Organisation de Coopération et de Développement Économiques
Organisation for Economic Co-operation and Development

06-Oct-2009

English text only

DIRECTORATE FOR FINANCIAL AND ENTERPRISE AFFAIRS
COMPETITION COMMITTEE

DAF/COMP/WD(2009)113
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ROUNDTABLE ON GENERIC PHARMACEUTICALS

-- Contribution by the Delegation of Sweden --

This note is submitted by the Delegation of Sweden to the Competition Committee FOR DISCUSSION at its forthcoming meeting to be held on 21 - 22 October 2009.

JT03271138

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GENERIC PHARMACEUTICALS

-- Note by Sweden --

1. The Swedish Competition Authority (SCA) focuses in this contribution primarily on the following suggested issues:

- Competition between different branded drugs
- Competition between branded and generic drugs
- Competition between different generic drugs
- Factors that influence demand
- Effects of generic competition

Conclusions

2. In Sweden, price competition is weak between branded drugs which are therapeutic substitutes. Mainly due to low out-of-pocket costs for the patients and the resulting price insensitivity of demand, the companies have incentives to try to maximize the price that the regulator allows the companies to set. Some aspects of the way drug prices are regulated in Sweden make these incentives even stronger than in many other countries.

3. Concerning price competition between branded and generic drugs, the pressure to cut prices is also low on branded drugs on patent which compete with generic drugs containing other active ingredients. The consequence of a drug's patent expiring and the accompanying launch of cheap generics, is that competing drugs still on patent – containing other active ingredients but still therapeutic substitutes – might become cost-ineffective. But usually physicians keep on prescribing these formerly cost-effective drugs, giving the drug companies no reason to cut prices.

4. More frequent evaluations of the cost-effectiveness of existing drugs by the authority responsible for drug price regulation, might lead to lower prices. When companies are faced with the consequence of having their drugs excluded from reimbursement, they may choose to cut prices to avoid the exclusion.

5. If physicians were better informed on the therapeutic similarity of different drugs containing different active ingredients, this could make physicians more aware of price differences when prescribing drugs, which would improve price competition between branded drugs as well as between branded and generic drugs.

6. Price competition between different generic drugs is rather stiff in Sweden since the introduction in 2002 of mandatory substitution to the cheapest available generic at the pharmacy. During the ongoing regulatory reform process of the Swedish pharmacy retail market, a much discussed issue has been how to

keep the price competition on generics as stiff in the future, although privately owned pharmacies may have incentives not to substitute to the cheapest generic available.

7. Concerning factors that influence demand, an important aspect is that an absolute majority of Swedish physicians are publicly employed and on salary and have therefore no financial incentives to prescribe expensive drugs.

8. The effect of generic competition on prices and sold quantities depends very much on the sales of the drug that loses its patent. If the patent of a large selling drug expires the price drops steeply and it has been observed that in Sweden the brand name drug will be able to keep only a small market share.

1. Competition between branded drugs

9. The prices of patented drugs are regulated in Sweden, as in almost all other European countries. The prices are set by the Dental and Pharmaceutical Benefits Agency (TLV).

10. Prices are regulated for all prescription drugs which are included in the reimbursement system. If producers do not wish to have a drug included – which is rare – they are free to set whatever price they want.

11. The basic principle for the price regulation is that the price cannot be higher than the requirement for cost-effectiveness allows. This means that a drug can be priced up to the point where it is just barely cost-effective, and still be reimbursed. Cost-effectiveness implies that higher quality drugs (drugs which improve life expectancy or quality of life the most) are allowed higher prices than lower quality drugs. This is believed to strengthen the pharmaceutical industry's incentives to develop drugs which have a large potential to improve life expectancy or quality of life, rather than drugs with very small advantages over existing drugs.

12. Drugs which are found to be cost-effective at the price the producer wish to set are approved reimbursement. For the last 7 years, the reimbursement authority has not used its bargaining power, to bid down prices further – below the cost-effective price – in direct negotiations. However, this will probably change since the Swedish government now have provided TLV with new guidelines on how to set prices, with more focus on cost containment.

13. TLV does not make any cross-country price comparisons when setting prices, which is a common practice in many other European countries.

14. A patented drug often belongs to a certain class of drugs. Even though these drugs contain different active ingredients they are still considered to be therapeutic substitutes. Examples of classes of drugs are beta-blockers for hypertension, statins for high cholesterol, and proton pump inhibitors (PPIs) for ulcers and dyspepsia. While, the producers of these drugs are in close competition, there is rarely any price competition between the drugs belonging to the same class, if all of them happen to still be on patent. This is the case in Sweden, and probably in most other countries.

15. Conversely, producers of patented drugs often try to get the highest price possible approved when applying for reimbursement. A main reason for this is that third party financing makes demand insensitive to price. However, another reason may be that a high price signals high quality – so that demand actually increases in price. Physicians are often lack information about evidence on the treatment effects of a particular drug – it is simply impossible for a physician to be perfectly informed about details in all clinical trials. But physicians are aware that the reimbursement authority only allows a higher price for a new drug – relative to the existing drugs – if the new drug is better than the already existing ones. Therefore, physicians may use the regulated price as a signal of high quality – if they trust the reimbursement

authority to do a good job. According to this logic it would be rational for originator companies to try to get the highest possible price approved.

16. This mechanism could be a contributing factor for the observed absence of price competition between patented drugs. And we believe this mechanism is more pronounced in Sweden than in other countries due to the importance the Swedish price regulator puts on cost-effectiveness, rather than cost containment. TLV only regulates prices for drugs used in outpatient care, and not drugs used in inpatient care. However, it is rather common that companies that launch drugs which only will be used in inpatient care still wish TLV to approve the price, because TLV's decisions provide a seal of approval for using the drug, i.e. that the drug is cost-effective.

2. Competition between branded and generic drugs

17. Patented drugs belonging to a certain class of drugs rarely lose their patents at the same time. Therefore, at a particular point in time, branded drugs on patent will compete with – usually – much cheaper generics containing other active ingredients.

18. The consequence of a patent expiring, and the price decrease that follows, is that competing drugs which earlier was cost-effective no longer are cost-effective, since a close substitute has become much cheaper. Thus, patients no longer should be prescribed the more expensive drugs. However, patients usually "migrate" very slowly from one drug to another, even though the difference in price can be large.

19. In Sweden, the reimbursement authority TLV has conducted reviews of different therapeutic groups, trying to weed out drugs that no longer are cost-effective. But this is a slow process, and in the meantime – usually for several years – former cost-effective drugs can go on being reimbursed and heavily prescribed, costing tax payers large sums.

3. Competition between different generic drugs

20. Sweden introduced mandatory generic substitution in 2002. The pharmacies are now obliged to substitute the prescribed drug to the cheapest available drug that the Medical Products Agency (MPA) has listed as substitutable. If a patient still prefers the prescribed drug, the patient has to pay the difference in cost direct out-of-pocket.

21. The reform is considered to be a success. Prices of generics have come down and the market share of generics, expressed in terms of defined daily doses (DDDs), has increased substantially. Sweden now has low prices on off-patent drugs compared with many other countries.

22. At the moment, the Swedish pharmacy retail market is going through a regulatory reform process. Until the 1st of June 2009 the state owned company Apoteket AB had a statutory monopoly on pharmaceutical retail sale. Following the reform, the monopoly has now been abolished and it is possible for other actors to enter the pharmacy market. Any companies who wish to open a pharmacy are allowed to do so, provided they live up to the regulatory frameworks. Thus, there will be no supply restrictions.

23. Sweden has low price on generics, which is a result of voluntary price cuts. Since the former monopolist Apoteket AB has been - reasonably - efficient in substituting to the cheapest available generic, the generic producers have found it worthwhile to compete to become the cheapest generic available and thereby gain a large market share. A lot of the discussions concerning the reform have focused on how to maintain the stiff price competition on off-patent drugs that has been established during the last years.

24. In order to make the system work also in a liberalised market, it is essential that all pharmacies try their best in ordering and dispensing the cheapest available drug. Otherwise the generic producer

setting the lowest price will not gain a large market share, and thus there will be no incentive to set a low price in the first place.

25. Therefore, there has been much discussion concerning how to get privately owned pharmacies to be as efficient as the former monopolist in substituting the prescribed drug to the cheapest available drug. To get all pharmacies to try their best, one could either rely on regulation (mandating pharmacies to always substitute, and possibly impose sanctions if pharmacies do not comply) or monetary incentives (for instance paying pharmacies a bonus in proportion to how often they succeed in dispensing the cheapest generic available).

26. In the end, the Government opted for regulation rather than incentives. So each pharmacy is obliged to substitute to the cheapest available alternative, and it will be closely monitored by the authorities that they actually do so. Since the system has not been in place for more than two months – and since no competitors to the former monopolist have yet entered the market – it is too soon to tell whether the generic competition will be as efficient in the future as it has been in the past.

27. Biologicals may prove to be a problem, since the current – and future – system relies to such a large extent on pharmacies substituting expensive drugs to cheaper drugs. Although there are generic biologicals, so called bio-similars, they will not be defined as substitutable by the Swedish Medical Products Agency, since they never will be identical to the brand name drug. A fear then is that prices of bio-similars, will neither decrease as much as ordinary generics, nor be able to capture a very large market share.

4. Factors that influence demand

28. The Swedish health care system resembles for instance the British NHS to the extent that all citizens are covered in the public health insurance program and most hospitals are publicly owned, i.e. both financing and production are taken care of by the public sector. A small share of the population is also covered by private add-on insurance that guarantees faster access to health care at private clinics.

29. An absolute majority of Swedish physicians are publicly employed and are on salary. Thus, they have no financial incentives to prescribe expensive drugs. The physician is free to prescribe any drug she wants to. However, not all drugs are reimbursed, which usually make them unattractive to patients. Hospitals also provide prescription guidelines to physicians.

30. The average share of drug expenditure paid out of pocket is roughly 20 percent.

5. Effects of generics competition

31. The magnitude of the discount that a generic firm offers, compared to the price of the branded drug, varies a lot. The larger the volume of sales of the drug, the more intense is the price competition between different generic manufacturers. For drugs which are rarely prescribed, the price drops hardly at all when the patent expires. However, if the patent of a large volume drug expires the price can drop 90-95 percent following the entry of generics. The table below, from a report by TLV in 2006 on the effects of generics competition, illustrates the drop in average price paid for five large selling substances a couple of years after patent expiration.

Table : Changes in average price paid for five large selling substances.

Substance	Brand name	Therapeutic area	Date of patent expiry	Price change* %
Citalopram	Cipramil	Depression	June 2002	-83
Felodipin	Plendil	High bloodpressure	Feb 2003	-61
Omeprazol	Losec	Ulcers	March 2003	-65
Sertralin	Zoloft	Depression	Oct 2005	-62
Simvastatin	Zocord	High cholesterol	Feb 2003	-92

*From the month the patent expired until December 2005. Source: ”Kraftig prispress på läkemedel efter introduktion av generiskt utbyte.”, Läkemedelsförmånsnämnden 2006. http://www.tlv.se/Upload/Pressmeddelanden/PM_060629_rapport_generiskt_utbyte.pdf