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GENERIC PHARMACEUTICALS

-- Note by Finland --

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This note is submitted by Finland to the Competition Committee FOR DISCUSSION under Item VI of the agenda at its forthcoming meeting to be held on 18-19 June 2014.

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Introduction

1. The Finnish Competition and Consumer Authority (the FCCA, previously the Finnish Competition Authority, the FCA) has not enforced competition law in the pharmaceuticals branch to date. Cases entering the FCCA relating to the pharmaceutical industry have mainly concerned problems arising from national regulation. The FCCA has, however, dealt with competition issues in the wholesale and distribution of pharmaceuticals.

2. In Finland, the controversies between originator and generic companies mainly derive from regulation. As competition law does not apply to regulation, the FCCA seeks to promote competition between companies through advocacy measures.

3. In August 2012, the FCA published an extensive report on the provision and sales of pharmaceuticals focusing on retail and pharmacies, and, in that context, interviewed both originator and generic companies. This contribution is largely based on interviews, as there are no precedent antitrust cases to refer to, and the views presented here are not cited in Finnish case law.

1. The Finnish pharmaceutical market

4. The Finnish pharmaceutical market is comparatively small with respect to other European countries. Pharmaceutical sales to pharmacies, hospitals and retail trade came to 2.11 billion euro in wholesale prices in 2013. Sales to pharmacies comprised 71% and hospital sales 27% of total sales. About half of pharmaceutical costs are reimbursed through the Finnish health insurance system, providing an incentive to regulate prices. The import of pharmaceutical substances and preparations and other drugs was approximately 1800 million euro in 2012 while pharmaceutical exports stood at 1100 million euro. Only a few companies produce drugs in Finland. The domestic pharmaceutical companies hold a substantial market share in generic drugs compared to other Nordic countries.

5. Generic drugs comprise approximately 20 % of the market in price terms and about 40 % measured in volume. Finland's biggest pharmaceutical company enjoys a significant market share (50%) in generic drugs, and a major part of its revenue is generated by generic and OTC drug sales. According to market operators, the distinction between originator and generic companies is no longer clear-cut. Many pharmaceutical companies trade in both original and generic drugs. By including original, generic and OTC drugs in their portfolio, they decentralize risk. An originator company's own generic drugs present one solution to patent expiration.

6. According to recent surveys, R&D activity has declined in Finland over the last ten years. The number of ongoing clinical trials conducted in Finland has fallen during 2003 - 2012. One reason for this is reported to be diminishing investment.

2. Regulation

7. The reference price system has been in place in Finland since 2009. Savings of 110 million euro in social welfare and for consumers were attained in the first year of its operation. Prior to the reference price system, the use of generic drugs was encouraged by generic substitution that made it possible for pharmacies to substitute the branded original drug with a generic alternative. The reference price system has thus lowered prices of prescription drugs significantly and led to price competition.

8. The Pharmaceuticals Pricing Board, which is in charge of reimbursement and pricing decisions, has the convention to set the prices of generic pharmaceuticals 40 % lower than the original drug when it confirms the generic drug to be reimbursed. This convention is not based on legislation. After this, price

competition can bring prices down even further since the Board confirms reasonable wholesale prices which are maximum prices in the reference price system.

9. Some market operators have expressed views that the Finnish regulation would favor generic drugs at the expense of originator companies. As an example, the authorization process in bringing the drug to market is more burdensome for original drugs than for generic drugs. Generic companies are mainly content with the authorization process, and generic entry is seen to succeed without delay.

10. Some problems with regulation and the authorities in the pharmaceutical field were pointed out as regards to generic entry, however. One is that the prescription of drugs by doctors is unregulated or unguided in any other way. Especially in the higher reimbursement categories where 65% or 100% of the drug's price is reimbursed are the financial incentives for customers to choose the lower priced drug weak. According to market operators, price competition is not very effective outside the reference price system as the incentive to buy a cheaper drug weakens. Outside the reference price system, the generic company does not necessarily gain market share at a lower price. The incentives to market entry are also weaker outside of the reference price system because the sales volume of drugs is smaller. It is estimated that about half of all prescription drugs are fall under in the reference price system. Biosimilars are not covered by the reference price system. Biosimilars, as well as original biological drugs, require R&D, and therefore price competition is not as aggressive as with "ordinary" original and generic drugs. According to the market operators interviewed, a problem was that the functions and responsibilities are split between different authorities so that no one takes full charge of the market mechanism operating in the pharmaceutical field.

11. Finnish IPR regulation differs somewhat from that in most European countries. In Finland, protecting a drug with a process patent is possible, thus securing the method but not the molecule, so that protection is weaker. In 2006 drugs protected by process patent were excluded from generic substitution, and then again included in the reference price system in 2009. Generic drugs manufactured by a different method than the original is substitutable under Finnish system. For this reason, price competition begins in some cases in Finland before the originator's patent expiration and thus earlier than in most European countries. However, the effects of the process patent are starting to diminish and the final patent expires in 2019.

3. Competition between originator and generic companies

3.1 *Generic entry*

12. Generic drugs are seen as a natural part of a drug's life cycle. Market operators point out that price competition is effective, especially between drugs classed within the reference price system because it encourages the lowering of the prices. Outside the reference price system, however, the incentive for market entry is, according to market operators, notably weaker. Especially when the drug is 100% reimbursed, the decision to buy it is not based on price. According to market operators, a generic company enters the market if it seems profitable, the decision usually being purely a matter of business and profitability.

13. A generic company can attempt to invent around the patent and bring the generic drug to market before patent expiration if it regards the risk low enough, as is usually the case with drugs protected by process patents. The generic company can also seek to invalidate a "weak" patent. Market entry during the original drug's patent period is more likely to be initiated if the drug has significant sales volume and the original drug is within the reference price system. If prices are expected to fall steeply after generic entry and involve a loss of revenue, entry during patent validity is normally not considered worth the risk. The incentive to bring a generic drug to market when the original drug's patent is still valid will be considerably smaller when process patents expire in 2019.

3.2 *Cases*

14. The FCCA has handled alleged cases in the field of pharmaceuticals that have not led to further investigation or competition law enforcement.

15. The FCA investigated practices where the originator company had advised doctors not to substitute the original drug with a generic version and referred to published articles stating that the generic version would not serve as efficiently as the original to treat the disease. The originator also provided a supplementary service for the drug which the generic version did not have. According to the National Agency for Medicines, the service was unnecessary for the safe use of the drug. The case was investigated as an abuse of dominant position and exclusionary practices. In 2010, the FCA concluded that the behavior of the originator company had no substantive effect on doctors' decisions when prescribing medication. Price competition had also greatly reduced the prices of drugs in question to the apparent benefit of competition.

16. In 2012, the FCA looked into a case in which generic and originator companies had set their prices at closely the same level. One generic company had also exited the market. During the investigations, however, the FCA discovered logical explanations for the alleged collusive agreements on price and generic market exit. The generic company involved had infringed the originator's patent and exited the market after court decision. The court proceedings also explained most of the pricing behavior.

3.3 *Other remarks on competition*

17. Patent disputes have arisen between originator and generic companies where the originator has claimed patent infringement by a generic company. Patent disputes notably emerged after the reference price system entered into force, and the number of IP court cases has now declined. Unjustified preliminary injunctions have also led to allegation and disputes.

18. Originator companies have developed their products by adding other active pharmaceutical ingredients, but the Pharmaceuticals Pricing Board does not always affirm the higher price proposed by the originator. These second generation drugs can nonetheless achieve a market share regardless of the higher price due to the extra clinical benefit.

19. When hospitals or hospital districts buy medicines, they invite pharmaceutical companies to bid with the result that hospitals acquire medicines at approximately 30-40%, or even as much as 80-90%, lower cost compared to wholesale prices. Hospitals are not allowed to distribute medicines to end costumers unless it is to ensure patients' uninterrupted medication when discharged. Hospital sales comprise approximately 27 % of pharmaceutical sales. Hospital sales are viewed to be risky for pharmaceutical companies because of low margins and high penalty fees. Supply failures are sanctioned by penalty fees, and, in addition, a company failing to supply is obliged to purchase the drugs from another company at a higher price.

20. As for distribution and loyalty schemes and other attempts to tie costumers, regulation makes it difficult for pharmaceutical companies to grant discounts. The Medicine Act (395/1987) prohibits pharmaceutical companies from giving discounts to pharmacies unless these are allowed to all pharmacies. The FCCA has not examined practices in which pharmaceutical companies provide drugs at discounted prices to hospitals to encourage doctors to prescribe the same medicine, but is aware of this possibility in hospital sales in Finland.

21. The capacity of the pharmaceutical sector to innovate is also a common concern in Finland. However, generic drugs are not regarded to be the biggest threat to R&D. Other factors such as budget cuts in subsidies to universities and other research institutions as well as sparse foreign investment can

constitute a greater restriction to R&D in the pharmaceutical industry. The market operators have pointed out that price competition does not necessarily have a direct effect on R&D activity since it occurs in the realm of the current drug portfolio, whereas R&D activity aims at better drugs and a new portfolio. No objective quantification of the impacts of generic competition on R&D activity in Finland has been presented, however.