufacturers of the originator drugs have succeeded in remaining the biggest supplier by far. Several possible explanations exist for the limited entry of biosimilars. In the first place, switching patients to a different version of a medicine entails a costly effort on the hospital's part. This is especially true for medicines administered by the patients themselves by means of a lancing device (subcutaneously). Patients need to be educated, and need to become accustomed to a different lancing device. Therefore, hospitals often do not realize a full switch of 100% with these drugs. A residual population of five to twenty percent per hospital usually remains on the originator product. Furthermore, the costs of switching offer the originator product a structural advantage: with equal net prices between originator and biosimilar brands but with extra costs for switching, the hospital may be more likely to continue to choose the originator.

Another possible explanation for the limited entry of biosimilars lies in the conditional discounts that originators use. Such a discount system gives the hospital an incentive to continue to use the originator's drug for almost all patients. If a hospital *does* want to switch to a biosimilar, it will pay a

much higher price for the group of patients who will not or cannot switch. This is because, if the hospital switches, the discount will be cancelled entirely while the original drug will still be necessary for the residual population. This is another reason why the switch to a biosimilar may be financially unattractive to the hospital, even though the biosimilar manufacturer offers a lower net purchasing price than the originator product.

What can hospitals do?

Purchasing hospital (whether or not within a purchasing group) play a crucial role in creating a level playing field on the markets for biological drugs. In this inquiry, ACM identified several good practices that contribute to this level playing field, and that are worth following. These good practices are:

I. **Procurement based on equal opportunities:** Creating a tender process with fair opportunities for all suppliers. This should include, in any case, a clear tender process with clear rules that will be enforced.
II. **Supported preference policy** to benefit from the room for competition when prescribing to new patients, in the case of medical equivalence of different active ingredients. A large majority of the hospitals has already been doing so to varying degrees.

What can health insurers do?

The contracts between health insurer and hospital are crucial for the financial incentives that hospitals experience in their purchasing policies. ACM establishes that health insurers vary in how they see their roles, especially when it comes to stimulating competition on the market between originators and biosimilars. ACM also sees that health insurers playing an active role help create a healthy market structure with long-term competition by biosimilars. For example, in specific cases, several health insurers provide a higher reimbursement for biosimilars than for originators. Health insurers are able to flesh out this role further by:

I. **Compensating (at least temporarily) the originator's first-mover advantage.** This could be in the form of a higher (temporary or otherwise) reimbursement for the biosimilar. In this way, hospitals are able to finance the extra costs that may come with a switch (for example having to pay the list price for the residual population).
II. **Further improvement of incentives for efficient procurement and for use of drugs.** ACM sees that health insurers actively think about the incentives that their reimbursements for effective procurement have. ACM encourages health insurers to continue to do so. Forms of shared savings between health insurers and hospitals may positively contribute to appropriate use, and to taking away margin differences, that compel hospitals to prescribe more expensive drugs with higher margins.

What can the government do?

Originators can threaten that, if a hospital switches to a different version of the medicine, the list price must be paid for the residual population that can or will not switch to a biosimilar. The stronger the intensity of the threat gets, the larger the difference is between the actual net purchasing price (the average price per daily dose for a specific drug that the hospital pays on the basis of the specific

volume consumed), on the one hand, and the pharmacy purchasing price (PPP) on the other hand. The PPP is capped by the WGP-max price laid down in the Dutch Medicine Prices Act (in Dutch: *Wet Geneesmiddelenprijzen* or WGP), which is based on reference prices from a number of neighboring countries.[1] A large difference between the WGP-max price and the net purchasing price (such as of 50% or more) gives the originator the concrete ability to use this price difference as leverage vis-á-vis the hospitals.

Therefore, ACM recommends the Ministry of Health, Welfare and Sport (VWS) to adjust the price regulation on this point in order to reduce the threat of high prices for the residual population, and, in that way, the risk of exclusion of biosimilars.

What will ACM do now?

The findings from this sector inquiry are reason for ACM to contribute actively to creating a level playing field between originator drugs and biosimilar drugs. To that end, ACM will pay particular attention to those situations in which the originator has a strong incumbent's advantage vis-à-vis the biosimilars. Switching costs, the existence of a residual population, and, the thereto-related hospitals' preference of keeping the originator when prices are comparable play an important role in those situations.

ACM is of the opinion that especially the practice of offering conditional discounts by originators to hospitals may be anticompetitive in certain circumstances. If there are reports of practices that might have an exclusionary effect, ACM will investigate such reports, and will take enforcement action if necessary.

[1] In principle, without a contract with the pharmaceutical manufacturer, the hospital pays the pharmacy purchasing price (PPP) also known as the list price. The list price charged by the manufacturer is capped by the WGP-max price (maximum price based on the Dutch Medicine Prices Act (*Wet Geneesmiddelenprijzen* or WGP)). This WGP-max price is determined on the basis of the list prices in a number of neighboring countries.