Pharma sector on Dutch competition regulator's radar: more antitrust enforcement imminent

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High prices in the pharmaceutical sector have caught the eye of various regulators, including the Dutch Authority for Consumers and Markets (ACM). Having identified prescription drug prices as one of its key priorities for 2018-2019, the ACM appears to be considering how to apply competition rules to this sector. Additionally, it has published two working papers on excessive drug prices and recently launched a sector inquiry into rheumatism drugs which, according to the ACM, have the highest costs for both hospitals and patients. In the sector inquiry, information will be requested from hospitals, health insurers, purchasing groups, patient groups, and pharmaceutical companies to get a better picture of how competition works in this particular market. The outcome of the sector inquiry could be used for upcoming antitrust enforcement. Pharmaceutical companies are advised to prepare for targeted investigations and to start flagging any possible competition compliance risks.

In June 2018, the ACM launched a sector inquiry into TNF inhibitors, a type of drug mainly used to treat rheumatism, to determine whether competition is working optimally in this market. The reason for starting the sector inquiry was the consistently high prices for these drugs, despite the various alternatives available. The ACM intends to "look into what choices between different alternatives (their active ingredients) prescribers have, and into the competitive landscape once a drug's patent has expired". The outcome of the sector inquiry may result in specific recommendations to market participants, alongside potential targeted investigations into abuse of dominance by pharma companies.

The sector inquiry follows two working papers the ACM published in 2018. The first working paper, titled *"Reconciling competition and IP law: the case of patented pharmaceuticals and dominance abuse"*, was published by ACM officials, in a personal capacity, in March 2018. With regard to excessive pricing, the working paper found that the United Brands test, which requires an examination of: (i) the relationship between costs and prices, and (ii) the unfair nature of the prices to determine excessive pricing, also holds true for the pharma sector.

The working paper identified two points in the application of this test to IP-protected pharmaceuticals. First, high prices usually encourage market entry, thereby promoting dynamic and allocative efficiency. However, for IP rights this is not necessarily true; IP rights generally constitute market barriers on their own, thus limiting the reliability of high prices as a signal for entry. Second, qualifying high prices as excessive could affect innovation incentives in the pharma industry. This may be resolved by including assumptions on the *ex-ante* probabilities of the relevant drug's success in the examination of costs and profit margins under the first stage of the United Brands test. Furthermore, when looking at social returns, particularly with regard to patented pharmaceuticals, innovation incentives are not necessarily better when they are higher. According to the working paper, applying the excessive pricing prohibition above the value-based quality of life per adjusted year (QALY) threshold would improve investment decisions. QALY is a measure used to determine the maximum willingness to pay for new drugs and healthcare technology in general. The working paper argued that the QALY test could be used when examining the second limb of the United Brands test.

In the ACM's second working paper, *"Lower drug prices can improve innovation"*, the ACM suggested that high drug prices are not always necessary for innovation. Drug prices can be considered too high if the price exceeds a drug's value to society, thus leading to inefficient innovation decisions. The working paper finds that the QALY threshold could be used as a benchmark to determine this.

It remains to be seen if, when and how the ACM will apply this benchmark to the pharma sector.