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THE GUIDE TO LIFE SCIENCES

Editors
Ingrid Vandenborre and Caroline Janssens

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Publisher's Note

One of the unexpected side-effects of the covid-19 pandemic is how the hunt for both vaccines and treatments has pushed the life sciences industry centre stage, with debates over price controls and IP waivers making headlines around the world. While many of these concerns are global, the same is not always true of the solutions adopted by national regulators. As Ingrid Vandenborre and Caroline Janssens point out in their introduction, there has been growing regulatory attention paid to mergers in this innovative space and increasing intervention by antitrust agencies in a range of practices particular to the biopharma sector. Practical and timely guidance for both practitioners and enforcers trying to navigate this fast-moving environment is thus critical.

The first edition of *The Guide to Life Sciences* – published by Global Competition Review – provides exactly this detailed analysis. It examines both the current state of law and the direction of travel for those jurisdictions with the most impactful life sciences industries. The Guide draws on the expertise and experience of distinguished practitioners globally, and brings together unparalleled proficiency in the field to provide essential guidance on subjects as diverse as biosimilar competition and product denigration, as well as a forensic examination of the most significant and far-reaching regulations and decisions from around the world.

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Contents

Introduction 1
Ingrid Vandenborre and Caroline Janssens

1 An Economist's Perspective 5
John Davies, Valérie Meunier, Rameet Sangha and David Sevy
Compass Lexecon

2 Excessive Pricing 24
George Zacharodimos
Skadden, Arps, Slate, Meagher & Flom LLP

3 Biosimilar Competition: an Economist's Perspective 43
Avantika Chowdhury, Adriano Barbera and Sam Carr
Oxera Consulting LLP

4 Product Denigration 56
Marta Giner Asins and Arnaud Sanz
Norton Rose Fulbright LLP

5 Merger Control: Procedural Issues 73
Miranda Cole, Luca Ghafelehbashi and Julien Haverals
Norton Rose Fulbright LLP

6 Merger Control: Substantive Issues 87
Maria Raptis, Michael Frese, Julia Zhu and Marta Navarro Hernández
Skadden, Arps, Slate, Meagher & Flom LLP

7 Cooperative Agreements: a Private Practitioner's Perspective 107
Niels Christian Ersbøll
Arnold & Porter Kaye Scholer LLP

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8 Australia: ACCC's Focus on Conduct Could Have Far-Reaching Implications 122
Elizabeth Avery and Susan Jones
Gilbert + Tobin

9 European Union: Commission Still at the Forefront, While Pay-for-Delay Cases Set New Precedents 131
Salomé Cisnal de Ugarte, Geneviève Michaux, Mélanie Perez, Ivan Pico and Georgios Symeonidis
King & Spalding LLP

10 France: FCA Increases Scrutiny Over the Sector..... 147
Adrien Giraud, Eveline Van Keymeulen, Julien Morize and Jeanne Fabre
Latham & Watkins LLP

11 Germany and Austria: Post-Covid Collaboration is on the Rise in this Key Economic Sector..... 161
Tobias Maier, Martin Bechtold, Aurelius Freytag and Karin Köller
Eversheds Sutherland

12 Italy: Antitrust Pioneer Continues to Break Ground on Theories of Harm..... 172
Maria Balestriero, Enzo Marasà, Irene Picciano, Elisa Stefanini and Claudio Todisco
Portolano Cavallo

13 Netherlands: Price and Supply Security Remain Regulator's Top Priorities 183
Jan Truijens Martinez and Florentine Snoeker
Stibbe

14 Switzerland: Merger Control Reform Could Have Big Impact, Especially for 'National' Markets..... 199
Philipp E Zurkinden, Bernhard C Lauterburg, Andrea Schütz and Marino Baldi
Prager Dreifuss AG

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15 United Kingdom: a Key Jurisdiction for Competition Law Compliance 216
Robert Eriksson and Gustaf Duhs
Stevens & Bolton LLP

16 United States: FTC Looks Set to Open up New Enforcement Front 233
Arman Oruc, Andrew Lacy, Elliot Silver and Brady Cummins
Goodwin Procter LLP

About the Authors 249
Contributors' Contact Details 275

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Introduction

Ingrid Vandenborre and Caroline Janssens[1]

Antitrust agencies around the world have been highly active in recent years, examining a range of practices, including alleged denigration of rivals' products, price increases, biosimilar entry, delayed entry of generic medicines, collaboration agreements and local regulatory/procurement practices. There is also growing attention to mergers, especially in dynamic, innovation-driven areas. While many of the concerns are similar in most jurisdictions, enforcers have addressed those specific to the functioning of their local markets and antitrust principles. This first edition of Global Competition Review's *Guide to Life Sciences* explores how enforcers have approached these practices and where key jurisdictions diverge or converge in their analysis.

Spending on pharmaceuticals constitutes a significant share of government spending on healthcare. This has driven increased regulatory focus on pharmaceutical pricing, including from competition authorities. While competition authorities in the European Union and the United Kingdom have historically been reluctant to intervene, the pharmaceutical sector has seen mounting regulatory interest in alleged excessive pricing practices in recent years. Even with economists highlighting the complexities and shortcomings around the enforcement of exploitative abuses of companies in a dominant position through excessive pricing, antitrust scrutiny of pharmaceutical pricing is expected to continue. By contrast, while we have seen a recent push from academics in the United States to recognise high (excessive) prices of pharmaceuticals as an antitrust violation, US courts have not yet recognised these claims.

1 Ingrid Vandenborre is a partner and Caroline Janssens is a senior professional support lawyer at Skadden, Arps, Slate, Meagher & Flom LLP.

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Biosimilars, and more generally biological medicines, have received growing attention from competition authorities across Europe. Recent antitrust investigations in the EU and the UK have examined how commercial practices adopted by incumbent suppliers may hinder biosimilar competition. However, the inherent features of biologicals, such as high costs and longer approval times, raise fundamental challenges in increasing biosimilar competition.

Product denigration cases in life sciences have been rare in the EU and around the world, and in most of them the denigration behaviour was combined with other infringements such as abuse of patent procedures or product hopping. There has since been an abundance of similar investigations at national level, with France leading the way, where cases have expanded the scope of the conduct to include product denigration and the provision of unsubstantiated, but not necessarily incorrect, information to consumers and other parties concerning either the company's own products or competing products.

Cooperative agreements have always played an important role in the pharmaceutical industry with companies partnering from early stage research and development through to late-stage commercialisation. The covid-19 pandemic has been an opportunity for the industry to demonstrate the benefits that expeditious and flexible cooperation can bring, and competition authorities have also recognised this. Beyond the pandemic, the pharmaceutical industry is facing increasing pressure to enhance affordable access to new medicines. In that context, cooperation agreements will remain of central importance to pharmaceutical companies, perhaps increasingly so.

With regard to merger control, clearance processes for some pharmaceutical transactions are expected to become more uncertain. This is due to several procedural developments in many countries designed to broaden jurisdiction over acquisitions by incumbents of nascent competitors that could play a significant competitive role in the market in the future ('killer acquisitions'), coupled with flexible and creative notification requirements and new theories of harm. The Multilateral Pharmaceutical Merger Task Force (a working group comprised of the US Federal Trade Commission (FTC), the Canadian Competition Bureau, the European Commission (EC) Directorate General for Competition, the UK's Competition and Markets Authority (CMA), the US Department of Justice Antitrust Division and offices of state attorneys general) can play an important role in brokering alignment in analysis between key jurisdictions.

Competition authorities in Europe, and in particular the EC, have historically been very active in antitrust enforcement and merger control review in the pharmaceutical sector. Consistent with its focus on innovation, the EC has significantly increased its scrutiny in recent years and is expected to continue

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doing so, including, as we have seen, by way of expanding jurisdictional scope of review. At Member State level, France has been leading the way on enforcement of product denigration, while Germany and Austria have increased their scrutiny of innovation-driven markets with the introduction of alternative transaction value thresholds in 2017, designed to capture high-value/low-revenue deals.

Italy has been a pioneer in antitrust enforcement in life sciences, with landmark cases on excessive pricing and product denigration influencing the EC's decisional practice. The Italian Competition Authority is likely to continue its enforcement efforts in this area in the future. In contrast, the activity of the Authority in merger control in recent years has been limited.

In the Netherlands, the focus has been on price levels, with the Authority for Consumers and Markets making important contributions to the debate on excessive pricing both through case practice and working papers.

In the UK, the CMA is expected to continue to regard the life sciences sector as an enforcement priority. With regard to merger control, recent cases have illustrated the CMA's willingness to push the limits of jurisdictional rules and intervene in deals in dynamic, innovation-driven sectors where target companies have limited (or no) revenues or direct activity in the UK. In addition, Brexit has created heightened risks of parallel conduct investigations and merger reviews in the EU and UK.

To date, the life sciences sector has not raised major competition law issues in Switzerland, under neither the cartels, abuse of dominance nor merger control rules. It remains to be seen whether recent and ongoing regulatory changes, as well as mutual market access concerns with the EU, will lead to a different competitive environment in the near future.

In the US, recent merger enforcement in the pharmaceutical sector continues to follow traditional principles and reasoning. However, it is increasingly likely that the FTC's enforcement actions will reflect more aggressive theories of harm. Recent behavioural enforcement has largely consisted of pay-for-delay litigation and continuing prosecution of price-fixing charges against generic manufacturers. However, the FTC has given strong indications that it has competitive concerns with fees and rebates paid by pharmaceutical manufacturers to pharmacy benefit managers, which is likely to lead to new fronts of enforcement.

In Australia, the life sciences sector is not currently identified as a priority area for Australian Competition and Consumer Commission (ACCC) enforcement. However, there have been some important regulatory developments affecting the sector, such as the repeal of a safe harbour for intellectual property assignments or licensing arrangements, and the ACCC has also taken some significant cases

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against companies in this sector in recent years. Lastly, in Brazil, the health sector is under close scrutiny from the Brazilian antitrust authorities, and this is not expected to change in the near future.

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CHAPTER 14

Switzerland: Merger Control Reform Could Have Big Impact, Especially for 'National' Markets

Philipp E Zurkinden, Bernhard C Lauterburg, Andrea Schütz and Marino Baldi[1]

Introduction

Swiss competition law

Swiss competition law is primarily governed by the Federal Law on Cartels and other Restraints of Competition (LCart).[2] The LCart is primarily enforced by the Competition Commission (ComCo) whose decisions can be appealed to the Federal Administrative Court and the Federal Supreme Court. Civil courts play only a marginal role in the enforcement of the LCart due to procedural hurdles.

The purpose of the LCart is to prevent harmful economic or social effects of cartels and other restraints of competition and for this purpose sets out behavioural and structural rules. It applies to anticompetitive practices that have an effect in Switzerland, even if they originate in another country. The current LCart has been in effect since 1 July 1996 and has twice been substantially amended (in 2004, with the introduction of direct sanctions and the precision of the market dominance definition, and in 2022, with an extension of the control of abusive conduct in Swiss competition law to companies with relative market power).

1 Philipp E Zurkinden is a partner, Bernhard C Lauterburg is counsel, Andrea Schütz is an associated partner and Marino Baldi is of counsel at Prager Dreifuss AG.

2 SR 251. The competition law system is complemented by the Law against Unfair Competition (SR 241), the Federal Law on the Internal Market (SR 943.02) and the Federal Law on Price Surveillance (SR 942.20).

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The LCart has largely been inspired by and rests on the same premise as EU competition law (i.e., Articles 101 and 102 of the Treaty on the Functioning of the European Union (TFEU) as well as certain secondary legislation). As it is in the EU, Swiss merger control is based on a preventive notification system. It is therefore common practice in Switzerland to look at pertinent EU precedent and guidelines.

In substance, the LCart rests on three pillars.

- It provides that agreements that significantly restrict competition in a market for specific goods or services and that are not justified on grounds of economic efficiency, and all agreements that eliminate effective competition, are unlawful.[3] For certain types of agreements, hardcore agreements, the LCart presumes they eliminate effective competition.
- The LCart provides that dominant undertakings and undertakings with relative market power behave unlawfully if they, by abusing their position in the market, hinder other undertakings from starting or continuing to compete, or disadvantage trading partners.[4]
- The LCart requires that planned concentrations of undertakings must be notified to the ComCo before their implementation if the undertakings concerned exceeded certain turnover thresholds in the financial year preceding the concentration.[5]

Life sciences regulation

The field of life sciences is heavily regulated in Switzerland. Various laws and regulations at federal and cantonal level interact to create a framework that promotes the development and spread of new technologies and minimises the risks associated with them. It would be beyond the scope of this chapter to enumerate all relevant laws.

The Therapeutic Products Act (TPA) is particularly relevant.[6] The purpose of the TPA is to protect human and animal health and to guarantee that only high quality, safe and effective therapeutic products (medicinal products and medical devices) are placed on the market. The TPA applies to the handling of therapeutic products, narcotics that are used as therapeutic products and therapeutic treatments such as gene therapy insofar as they directly relate to therapeutic products.

3 Article 5(1), Federal Law on Cartels and other Restraints of Competition (LCart).
4 id., Article 7(1).
5 id., Article 9(1).
6 SR 812.21.

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The provisions of the TPA are specified in various ordinances (e.g., the Medicinal Products Licensing Ordinance,[7] the Ordinance on Medical Devices (MedDO)[8] and the Ordinance on In Vitro Diagnostic Medical Devices (IvDO)).[9]

The Epidemics Act (EpidA)[10] has gained increasing importance recently as a result of the covid-19 pandemic. This Act regulates protecting people against communicable diseases and provides for the measures required to do so. On the basis of the EpidA, various new implementing regulations with limited validity have been adopted (e.g., Ordinance 3 on Measures to Combat the Coronavirus).[11] This Ordinance serves to ensure Switzerland's capacities to manage the pandemic, particularly to provide the population with adequate care and a sufficient supply of essential medical goods.

Behavioural control

Unlawful agreements

Agreements affecting competition are binding or non-binding agreements and concerted practices between undertakings operating at the same or at different levels of production that have a restraint of competition as their object or effect.[12] Pursuant to Article 5(1) of the LCart, these agreements are unlawful if they significantly restrict competition in a market for specific goods or services and are not justified on grounds of economic efficiency or they eliminate effective competition.

The anticompetitive effects of an agreement need not arise in the market in which it was concluded.

The LCart presumes that certain types of agreement eliminate effective competition:

- agreements between actual or potential competitors to directly or indirectly fix prices, to limit the quantities of goods or services to be produced, purchased or supplied, or to allocate markets geographically or according to trading partners;[13] and

7 SR 812.212.1.
8 SR 812.213.
9 SR 812.219.
10 SR 818.101.
11 SR 818.101.24.
12 Article 4(1) LCart.
13 id., Article 5(3).

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- agreements between undertakings at different levels of the production and distribution chain regarding fixed or minimum resale prices, and agreements contained in distribution contracts regarding the allocation of territories to the extent that sales by other distributors into these territories are not permitted.[14]

Article 5(3) and (4) of the LCart are procedural provisions containing a statutory, rebuttable presumption that the agreements covered in these provisions are deemed to eliminate effective competition.[15] As the Federal Supreme Court confirmed, these agreements, if the presumption can be rebutted, significantly restrict effective competition *a maiore ad minus*.[16] The competition authorities need not establish actual effects; it suffices that the competition authorities establish that an agreement has as its object a restraint of competition[17] and therefore at least significantly affects effective competition.

The ComCo issued notices setting out under which conditions it considers that certain agreements are unlikely to affect competition or may be justified on grounds of economic efficiency. The most relevant of these is the Notice on the Competition Law Treatment of Vertical Agreements of 28 June 2010 (the Notice),[18] which sets out:

- which vertical agreements – outside the legal presumptions set out in Article 5(4) of the LCart – are considered to significantly restrict effective competition and possible justifications; and
- which vertical agreements are considered to be insignificant due to their marginal effects on the market.

The Notice aims to create, as far as possible, the same rules on vertical agreements as applicable in the European Union and therefore is largely based on the European Commission's (the EU Commission) previous Vertical Block Exemption Regulation.[19] It aims to ensure a certain harmony between the two legal systems so that the European rules by analogy also apply in Switzerland. It remains to be seen how and when the Notice will be adapted to reflect the new

14 id., Article 5(4).

15 Marino Baldi, 'Zur "Grundsätzlichkeit" der Bundesgerichtsurteile GABA und BMW', *AJP* 2018, pp. 68, 71.

16 Federal Supreme Court (BGer) 143 II 297 (*Gaba*).

17 Article 4(1) LCart.

18 An interpretative note has been published by the competition authorities, following the *Gaba* judgment of the Federal Supreme Court of 12 June 2017.

19 Commission Regulation (EU) No. 330/2010.

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Vertical Block Exemption Regulation.[20] At this juncture, it can only be reported that the ComCo recently published its proposed revisions of the Notice and has opened a public consultation proceeding on these revisions.

Although the Notice may be a helpful instrument to identify possible competition law issues, the Federal Supreme Court clearly held that the Swiss courts are not bound by the practice of the administrative authorities when interpreting and applying legal norms, otherwise the constitutionally guaranteed legal protection of the correct application of the law would be undermined.[21]

Abuse of dominance and relative market power

Pursuant to Article 4, Paragraphs 2 and 2 *bis* of the LCart, market dominance and relative market power are defined as follows:

> *Dominant undertakings are one or more undertakings in a specific market that are able, as suppliers or consumers, to behave to an appreciable extent independently of the other participants (competitors, suppliers or consumers) in the market.*
>
> *An undertaking with relative market power is an undertaking on which other undertakings are dependent for the supply of or demand for goods or services in such a way that there are no adequate and reasonable opportunities for switching to other undertakings.*

According to the statutory definition, market dominance can arise, on the one hand, due to the absolute position on a specific market or, on the other hand, due to specific circumstances between the company concerned and its competitors, customers or suppliers (e.g., dependencies due to market structure). The recently introduced relative market power, according to the new provision in Article 4, Paragraph 2 *bis* of the LCart, exists if a company is dependent on another company for the supply of or demand for a product or service in such a way that there are no sufficient and reasonable possibilities to substitute supply or demand with other companies. As a rule,[22] the Secretariat of the ComCo considers substitute supply or demand possibilities to be sufficient and thus reasonable if other

20 Commission Regulation (EU) 2022/720.

21 *Gaba*.

22 Fact sheet on relative market power issued by the Secretariat of the Competition Commission (ComCo) on 6 December 2021, paragraph 8. The fact sheet is not binding for ComCo or the Swiss courts.

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offers are available that can also adequately satisfy the needs of the presumably dependent company. However, an assessment on whether these substitute channels are adequate must be made using objective, not subjective, criteria.

The problem of dependency due to particular market structures was previously dealt with under the statutory definition of market dominance, and the ComCo established certain criteria to assess whether suppliers or purchasers are dependent on another company.[23] Accordingly, difficulties could arise when it comes to distinguishing situations of a dependency based on market dominance from that based on relative market power, in particular with respect to the concept of market structure dependency as developed under the concept of market dominance.[24] The latter includes, for example, situations where substantial investments have been made in the distribution of a company's products or if a supplier is dependent on a particular customer, or if a supplier generates a substantial share of its sales with a single customer or has aligned its production to a particular customer through no fault of its own and the termination of that business relationship poses an existential threat to the supplier.[25]

According to Article 7(1) of the LCart, dominant companies and companies with relative market power behave unlawfully if they hinder other undertakings from starting or continuing to compete, or disadvantage trading partners, unless there are objective, economic reasons that justify the anticompetitive effects. Article 7(2) of the LCart (similar to Article 102 of the TFEU) contains a non-exhaustive list of circumstances that, according to recent case law, are presumed to have anticompetitive effects:

- any refusal to deal (e.g., refusal to supply or to purchase goods);
- any discrimination between trading partners in relation to prices or other conditions of trade;
- any imposition of unfair prices or other unfair conditions of trade;
- any undercutting of prices or other conditions directed against a specific competitor;
- any limitation of production, supply or technical development;
- any conclusion of contracts on the condition that the other contracting party agrees to accept or deliver additional goods or services; and

23 *CoopForte*, *Recht und Politik des Wettbewerbs* (*RPW*), 2005/1, p. 146 ff, paragraph 98; *Denner/Pick Pay*, RPW 2006/1, p. 131 ff, paragraph 57; *Migros/Denner*, p. 129 ff, paragraph 607; *Coop/Carrefour*, RPW 2008/1, p. 593 ff, paragraph 479.

24 ibid.

25 See footnote 22.

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- the restriction of the opportunity for buyers to purchase goods or services offered both in Switzerland and abroad at the market prices and conditions customary in the industry in the foreign country concerned.

As mentioned above, the distinction between relative market power and market dominance is not entirely clear at present and therefore harbours the risk that civil courts, having regard to earlier practice of the ComCo on economic dependency, could lower the threshold for an abuse of market power.

Life sciences practice

The life sciences sector has seen some notable cases in the past. A very early case is the *Sanphar* case, in which the ComCo, in 2000, prohibited a rebate and profit margin scheme by Sanphar, an association among Swiss pharmaceutical companies. The ComCo found that the scheme set rebates and profit margins at each stage of the distribution of medicinal products and had been applied by almost all manufacturers and importers, wholesalers, pharmacies and drugstores, as well as physicians and doctors who dispense medicines themselves.[26] Following the ComCo's verdict, Sanphar was dissolved.

Also in 2000, the ComCo found that a worldwide vitamin cartel had negative effects in Switzerland. The ComCo, in essence, relied on the presumption in Article 5(3) of the LCart, which was not disputed by the cartel members. The cartel members admitted that they terminated the cartel prior to the opening of the investigation, which the ComCo did not doubt. Thus, the ComCo concluded the investigation, noting that there were no longer any harmful consequences for the Swiss economic order. Moreover, the cartel members declared to the ComCo that they would no longer participate in these types of agreements and that they would implement measures within their company to ensure that this type of conduct would not be repeated.[27]

A relatively important case concerned price recommendations for medicine for erectile dysfunction, which concerned Pfizer and its Viagra pill.[28] Pfizer transmitted price recommendations for Viagra directly to the point-of-sale terminals at drugstores. Whenever the Viagra barcode was scanned, the manufacturer's recommended resale price appeared at the terminals. The recommended resale prices were largely followed because otherwise an additional effort by resellers to

26 RPW 2000/3, p. 320 ff.
27 RPW 2000/2, p. 186 ff.
28 BGer 2C_149/2018. ComCo's investigation also included Bayer and Eli Lilly.

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calculate their own price would be required. The Federal Supreme Court characterised this conduct as a concerted practice and agreement on resale prices. Most important from a practical point of view are the following points held by the Federal Supreme Court.

- The concept of concerted practice requires a direct or indirect contact between the companies (i.e., coordination (two-sided)) and corresponding market behaviour. The contact alone is therefore not sufficient – there must also be corresponding market behaviour by the companies.[29]
- If concertation among companies is established, there is a presumption that the involved companies used the exchanged information when determining their market behaviour. This applies all the more if the coordination takes place regularly over a long period of time.[30]
- Referring to the European Court of Justice's *Eturas* case, the Federal Supreme Court concluded that by transmitting the price recommendation knowingly and willingly to the point-of-sale terminals, Pfizer could assume that resellers knew the price recommendation and that any departure from the price recommendation would cause additional efforts for which reason a price adjustment would not be made. Conversely, resellers could assume that the price recommendation reflected an optimal resale price made available to all resellers.[31]
- The Federal Supreme Court considered two degrees of adherence by resellers: first, the number of distributors applying the recommended price (relevant for the question of whether concerted practice existed) and second, the number of units sold by the distributors at the recommended price (relevant for the question of whether resale price maintenance existed). With respect to the first degree of adherence, the Federal Supreme Court concluded that more than 50 per cent of the resellers followed the price recommendation, which represented a threshold that raises a presumption of concerted practice.[32] In terms of the second degree of adherence, the Federal Supreme Court concluded that doctors sold more than 70 per cent of Viagra at the recommended sales price whereas the degree of adherence was slightly lower with pharmacies (over 60 per cent).[33]

29 id., consideration 3.4.
30 id., consideration 3.4.4.
31 id., consideration 5.2.
32 id., consideration 5.3.
33 id., consideration 6.4.

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- According to the Federal Supreme Court, the high degree of adherence meant that Pfizer and its resellers entered into an unlawful price agreement pursuant to Article 5(4) of the LCart, which did not eliminate competition but – *a maiore ad minus* – significantly affected effective competition.[34]

The Federal Supreme Court's decision caused significant uncertainty as regards the question of under which conditions price recommendations can be considered lawful under Swiss competition law. Although the circumstances of this case were very specific, it is important to note that the Federal Supreme Court did not consider pressure on or incentives for resellers following the price recommendation as a relevant criterion.[35] Rather, it heavily relied on the degree of adherence, which could mean the mere fact that more than 50 per cent of resellers follow a price recommendation may in itself constitute unlawful resale price maintenance.

Merger control

Current Swiss merger control system

The LCart foresees a preventive merger control system that is mainly inspired by the EU merger control system that was in place before the current Merger Control Regulation entered into force.[36] According to Article 9 of the LCart, a proposed merger must be notified to the ComCo if, in the audited annual reports of the business year before the notification, the turnover figures of the undertakings concerned exceeded 2 billion Swiss francs worldwide or 500 million Swiss francs in Switzerland and if at least two of the undertakings concerned each had a turnover of more than 100 million Swiss francs in Switzerland. A proposed concentration is always subject to clearance by the ComCo even if the turnover thresholds are not met if one of the undertakings concerned has, in proceedings under the LCart in a final and formally binding decision, been held to be dominant in a market in Switzerland and if the concentration concerns either that market or an adjacent market, or a market upstream or downstream thereof.

The merger control procedure is divided into two phases. Following the submission of a complete merger notification, the ComCo and, respectively, its Secretariat examine within a period of one month whether there are indications

34 Article 5(1) LCart; BGer 2C_149/2018, consideration 6.5.

35 See section 15 of the Vertical Notice (28 June 2010 (as of 22 May 2017)), www.weko.admin.ch/dam/weko/de/dokumente/2017/Vertikalbekanntmachung_2010_(24%20Oktober%202017).pdf.download.pdf/Vertikalbekanntmachung%20vom%2028.%20Juni%202010%20(Stand%2022.%20Mai%202017).pdf.

36 Council Regulation (EC) No. 139/2004.

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that the proposed concentration would create or strengthen a dominant position. In the absence of these indications, the ComCo is barred from further examining the proposed concentration and it may be implemented without reservations. Although a formal notice that no in-depth investigation will be conducted is not foreseen in the LCart, the ComCo regularly informs the undertakings concerned of this fact. Conversely, if the preliminary examination shows indications that the concentration would create or strengthen a dominant position, the ComCo and, respectively, its Secretariat conduct an in-depth investigation, which can take up to four months. The ComCo may either approve, prohibit or approve subject to conditions notified concentrations.

As substantive assessment criteria, the dominance test was introduced. Accordingly, a proposed merger may only be prohibited by the ComCo if the newly merged entity would create or strengthen a dominant position that results in an elimination of effective competition (qualified dominance). As a matter of law, unilateral effects below the market dominance threshold are not within the scope of the ComCo's review powers. Practice shows that this qualified dominance test makes it very difficult to prohibit mergers. This is proved by the fact that since the introduction of the preventive merger system in 1995, only three merger projects have been prohibited, whereby only one prohibition decision became final and binding.[37]

Recent life sciences practice

The life sciences sector has never been a focus for the Swiss competition authorities and has not caused major issues in Swiss merger control even if some important life sciences markets are defined as national or even regional or local

37 The first case was a merger in the media sector, which was approved on appeal. The second case was the merger between France Telecom Switzerland (Orange) and Sunrise. ComCo stated the creation of a collective dominance between the newly merged entity and the Swiss incumbent Swisscom. The decision was not appealed. The third case concerned a merger between Ticketcorner and Starticket, the two only significant ticketing enterprises active in Switzerland. The ComCo determined that the proposed merger between Ticketcorner and Starticket would have strengthened Ticketcorner's dominance and eliminated effective competition in the market of the distribution of tickets by third parties. In its competition assessment, the ComCo examined the position of the current providers of ticketing services active in Switzerland as well as potential market entries. It examined the market development as well as the role technology could play, such as that of Spotify, Facebook or Google. Despite advances in technology, the ComCo concluded that current and potential competitors would not be able to exert sufficient competitive pressure on the merged entity. This decision was under appeal before the Federal Supreme Court when the merger was abandoned by the parties.

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in scope. This is particularly true for the distribution (pre-wholesale, wholesale, retail) and the demand of drugs,[38] as well as the markets for acute inpatient medical services,[39] outpatient medical interventions and supplies,[40] medical laboratory analysis services[41] and digital health services and platforms.[42] In the health and personal accident insurance sector, as well as in the life and non-life insurance sector, the ComCo, again for regulatory reasons, equally considers whether the market is cantonal or national.[43]

In the poultry genetics and animal health area, in a very early decision following the total reform of the LCart, the ComCo took the view that the relevant markets were national.[44] With regard to crop protection products, in an early decision the ComCo left the geographical scope open but tended to define the markets as international markets.[45]

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38 *Medbase/Zur Rose*, RPW 2020/1, p. 251 ff; *Galexis AG/Pharmapool/Aktiengesellschaft*, RPW 2018/2, p. 386 ff; see also *Sun Store SA/Aristea SA/Distripharma SA/Galenica AG*, RPW 2009/2, p. 173 ff; *Amedis AG/F. Uhlmann-Eyraud*, RPW 2001/3, p. 553 ff.

39 *Medbase/LUKS/Medbase ZS*, RPW 2019/4, p. 1199 ff.

40 *Spital STS AG/Medbase*, RPW 2019/4, p. 1186 ff; *Medbase/HCH/SDH/Zahnarztzentrum.ch*, RPW 2020/4b, p. 1909 ff.

41 In *Unilabs/Medbase/Unilabs St. Gallen*, RPW 2020/4b, section 2011 ff, in vitro and in vivo diagnostic markets are equally defined nationally (see *Roche/Corange*, RPW 1998/1, p. 61 ff. In this case, the ComCo took the following position on an important procedural issue: it stated that extraordinary structural changes of the merger parties influencing the thresholds triggering the notification obligation can only be taken into consideration if they take place before the parties conclude the agreement to merge).

42 *CSS/Visana/Zur Rose/medi24 WELL*, RPW 2021/3, p. 679 ff.

43 *Mutuel/Supra*, RPW 2015/1, p. 93 ff; *Helvetia Holding AG/Schweizerische National-Versicherungsgesellschaft*, RPW 2014/2, p. 542 ff; *Helsana AG bzw. Helsana Unfall AG/La Suisse*, in: 2005/2, p. 392 ff.

44 *Merial*, RPW 1997/3, p. 350 ff. This merger case also raised the question of whether merger transactions in which the parties do not have domiciles in Switzerland but fulfil the thresholds in Article 9 of the Cartel Act must be notified to the ComCo. On 24 April 2001, the Swiss Federal Court confirmed the notification obligation (BGer 127 III 219). In the meantime, the ComCo has issued a notice stating that planned mergers without any reference to Switzerland do not have to be notified (www.weko.admin.ch/dam/weko/de/dokumente/2019/Praxis%20zur%20Meldung%20und%20Beurteilung%20von%20Zusammenschl%C3%BCssen.pdf.download.pdf/v4_D_Praxis_zur_Meldung_und_Beurteilung_von_Zusammenschl%C3%BCssen_(deutsch).pdf).

45 *Hoechst/Rhône Poulenc*, RPW 1990/3, p. 516 ff.

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Since the entry into force of the revised LCart in 1995, the ComCo has followed EU practice in defining drugs product markets by applying the Anatomical Therapeutic Chemical Classification Index.[46] With regard to diagnostics markets, the ComCo applies the European Diagnostic Manufacturers Association Code.[47]

Current reform of the LCart and possible impact on merger control in life sciences

There is currently a partial reform of the LCart taking place. Among other amendments to the LCart, a reform of Swiss merger control is on the government's agenda. On a substantive level, the current (qualified) dominance test shall be replaced by the significant impediment to effective competition (SIEC) test, which was introduced into EU merger control in 2004 and significantly lowers the barriers for the competition authorities to intervene. It is further planned that merger cases affecting markets within the EU and European Economic Area (EEA) shall fall within the exclusive competence of the EU Commission even if the notification criteria in Article 9 of the LCart are fulfilled.[48]

If this merger control reform is approved by the Swiss Parliament, many of the transactions affecting life sciences will remain in the competence of the ComCo as many of these markets, as described above, are geographically defined as national or even local in scope. With regard to the introduction of the SIEC test, it will be interesting to view the ComCo's position on concentration in the Swiss drugs distribution markets and the increasing presence of the Migros group, the largest Swiss retailer in the food and non-food area with a market share of about 40 per cent[49] in the health markets.

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46 It follows the third therapeutic level within the Anatomical Therapeutic Chemical Classification Index; see *Bristol Myers Squibb Company/Astra Zeneca PLC/Amylin Pharmaceuticals Inc.*, RPW 2013/1, p. 106 ff; see also *Galenica/Fresenius Medical Care*, RPW 2011/4, p. 414 ff; *Merck&Co/Schering Plough*, RPW 2009/4, p. 442 ff; *Pfizer/Wyeth*, RPW 2009/4, p. 349 ff; *Sanofi-Synthélabo SA/Aventis SA*, RPW 2004/3, p. 812 ff; *Pfizer Inc./Pharmacia Corp.*, RPW 2003/2, p. 314 ff.

47 *Roche/Corange*, RPW 1998/1, p. 61 ff.

48 www.newsd.admin.ch/newsd/message/attachments/69174.pdf.

49 See *Neue Zürcher Zeitung NZZ*, 17 May 2022, 'Schröpfen Migros und Coop die Konsumenten? Wie es um den Wettbewerb im Lebensmittelhandel steht'.

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Developments in medical device law

Switzerland's third-country status

Since 2001, Switzerland has regulated medical devices in the same way as the EU and has been integrated in the European market surveillance system and European internal market for medical devices via the mutual recognition agreement (MRA).[50] As a result, there was a practically barrier-free market between the EU and Switzerland with regard to medical devices. Due to various incidents and scandals connected with medical devices, doubts were raised about the surveillance system for medical devices in the EU. To improve the safety of medical devices, the EU passed the Medical Device Regulation (MDR)[51] and the In Vitro Diagnostic Medical Device Regulation (IVDR).[52] Switzerland adapted its national legislation for medical devices to the MDR and IVDR to ensure the existing equivalence with the EU. In particular, a new MedDO and new IvDO were adopted.[53] To maintain the free trade of medical devices between the EU and Switzerland, an update of the MRA was necessary. However, the EU made the update of the MRA dependent on the conclusion of an institutional framework agreement with Switzerland (InstA). On 26 May 2021, the Swiss Federal Council terminated the negotiations with the EU because of substantial differences on key aspects of the InstA.[54] Since then, the EU has considered Switzerland as a third country with regard to medical devices.[55]

Impact on the medtech industry in Switzerland

Due to Switzerland's third-country status, the EU Commission is of the opinion that Swiss manufacturers – as required for other non-EU manufacturers of medical devices – as of 26 May 2021, must mandate an EU representative (EC-REP) and

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50 State Secretariat for Economic Affairs, MRA Switzerland–EU, www.seco.admin.ch/seco/en/home/Aussenwirtschaftspolitik_Wirtschaftliche_Zusammenarbeit/Wirtschaftsbeziehungen/Technische_Handelshemmnisse/Mutual_Recognition_Agreement_MRA0/MRA_Schweiz_EU.html.

51 Regulation (EU) 2017/745 of 5 April 2017 on medical devices.

52 Regulation (EU) 2017/746 of 5 April 2017 on in vitro diagnostic medical devices.

53 Federal Office of Public Health, Revision of Swiss medical device legislation, www.bag.admin.ch/bag/en/home/medizin-und-forschung/heilmittel/aktuelle-rechtsetzungsprojekte/revision-med-prod-verord-mepv.html.

54 Federal Council, 'No signing of Swiss–EU institutional agreement', www.admin.ch/gov/en/start/documentation/media-releases.msg-id-83705.html.

55 European Commission, Notice to Stakeholders: Status of the EU–Switzerland Mutual Recognition Agreement (MRA) for Medical Devices, 26 May 2021, https://ec.europa.eu/health/sites/default/files/md_dialogue/docs/mdcg_eu-switzerland_mra_en.pdf (EC Notice).

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label their medical devices with the relevant information about the EC-REP to continue selling their medical devices in EU and EEA states.[56] The EC-REP acts as representative of the Swiss manufacturer to the European authorities and is jointly liable with the Swiss manufacturer for defective medical devices.[57] The new obligation to determine an EC-REP and the corresponding labelling requirements give rise to considerable additional costs. According to industry estimates, this initially cost the Swiss medtech industry 114 million Swiss francs with annual recurring costs of around 75 million Swiss francs.[58]

Moreover, the EU Commission stated that, due to the lack of update of the MRA, certificates issued by Swiss notified bodies – as well as certificates issued under the former European directives prior to the MDR and IVDR's entry into force – are no longer valid for the EU.[59] This has the effect that the only remaining notified body in Switzerland, the SQS, loses a significant business sector. More serious consequences, however, arise for Swiss manufacturers that have certified their medical devices with the SQS. Their SQS certificates are no longer valid and they are no longer able to place their medical devices with SQS certificates on the EU or EEA market. Several legal experts consider the EU Commission's view to be illicit. Some Swiss manufacturers with SQS certificates have therefore filed a claim with the General Court of the European Union, which is still pending. Germany, which is an important export country for the Swiss medtech industry, has also objected to the view of the EU Commission and decided that SQS certificates will continue to be valid in Germany until the deadlines set out in the MDR. Swiss manufacturers may therefore continue to sell their medical devices with SQS certificates in Germany, but not in other EU or EEA states, provided they have appointed an EC-REP for these devices.[60] According to the EU, however, the decision by the German authorities does not conform to the rules.[61]

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56 ibid.

57 Article 11, Medical Device Regulation; Article 11, In Vitro Diagnostic Medical Device Regulation.

58 Swiss Medtech, 'Downgraded to "Third Country" Status today', www.swiss-medtech.ch/en/news/swiss-medtech-downgraded-third-country-status-today.

59 EC Notice (footnote 55).

60 Swiss Medtech, 'Germany recognises SQS certificates', 25 January 2022, www.swiss-medtech.ch/en/news/information-swiss-medtech-sqs-certificates.

61 'Brüssel akzeptiert den Schweizer Medtech-Deal mit Deutschland nicht', *Tagesanzeiger*, 28 January 2022, www.tagesanzeiger.ch/bruessel-akzeptiert-den-medtech-deal-zwischen-der-schweiz-und-deutschland-nicht-473864975623.

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EUDAMED is the IT system established by the MDR and IVDR, which should improve transparency and coordination of information on medical devices available on the EU market. Due to Switzerland's third-country status, the EU Commission has refused Swissmedic, the Swiss enforcement authority, access to EUDAMED.[62] Switzerland is thus denied participation in this key element of the MDR and IVDR structure, which is intended in particular to enhance joint market surveillance. At present, Switzerland can cope with the lack of access to EUDAMED with regard to market surveillance, as the relevant module is not yet functional.

Irrespective of the question of whether the actions of the EU Commission are lawful,[63] the Swiss medtech industry has lost its previously barrier-free access to the EU and EEA market. This loss is undoubtedly serious. However, the majority of Swiss medtech companies, in particular the big medtech companies, adjusted to the third-country scenario at an early stage and took the necessary precautions to continue exporting their medical devices to EU and EEA countries. Nevertheless, the Swiss medtech industry is concerned about the possible loss of attractiveness associated with its third-country status. Switzerland might lose its investment attractiveness compared to EU countries due to the third-country bureaucracy.[64]

Impact on the medtech Industry in EU/EEA states

Despite Switzerland's third-country status, the Swiss medical devices legislation still largely adopts the MDR and IVDR. Switzerland continues to recognise the European conformity markings as well as the certificates issued by notified bodies based in EU and EEA states,[65] even if the EU no longer recognises the certificates of the only existing Swiss notified body, SQS. Medtech companies from EU and EEA countries are therefore still permitted to distribute their medical devices certified in the EU in Switzerland. Since 26 May 2021, however, they no longer

62 EC Notice (footnote 55).

63 For supplementary information on this question, see: MedTech Europe, 'EU/EEA Market Access for "Swiss Legacy Devices" following entry into application of the MDR', 3 August 2021, www.medtecheurope.org/resource-library/eu-eea-market-access-for-swiss-legacy-devices-following-entry-into-application-of-the-mdr/.

64 Swiss Medtech, 'Downgraded to "Third Country" Status today', 26 May 2021, www.swiss-medtech.ch/en/news/swiss-medtech-downgraded-third-country-status-today.

65 Article 13, Ordinance on Medical Devices (MedDO); Article 13, Ordinance on In Vitro Diagnostic Medical Devices (IvDO).

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benefit from the previously almost barrier-free market access to Switzerland, but rather have to meet more stringent requirements, as the following sections illustrate.

As a result of the non-updated MRA, Switzerland requires that manufacturers from EU or EEA countries have to mandate a Swiss authorised representative (CH-REP) – whose rights and obligations are comparable to those of an EC-REP[66] – and label their medical devices with the relevant information about the CH-REP within certain legal transitional periods[67] to continue placing their medical devices in Switzerland. These additional requirements are associated with considerable costs.

Until the MRA is updated, Swissmedic is unable to assign a European single registration number via EUDAMED for economic operators that are domiciled in Switzerland. To mitigate the consequences of this loss and to continue to ensure market surveillance in Switzerland, manufacturers, authorised representatives and importers domiciled in Switzerland are required to register once with Swissmedic to market their medical devices in Switzerland. Economic operators must register within three months of placing their first medical device on the Swiss market.[68] Swissmedic then issues them with a Swiss single registration number.[69]

Due to Switzerland's third-country status, manufacturers from EU or EEA countries that have previously profited from a barrier-free market access to Switzerland must overcome increased hurdles to sell their medical devices in Switzerland. It is expected that many EU and EEA manufacturers will be reluctant to take on this additional effort for the small Swiss market. The Swiss healthcare sector is therefore concerned that there will not be enough medical devices available to supply the Swiss population in the future. Forecasts assume that around one in eight medical devices will no longer be available in Switzerland.[70]

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66 Article 51 MedDO; Article 44 IvDO.

67 Article 104a MedDO; Article 86 IvDO.

68 Article 55 MedDO; Article 48 IvDO.

69 Swissmedic, Swiss Single Registration Number (CHRN), www.swissmedic.ch/swissmedic/en/home/medical-devices/market-access/registriernummer-chrn.html.

70 Swiss Medtech, 'Verfügbarkeit von Medizinprodukten ist stark gefährdet', www.swiss-medtech.ch/sites/default/files/2021-02/Anhang_210205_Brief_Gesundheitsakteure_DE.pdf.

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Possible consequences of Switzerland's third-country status from a competition law perspective

The lack of an amended MRA certainly makes the supply of medical devices in Switzerland more complicated. Switzerland (as well as the EU and EEA) can no longer be deemed open markets, which may have implications on the market position of suppliers as well as behavioural consequences. For instance:

- Swiss customers may have a limited choice of suppliers for medical devices and these suppliers may more easily acquire market power or dominance; and
- as imports of medical devices have become more complicated, Swiss customers may seek to cooperate through joint purchasing agreements, which, if their market share is below 15 per cent, is not expected to entail any anticompetitive effects.[71] However, if the market share of the participating hospitals exceeds 15 per cent, anticompetitive effects cannot be excluded, resulting in the necessity of a careful assessment of the joint purchasing strategy, as the competition authorities consider joint purchasing agreements to be agreements within the meaning of Article 5(3)(a) of the LCart.

Outlook

The life sciences sector has hitherto not raised major competition law issues in Switzerland. This is true with regard to cartels, abuse of dominance and merger control. It remains to be seen if the recent regulatory changes and the mutual market access problems with the EU, respectively, will lead to a different competitive environment. The companies active in these affected markets are well advised to remind their employees to observe Swiss and EU competition law.

If the reform of the Swiss merger control and the introduction of the SIEC test, respectively, should pass, this may have consequences for future mergers in the life sciences sector, in particular in markets defined as national in geographical scope, such as the distribution of drugs markets.

71 Pursuant to EU competition law practice.

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The covid-19 pandemic – and the amount of public money that governments are spending on healthcare – has thrust the life sciences industry into the international spotlight, with debates over price controls and IP waivers making headlines around the world. While many of these concerns are global, the same is not always true of the solutions adopted by national regulators. The first edition of *The Guide to Life Sciences* – edited by Ingrid Vandenborre and Caroline Janssens – provides practical and timely guidance for both practitioners and enforcers trying to navigate this high-stakes environment. The Guide draws on the wisdom and expertise of distinguished practitioners globally to provide essential guidance on subjects as diverse as biosimilar competition and product denigration, as well as a forensic examination of the most significant and far-reaching regulations and decisions from around the world.

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