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COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMACEUTICALS

Contribution from Switzerland

-- Session III --

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COMPETITION ISSUES IN THE DISTRIBUTION OF PHARMECEUTICALS

-- Switzerland --

1. Introduction

1. The Swiss drug market is interesting in more ways than one, and there are a number of particular aspects to the distribution of pharmaceuticals that warrant examination from the standpoint of competition.

2. In 2010, in order to investigate a number of complaints involving the drug distribution market, the Swiss competition authorities launched a sectorial analysis in the form of a prior-survey procedure. This procedure, which is still ongoing, covers distribution circuits and deals with drug sales in Switzerland.

3. Before reviewing the various stages comprising drug distribution in Switzerland and the competition issues arising at each stage, it would be useful to look at the main legal provisions shaping the Swiss market for pharmaceuticals.

2. Legal framework

4. The federal Therapeutic Products Act (LPT_h, RS 812.21) regulates the marketing and (parallel) import of medicinal drugs in Switzerland.

5. The **marketing** of drugs in Switzerland is subject to authorisation. Swissmedic, the Swiss Agency for Therapeutic Products, asks each pharmaceutical firm wishing to market drugs in Switzerland to submit a comprehensive application file so that the Agency can review market introduction criteria. In principle, Swissmedic relies on trials conducted with a view to obtaining authorisation if a drug or a procedure has already been authorised for marketing in a country that has instituted equivalent drug supervision provisions.

6. Under the Therapeutic Products Act, **(parallel) drug imports** are subject to authorisation and must meet a number of conditions. A company wishing to import a drug to Switzerland is required not only to submit the drug to Swissmedic for authorisation to market (even if it is already being sold in Switzerland), but it must also apply for authorisation with regard to packaging, name and the dimensions and colour of packaging if those aspects differ from the product already being sold in Switzerland, failing which the prospective importer must remove the packaging and repackage the drugs in line with Swiss standards. One consequence of this is that patient information sheets must be written in the three national languages (German, French and Italian). Consequently, drugs are not subject to the “Cassis de Dijon”¹ principle, and they may not be imported directly.

7. The Swiss drug market is also influenced by the federal Law on Health Insurance (LAMal, RS 832.10), which stipulates which drugs are covered by the basic health insurance scheme; these drugs appear on the “List of Specialities”. At the same time, LAMal sets the ex-factory prices of those drugs

¹ Federal Law on Technical Barriers to Trade (LETC, RS 946.51).

based on a basket of reference countries, along with the distributors' margins and maximum selling prices. These prices are *de facto* State-set. There are, however, no legal provisions setting the prices of drugs that are not reimbursed by the basic health insurance scheme (the so-called "off-List" drugs).

8. Lastly, it should be added that drugs covered by patents and the prices of which are imposed by the State (as is the case for drugs on the LAMal List of Specialities) may not be imported without authorisation from the patent owner,² insofar as they do not fall under the principle of regional exhaustion of patents,³ but under that of national exhaustion.⁴ This provision does not apply to "off-List" drugs. In contrast, imports of off-List drugs run up against other impediments cited above.

3. Particularities of the Swiss drug market

9. As mentioned above, the Swiss legal framework is fairly dissuasive to drug imports. Over the years, one highly vertically integrated firm has managed to take on an important role in drug distribution and dispensing. That firm's lines of business go from manufacturing the drugs to pre-wholesaler services for wholesaling (see section 4.2 below) to managing a third of the pharmacies operating in Switzerland. In some cases this extreme vertical integration makes the firm an all-important player with influence over drug distribution in Switzerland.

4. The various levels of drug distribution in Switzerland and competition issues

4.1 Pharmaceutical firms

10. In 2013, roughly 300 firms were granted marketing authorisations from Swissmedic to introduce at least one new drug. Total drug sales in Switzerland generated annual turnover of some CHF 6 billion (in terms of public selling prices),⁵ accounting for 9.4% of aggregate health care expenditures in Switzerland. According to the statistics available, the annual turnover of pharmaceutical firms in 2012 was approximately CHF 5 billion,⁶ with distribution accounting for the remaining CHF 1 billion. Over a third of the drugs sold in Switzerland in 2012 came from firms having their corporate headquarters within the country, whereas two-thirds of them were of foreign origin, even if most of the major drug firms have subsidiaries in Switzerland. The basic health insurance scheme reimbursed CHF 4.5 billion⁷ of the outlays, with patients bearing the remainder of the cost (over-the-counter drug sales).

² Art. 9a, par. 5 of the federal Patents Law (RS 232.14, LB).

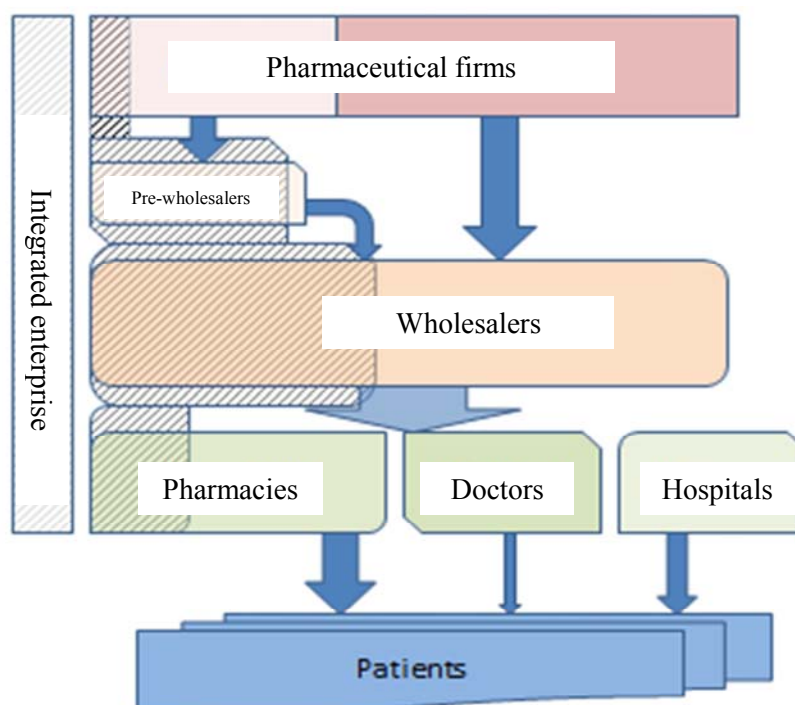
³ In principle, Switzerland applies the regional exhaustion scheme unilaterally (*i.e.* with no reciprocity agreements) with member States of the European Economic Area (EEA). In other words, patented products distributed in the EEA with the patent-holder's consent may be imported to Switzerland without the patent-holder's consent.

⁴ By virtue of which patent-holders may petition the courts to prevent patented products they have marketed abroad from being imported to Switzerland without their consent.

⁵ Interpharma, *Le marché du médicament en Suisse*, 2013, p.7. Downloadable on www.interpharma.ch in French (http://www.interpharma.ch/sites/default/files/rz_pms_2013_f_web.pdf) or German (http://www.interpharma.ch/sites/default/files/rz_pms_2013_d_web.pdf).

⁶ *Ibid.*, p. 18.

⁷ *Ibid.*, p. 20.



11. It is also interesting to note the impact on the Swiss market of **concentration operations** having a Community-wide dimension between pharmaceutical firms. Insofar as Switzerland does not belong to the European Union (EU), concentration operations exceeding a certain threshold must be notified to both Brussels and Bern. Since the Swiss competition authorities cannot co-ordinate their practices with their EU counterparts, Switzerland runs the risk of having to bear the consequences of decisions taken by the EU, especially when those decisions entail stipulations requiring the pharmaceutical firms involved to relinquish a line of business in which a concentration operation would lead to a substantial lessening of competition within the EU.⁸ In such cases, it is not uncommon for the European Commission to request that production rights be transferred to a third-party buyer not involved in the merger. As a result, two scenarios that would be problematic from a competition standpoint would be possible. Under the first, if the buyer chosen to resolve competition problems within the EU were strong in the Swiss market, its purchase of that line of business might enable it to achieve a substantial, if not dominant, position there, which would run counter to concentration control in the Swiss market. No law obliges the European Commission to take account of the effects of the remedies it imposes on markets not involving a Member State. Under the second scenario, if the new buyer were not already operating in Switzerland, it would be possible that the drugs in question would be withdrawn from the Swiss market, enabling the direct competitors to bolster their Swiss market positions.

12. The problem of the **financial incentives** that pharmaceutical firms give doctors and hospitals to prompt them to sell or prescribe their drugs has not yet been solved, even though the legal provisions of the

⁸ Not to mention the fact that the intervention thresholds are not the same in Switzerland (LCart, Art. 9) as they are in the EU [Art. 1 of Council Regulation (EC) No.139/2004 of 20 January 2004 on the control of concentrations between undertakings].

LPT_h and LAM_{al} are attempting to curb the problem from the ethical and patient safety standpoints by imposing limits on such incentives and/or requiring them to be passed along to patients/customers (primarily in the form of discounts). Neither measure, the legality of which has been challenged, seems to have had much impact. For the competition authorities, it remains to be seen to what extent such practices fall within their remit as functionally equivalent to predatory strategies or tied sales which could drive certain competitors out of the Swiss market. For the moment, these questions have no satisfactory answers.

13. Another problem is that of agreements between firms that produce **generic drugs** and the largest pharmacy chains, to favour the producers' products in exchange for **substantial discounts**. Two generic-drug producers operating in Switzerland seem to have adopted this marketing strategy: in order to boost sales of their products, each of the firms involved extend preferential terms (discounts) to certain pharmacy chains only. This practice, which does not seem to be co-ordinated, might drive smaller generic drug makers to withdraw from, or to refrain from entering, the Swiss market. At the same time, however, this discounting could also work to the benefit of all generic drug producers if the practice resulted in ever-greater substitution of generics for the original brand-name drugs.

14. Lastly, it should be noted that the Swiss competition authorities have not undertaken any prosecutions of "pay for delay" cases or "reverse patent settlements" between pharmaceutical companies (*i.e.* cases in which originating drug manufacturers reach agreement with makers of generics to delay the latter's entry into the market). It is possible that agreements between pharmaceutical firms in the United States or the European Union have consequences for Switzerland as well. In contrast, it is unlikely that any agreements specifically relating to Switzerland are concluded, for multiple reasons: first, the Swiss market for generics, although growing, is relatively undeveloped in volume and value (9.8% of all drugs) as compared to those of other countries. In addition, the basic health insurance scheme's drug reimbursement system would not seem to encourage patients to opt for generics (*e.g.* by dispensing them from any co-payments). Moreover, producers are not free to set the ex-factory prices of any of their products that are reimbursed by the basic insurance scheme. Lastly, a number of large producers are also involved with their subsidiaries in the production and distribution of generics in Switzerland. It is therefore possible that all of the above is not conducive to pay-for-delay agreements as they seem to exist in other countries.

4.2 *Pre-wholesalers*

15. The use of distribution systems involving one or more pre-wholesalers (PWs) can potentially be problematic in Switzerland insofar as it is difficult, if not impossible, for market players to obtain supplies abroad via parallel imports. Under the circumstances, the more exclusive distribution contracts there are between pharmaceutical firms and PWs, the greater the market power of the PWs, especially if those contracts call for ever-greater outsourcing of activities to the PWs.

16. Here, the risks of creating a monopoly with abusive behaviour towards players upstream and downstream need to be examined. For example, the application of different terms of sale (*e.g.* delivery and payment deadlines, quantities, drug expiration dates, etc.) to wholesalers, and to "full-liners"⁹ in particular, could be problematic insofar as these differences would have a substantial impact on competition between wholesalers, and thus on the efficiency of distribution downstream. The effects of this impact would be even more complex (*e.g.* transfers of sensitive information) if pre-wholesalers were vertically integrated with the leading wholesalers, as is the case in Switzerland.

17. The ongoing sectorial analysis factors in these aspects. Explorations are underway into the competition-effectiveness of such distribution systems, even if Switzerland has not (yet) been confronted

⁹ Wholesalers who by definition are/should be able to deliver all of the medicinal drugs available for sale in Switzerland.

with systems of exclusive drug sales through a sole distributor, as is the case in some other countries.¹⁰ Given the legal compartmentalisation of the Swiss market, the competition effects of such practices require attentive examination.

4.3 Wholesalers

18. Two full-liners (holding a combined market share of about 80%) and a number of “short-liners”¹¹ comprise the wholesale market in Switzerland.

19. Two complaints have been voiced in Switzerland about **full-line wholesalers** that pressure certain pharmacies, either directly or indirectly (through loyalty discounts), to buy a large share of their drug requirements from them. These complaints are still low-key, however, insofar as the terms of supply are profitable for both parties (wholesalers and distributors). Even though the issue could also be analysed from the standpoint of a possible joint dominant position, it should be emphasised that while such practices seem to have been influencing the market for a number of years, they have not prompted any substantial change in the market’s structure. It might be concluded from this that the existence of predatory practices could be ruled out, or it might at least suggest that such practices do not have (or have not had) significant effects on the Swiss market. Insofar as the non-competition requirements do not affect over 80% of aggregate turnover, these practices would not seem to pose any problems.¹²

4.4 Drug sales

20. There are approximately 1 700 pharmacies¹³ in Switzerland, which dispense 52%¹⁴ of the country’s drugs (in value), the remaining 48% being dispensed by dispensing physicians, hospitals and dispensing institutions. Most of them belong to single firms or are parts of groups.

21. Price competition in drug sales is fairly slight, primarily for two reasons. First, the majority of the drugs sold are reimbursed by the basic health insurance scheme on the basis of the List of Specialities, which prompts pharmacies to charge the maximum price allowable by law. Second, with respect to “off-List” drugs, pharmacies tend for the most part to charge the prices recommended by pharmaceutical producers – a sector in which prices ought to be subject to competition.

22. Against this backdrop, the Swiss Competition Commission (COMCO) in 2009 sanctioned three pharmaceutical firms, prohibiting them from recommending prices for their erectile dysfunction drugs.¹⁵ In this case, the charging of recommended prices had a notable effect on intra- and inter-brand competition, in

¹⁰ See, for example, *Medicines distribution, An OFT market study*, 2007 (http://www.of.gov.uk/shared_of/reports/comp_policy/of967.pdf).

¹¹ Firms active in wholesale distribution that concentrate on the delivery/sale of higher-margin drugs and generally grant deeper discounts.

¹² *Communication concernant l'appréciation des accords verticaux* of 28 June 2010, *Chiffre 6*, p. 4. Downloadable (in French) from www.weko.admin.ch/dokumentation/01007/index.html?lang=fr.

¹³ Of which 29% belong to chains, 48% operate in co-operative groups and 23% are independent (<http://www.pharmasuisse.org/FR/verband/strategie/pages/geschaeftsbericht.aspx> – in French).

¹⁴ 24.3% of drugs (in value) are sold by dispensing physicians (doctors having their own pharmacies in their offices), 22.1% by hospitals and 1.5% by dispensing institutions (See Interpharma, *op.cit.*, p. 25).

¹⁵ *Hors-Liste Medikamente: Preise von Cialis, Levitra und Viagra*, RPW/DPC 2010/4, pp. 649ff (<http://www.weko.admin.ch/dokumentation/00157/index.html?lang=fr> – in French and German).

violation of Article 5.4 of the Federal Act on Cartels and other Restraints of Competition (LCart).¹⁶ COMCO's ruling was appealed to the Federal Administrative Tribunal, which recently held that the market in question lay outside LCart's scope of application insofar as Swiss law did not authorise the advertising of so-called "off-List" drugs.¹⁷ COMCO decided to take the case to the Federal Tribunal.

23. Lastly, it should be noted that in 2004 COMCO undertook a procedure concerning veterinary drugs and required pharmaceutical firms to deliver those products to any pharmacies that requested them.¹⁸ Apart from a few exceptions, this measure did not have the intended results, insofar as most veterinary drugs are sold by prescription and animal owners prefer to buy them directly from their veterinarians.

4.5 *Marketing of information about drugs*

24. Competition authorities have been looking into the marketing of information about drugs for over a year. The information involved – active ingredients, dosage, contra-indications and interactions, but also packaging dimensions, pharmaceutical codes, VAT numbers, etc. – are essential for distributing, dispensing and invoicing the drugs. If this information cannot be retrieved in the current electronic systems of pharmacies, doctors and hospitals, the drugs concerned may be more difficult to deliver and to sell. This is why this information is so important for pharmaceutical firms, pharmacies and ultimately patients.

25. In Switzerland, for decades just one firm – belonging to a vertically integrated group in the physical distribution of medicinal drugs – took care of making this information available (first in paper form and subsequently in electronic form as well) to end-users (pharmacies, doctors, hospitals, wholesalers and insurers). Until 2011, pharmaceutical firms were legally required¹⁹ to have that firm publish the information intended for specialists and patients (the information contained in the packaging). Subsequent to a decision of the Federal Administrative Tribunal²⁰ that effectively lifted that obligation, Swissmedic set up a computerised platform available to pharmaceutical firms for publishing information about their drugs. However, according to the information available when the inquiry began at year-end 2012, the firm in question seemed to be pressuring pharmaceutical firms to continue doing business with it, *i.e.* to continue paying to publish information about their drugs or else no longer be listed in the databanks of the firm in question – databanks of vital importance to industry players.

26. The Federal Tribunal ruling, Swissmedic's creation of a State-run platform and the filing of a cartel procedure have been criticised by the firms directly involved, and by end-users who fear that access to this information will be made more difficult and costlier. The procedure is still in progress.

¹⁶ Federal Act on Cartels and other Restraints of Competition of 6 October 1995 (RS 251, LCart, <http://www.admin.ch/opc/en/classified-compilation/19950278/index.html>).

¹⁷ *Hors-Liste Medikamente: Preise von Cialis, Levitra und Viagra*, RPW/DPC 2010/4, pp. 649ff (<http://www.weko.admin.ch/dokumentation/00157/index.html?lang=fr> – in German).

¹⁸ *Vertrieb von Tierarzneimitteln*, RPW/DPC 2004/4 pp. 1040ff (<http://www.weko.admin.ch/dokumentation/index.html?lang=fr> – in German).

¹⁹ Under Article 16a, paragraph 1 of the Ordinance of 17 October 2001 on medicinal drugs (Omèd, RS 812.212.21).

²⁰ Decision C-6885/2008 of 17 June 2011 (<http://www.bvger.ch/gericht/index.html?lang=fr> – in French).

5. Conclusion

27. The Swiss market for the distribution of medicinal drugs is concentrated, protected from parallel imports and heavily regulated.

28. The main challenges in the realm of competition are to prevent that concentration from leading to abuses that would have a significant effect on competition in the drug distribution market, in particular by thwarting competition from neighbouring countries. Another challenge is to ensure that the regulations allow more room for effective competition.

29. To achieve this, special attention will be paid to practices that lead to greater market concentration, especially when those practices emanate from firms active at different levels of the drug distribution chain. Another measure will be to allow parallel imports without endangering drug distribution or patient safety. Lastly, it must be ascertained whether the regulatory provisions currently in force are necessary and effective, or whether they needlessly lessen competition.