
CHAMBERS GLOBAL PRACTICE GUIDES

Healthcare M&A 2024

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**Switzerland: Law & Practice and
Trends and Developments**

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SWITZERLAND



Law and Practice

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Contents

1. Market Trends p.5

- 1.1 Healthcare M&A Market p.5
- 1.2 Key Trends p.5

2. Establishing a New Company p.7

- 2.1 Establishing a New Company p.7
- 2.2 Type of Entity p.7
- 2.3 Early-Stage Financing p.7
- 2.4 Venture Capital p.8
- 2.5 Venture Capital Documentation p.8
- 2.6 Change of Corporate Form or Migration p.8

3. Initial Public Offering (IPO) as a Liquidity Event p.8

- 3.1 IPO v Sale p.8
- 3.2 Choice of Listing p.8
- 3.3 Impact of the Choice of Listing on Future M&A Transactions p.9

4. Sale as a Liquidity Event p.9

- 4.1 Liquidity Event: Sale Process p.9
- 4.2 Liquidity Event: Transaction Structure p.9
- 4.3 Liquidity Event: Form of Consideration p.9
- 4.4 Liquidity Event: Certain Transaction Terms p.9

5. Spin-Offs p.10

- 5.1 Trends: Spin-Offs p.10
- 5.2 Tax Consequences p.10
- 5.3 Spin-Off Followed by a Business Combination p.10
- 5.4 Timing and Tax Authority Ruling p.11

6. Acquisitions of Public (Exchange-Listed) Healthcare Companies p.11

- 6.1 Stakebuilding p.11
- 6.2 Mandatory Offer p.12
- 6.3 Transaction Structures p.12
- 6.4 Consideration; Minimum Price p.13
- 6.5 Common Conditions for a Takeover Offer/Tender Offer p.13
- 6.6 Deal Documentation p.13
- 6.7 Minimum Acceptance Conditions p.14
- 6.8 Squeeze-Out Mechanisms p.14

- 6.9 Requirement to Have Certain Funds/Financing to Launch a Takeover Offer p.15
- 6.10 Types of Deal Protection Measures p.15
- 6.11 Additional Governance Rights p.15
- 6.12 Irrevocable Commitments p.16
- 6.13 Securities Regulator's or Stock Exchange Process p.16
- 6.14 Timing of the Takeover Offer p.17

7. Overview of Regulatory Requirements p.17

- 7.1 Regulations Applicable to a Healthcare Company p.17
- 7.2 Primary Securities Market Regulators p.17
- 7.3 Restrictions on Foreign Investments p.17
- 7.4 National Security Review/Export Control p.18
- 7.5 Antitrust Regulations p.18
- 7.6 Labour Law Regulations p.18
- 7.7 Currency Control/Central Bank Approval p.18

8. Recent Legal Developments p.19

- 8.1 Significant Court Decisions or Legal Developments p.19

9. Due Diligence/Data Privacy p.19

- 9.1 Healthcare Company Due Diligence p.19
- 9.2 Data Privacy p.20

10. Disclosure p.20

- 10.1 Making a Bid Public p.20
- 10.2 Prospectus Requirements p.21
- 10.3 Producing Financial Statements p.21
- 10.4 Disclosure of Transaction Documents p.21

11. Duties of Directors p.21

- 11.1 Principal Directors' Duties p.21
- 11.2 Special or Ad Hoc Committees p.22
- 11.3 Board's Role p.22
- 11.4 Independent Outside Advice p.22

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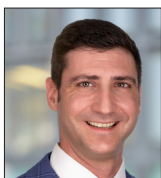
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1. Market Trends

1.1 Healthcare M&A Market

High inflation, rising interest rates, the ongoing war in Ukraine and a strong Swiss franc, combined with the turbulences in the Swiss financial sector posed challenges on the deal activity in Switzerland in 2023, leading to longer deal processes and added complexity in deal structures. Nonetheless, the Swiss healthcare M&A market has shown resilience with an increased deal activity in 2023 compared to the previous years, both in terms of deal numbers and deal value. This development is particularly noteworthy given the overall depressed M&A deal activity in Switzerland in 2023; the number of deals involving Swiss businesses (outbound, inbound and domestic transactions) dropped by 25% compared to 2022.

1.2 Key Trends

Deal Activity

In general, M&A activity in Switzerland has seen an overall decrease in 2023. However, M&A activity in the Swiss healthcare sector has remained strong and increased in 2023 compared to the previous year, both in terms of number of deals and value.

Private equity and venture capital investors have been particularly active in healthcare M&A. In 2023, more than 50% of the M&A deals in the Swiss healthcare industry involved either private equity or venture capital investors. Whereas in the past, private equity investors mainly focused on healthcare service providers, their focus shifted in 2023 towards investments in pharmaceutical and medtech companies. In contrast, venture capital investors continued to focus on the Swiss biotech sector. Beside private equity and venture capital, larger pharmaceutical companies were heavily involved in the Swiss M&A market: the three Swiss pharmaceutical companies Roche, Novartis and Lonza were involved in almost half of the ten largest M&A deals by value in the Swiss healthcare industry.

Swiss Adaption to the European Regulation Governing Medical Devices

Since the Mutual Recognition Agreement between the European Union (EU) and Switzerland was not updated in 2021, Switzerland is now considered a “third country” under the EU regulations and Swiss registrations/authorisations are not recognised in the EU any more and vice versa. The Swiss Federal Council tried to mitigate the negative consequences of this non-recognition by aligning the Swiss legislation on medical devices and in vitro diagnos-

tics with the European Union Medical Devices Regulation (MDR) and In Vitro Diagnostics Regulation (IVDR) and imposing certain additional measures. For example, medical devices with an EU conformity assessment (CE marking) are unilaterally recognised in Switzerland. These legislative developments may be relevant to M&A activity in the field of medical devices. For example, if a non-European company acquires a Swiss manufacturer of medical devices with the respective authorisation(s) under Swiss law, this does not suffice for the targets to be recognised as manufacturer or distributor in the EU. The appointment of an authorised representative or other authorisations may be necessary under EU regulation to such purpose. Generally, Swiss medtech companies have timely addressed this topic and implemented the measures required to be compliant under EU law.

Revision of the Swiss Data Protection Act

On 1 September 2023, the new Swiss Data Protection Act (revDPA) came into force. The aim of the revDPA was, on the one hand, to modernise Swiss data protection law and, on the other hand, to bring it into line with EU law, in particular with the EU General Data Protection Regulation (GDPR). Companies that were already compliant with GDPR had only minimal adaptations to implement under the revDPA. The revDPA may be relevant in the context of Swiss healthcare M&A if the business of a target company involves processing of Swiss personal data or generally processing personal data in Switzerland. It is noted that the transfer and processing of personal data in the context of a due diligence exercise may trigger obligations and restrictions under the revDPA.

Failure to comply with the revDPA may result in criminal sanctions against the individuals involved.

Foreign Direct Investment Screening

Currently, Switzerland does not have any general foreign direct investment (FDI) screening mechanisms in place. However, certain regulatory requirements apply to certain industries and sectors, for example, banking and real estate. Several additional business activities require a governmental licence, and the licensing conditions include specific requirements regarding foreign investors. Examples of such business activities are aviation, telecom, radio and television, and nuclear energy.

Mid December 2023, the Federal Council adopted the dispatch on a new Investment Screening Act. Under the new draft legislation, investment screening is intended to only apply when a foreign state-controlled investor takes over a domestic company that operates in a particularly critical area, such as health infrastructure. This means that the takeover of Swiss hospitals and companies active in the research, development, production or production or distribution of medical products, devices or other equipment by a foreign state-controlled investor would need an approval subject to reaching certain turnover thresholds. The proposal is still subject to the approval of the Swiss parliament.

EU Artificial Intelligence Act (EU AI Act)

Artificial Intelligence (AI) is making its way into the healthcare sector, in particular in the area of pharmaceuticals where AI is used in research and development, including for better processing of large amounts of data and quicker evaluation of different combinations of active ingredients. In medical treatment, AI increasingly comes into use in medical devices, either as standalone software or integrated into hardware components.

On 8 December 2023, the EU Commission published a draft of the AI Act, the first-ever legal framework on AI that aims to provide AI developers, deployers and users with clear requirements and obligations regarding specific uses of AI. Like the GDPR, the AI Act will have an extraterritorial reach and will not only be applicable to a Swiss company that makes an AI system available in the EU market but will also apply if the output generated by the AI system of a Swiss company is used in the EU. Once it is formally adopted, it is expected to be fully applicable after two years.

There is currently no specific AI systems regulation in the Swiss legal system. On 22 November 2023, the Federal Council has instructed the Federal Department of the Environment, Transport, Energy and Communications to prepare a report on the possible regulatory approaches to AI systems for Switzerland that are particularly compatible with the EU AI Act and the Council of Europe's AI Convention, which should create the basis to issue a concrete mandate for an AI regulatory proposal in 2025.

2. Establishing a New Company

2.1 Establishing a New Company

Among other features that make Switzerland one of the most innovative countries in the world, it offers a business-friendly legal framework ensuring fast and cost-effective incorporations. Therefore, it is attractive to incorporate a start-up company in Switzerland. Swiss corporate law offers all relevant features required for a start-up company to operate successfully, in particular also with regard to initial seed financings and subsequent capital contributions from financial sponsors or strategic investors. Different share classes with voting/non-voting structure, divi-

dend and/or liquidation preferences are some of these prominent features. The entire incorporation process for a new company typically requires two to four weeks, depending, among other things, on the canton of the company's intended seat, the country of residence of the investors (in particular for opening the required blocked bank account) and the efficiency of the founders in delivering the necessary documents. Unless the founders choose a partnership with full personal liability, an initial capital contribution is required to establish a new company (see 2.2 **Type of Entity** for required capital amounts).

2.2 Type of Entity

Entrepreneurs are typically advised to incorporate an entity in the form of a corporation ("*Aktiengesellschaft*") or a limited liability company ("*GmbH*"). Both types of entities are endowed with a separate legal personality and provide for a limited liability with its share capital. The minimum share capital to incorporate a corporation is CHF50,000 (partially paid-in) or CHF100,000 (fully paid-in), whereas investors naturally favour a fully paid-in capital to have recourse to a higher adhesion substrate. An entity may also be incorporated as limited liability company. The main difference from a corporation relates to its lower minimum share capital requirement of CHF20,000, the disclosure of the shareholders in the commercial register and somewhat limited flexibility in terms of capital-raising features.

2.3 Early-Stage Financing

As professional investors such as venture capitalists usually expect recurring annual revenues, early-stage financing is typically provided by family and friends as well as wealthy individuals ("*angel investors*"). They do not require an accreditation or another qualification, professional experience or net worth. In fact, these are private individuals investing their own money

into a start-up and – unlike professional venture capitalist investors – do not get paid for making the investment. Ideally, angel investors provide knowledge to develop a company and promising products. In terms of investing volume, angel investors are followed by seed and series A funds, corporate ventures and family offices. Over the past years, Switzerland has seen a large increase in seed investments, both in terms of numbers (166 investments) and value (average investment amount of CHF2 million). The documentation for early-stage financing for a start-up company in Switzerland is usually rather basic, consisting of a subscription form (rather than an eloquent subscription agreement) to subscribe for newly issued shares resolved at a shareholders' meeting and a basic shareholders' agreement including some form of tag- and drag-along rights, if at all.

2.4 Venture Capital

Although the Swiss start-up scene has developed impressively over the last ten years, its venture capital industry is still relatively young. Some of the sponsors are in their second or third fund generation, but a lot are in their first round. However, Swiss start-ups are attracting large international investors due to attractive valuations and innovative ideas. In general, foreign venture capital firms foremost provide funds in mid- and late-stage financing rounds.

2.5 Venture Capital Documentation

The Swiss Private Equity & Corporate Finance Association (SECA) has developed a well-regarded set of model documents that are available on its website. In general, there is substantial standardisation of the documentation. Primarily, a term sheet lays out the financial terms of the investment and forms the basis for implementing an equity investment. These terms may subsequently be implemented in a legally

binding investment and shareholders' agreement with the purpose of outlining the rights, obligations and relationships among the shareholders. Minority shareholders such as start-up investors strive to implement special rights to protect their investment.

2.6 Change of Corporate Form or Migration

In principle, start-ups continue to stay in the same corporate form and jurisdiction. Especially if the start-up is incorporated as a corporation, there is no need to change the corporate form in a later stage of venture capital financing. A general necessity to change jurisdiction is not apparent, rather subject to the start-up's long-term strategy and goals.

3. Initial Public Offering (IPO) as a Liquidity Event

3.1 IPO v Sale

Generally, a liquidity event in Switzerland is still run through a sale process, rather than an IPO. Dual-track processes are sometimes pursued, but there is no general trend to have a dual-track process at the outset.

In the past years, the number of IPOs at the SIX Swiss Exchange has been rather low. Therefore, in 2022, the SIX Swiss Exchange launched a new segment for small and mid caps to revive the IPO market as an alternative to sale processes. However, the effects have been limited so far. The costs, time and effort for an exit via an IPO remain significantly higher than via a sale process.

3.2 Choice of Listing

A Swiss company is most likely to list in Switzerland unless it has specific interests in listing in

another country. Usually, the decisive factor for a listing abroad would be a larger investment base and higher industry/sector valuations. In fact, in the last years, a couple of healthcare companies have chosen a foreign exchange (SUA) instead of a listing at SIX Swiss Exchange. The main advantages of a “home country” listing in Switzerland are (i) the efficiency of the listing procedure and listing maintenance, and (ii) the avoidance of heavier regulatory burdens and additional exposure to litigation risks in multiple jurisdictions. In general, while there are Swiss companies that are listed on multiple stock exchanges in different jurisdictions, the costs of such multiple listings are usually considered higher than their benefits.

3.3 Impact of the Choice of Listing on Future M&A Transactions

A listing on a foreign exchange will have the effect that the company will continue to be subject to Swiss corporate law, but will, in addition, have to comply with the rules of the foreign exchange. This dual applicability of legal systems may lead to increased complexity in structuring a future sale, especially in case of potential conflicts between domestic and foreign law. Moreover, the Swiss tender offer rules (including squeeze-out rules in the context of tender offers) will not apply to a sale of a company that is only listed on a foreign exchange. Therefore, additional steps, such as the implementation of a squeeze-out merger pursuant to the Swiss Merger Act, may be required to successfully achieve a sale of 100% of the shares in the company.

4. Sale as a Liquidity Event

4.1 Liquidity Event: Sale Process

There is no typical rule for a sale being run as an auction or in a bilateral negotiation. Auctions

are usually chosen if the investors are keen to maximise the purchase price. However, the uncertainties and costs of an auction process may keep potential buyers from participating in the auction. Bilateral negotiations are usually conducted by strategic investors that approach potential targets directly if they see a strategic fit.

4.2 Liquidity Event: Transaction Structure

Usually, the sale of a privately held healthcare company is structured as a share purchase whereby all the shares in the company are sold to the purchaser. In recent months and in connection with a sale to a financial sponsor, however, it has become increasingly popular to provide VC fund shareholders of a healthcare company the choice to co-sell or roll over their investment. Key members of the management holding equity in the company are usually required to roll over part of their sale proceeds in the equity of the buyer.

4.3 Liquidity Event: Form of Consideration

The consideration in a sale of a Swiss privately held venture capital-financed healthcare company is usually cash. Certain rollovers for the key management are structured in a way that the management holding equity in the company is paid with a mix of cash and equity.

4.4 Liquidity Event: Certain Transaction Terms

Customarily, shareholders agreements between the founders and VC investors provide for drag- and tag-along rights in relation to liquidity events. Such drag- and tag-along rights contain provisions on the key terms and conditions that apply to shareholders in case of a sale event. The terms of such provisions are usually heavily negotiated and may contain more or less detailed provisions on what representations, warranties

and indemnities the shareholders are required to give in a sale process. In general, any such liability is limited to each shareholder's share in the purchase price and is several, and not joint with the other shareholders. Obligations to enter into escrows or agree to holdbacks may also be contained in the drag- and tag-along rights.

The use of warranty and indemnity (W&I) insurance is growing in Switzerland and is generally an accepted instrument among professional players in the market.

5. Spin-Offs

5.1 Trends: Spin-Offs

There is a clear trend for Swiss healthcare companies to focus on core competencies and divest non-core assets. Divestitures are usually structured as spin-offs (see **1.2 Key Trends**). Further divestments in the healthcare industry are expected in the form of spin-offs.

5.2 Tax Consequences

Spin-offs can be structured as tax-neutral reorganisations at the corporate level (including a so-called holding spin-off) if certain requirements are fulfilled, irrespective of the execution under civil law – eg, asset deal, two-step demerger or statutory demerger. The most important requirements for Swiss tax purposes are the following:

- the spin-off business remains taxable in Switzerland;
- the values previously relevant for income tax are taken over;
- one or more businesses or parts of businesses are transferred; and
- the legal entities that exist after the spin-off continue to operate a business or part of a business.

It should be noted that, especially in the case of tax-neutral spin-offs, the key element is the so-called double business requirement, meaning that an independent business must remain operative within the transferring entity.

If the above-mentioned conditions are fulfilled, the tax neutrality of spin-offs also applies to the shareholders, provided there will be no gain in the nominal value or so-called capital contribution reserves (for individuals).

There is no blocking period for Swiss tax purposes, provided the spin-off qualifies as tax-neutral spin-off.

5.3 Spin-Off Followed by a Business Combination

In principle, and bearing in mind that a tax-neutral spin-off is based on the requirement of two separate businesses without being subject to a blocking period, a spin-off immediately followed by a business combination should be possible for Swiss tax purposes.

It should always be considered whether the general rules for tax avoidance may be applicable to the case at hand. Generally, tax avoidance would be assumed if:

- a legal arrangement chosen by the parties involved appears to be unusual (“insolite”), improper or outlandish, or in any case completely inappropriate to the economic circumstances (“objective element”); and
- it can be assumed that the chosen legal arrangement was made abusively merely in order to save taxes that would be due if the appropriate circumstances were in place (“intention to avoid”; “subjective element”); and

- the chosen course of action would actually lead to significant tax savings, if accepted by the tax authority (“effective element”).

Particular attention should be paid to the transfer of tax losses carry forward as part of the spin-off and subsequently the transfer of such tax losses carried forward and the offset with taxable profit of the acquiring business. In general, the offset of tax losses carry forward is possible to the extent that the business will be taken over and continued and that the structure would not be considered as a tax avoidance.

It should be noted that a contribution of a business followed by an upstream merger could trigger adverse Swiss tax consequences.

5.4 Timing and Tax Authority Ruling

The timing of a spin-off usually depends on the preparation of the transaction from a tax and legal perspective, including the information and consultation of employees, as well as from an operational perspective. From a legal perspective, a spin-off may be structured in different ways, including via:

- a direct business transfer by means of an asset deal (“singular succession”) or as a bulk transfer pursuant to the Swiss Merger Act (“universal succession”);
- a two-step demerger (transferring the business to a newly incorporated subsidiary – “newco” – and selling the shares in the newco to the buyer); or
- a statutory demerger.

Where there is a transfer of a business with employees, the employer has certain information obligations and, if measures apply that affect the employees, a consultation procedure must be implemented. While no specific waiting period

applies for the employees’ information and consultation, it is usually recommended to inform and consult the employees at least one month prior to the effective date of the spin-off.

From a tax perspective, it is best practice to file advance tax rulings with (i) the competent cantonal tax authority for corporate income tax and annual capital tax purposes – ie, the cantonal tax authority responsible for the assessment of corporate income tax and annual capital tax of the company, and (ii) the Swiss Federal Tax Administration for Swiss withholding tax and stamp duties purposes (usually levy and refund). It is critical that the tax rulings will be filed prior to the implementation of the spin-off as a confirmation will only be granted for transactions that have not yet occurred.

Depending on the complexity of the spin-off, a confirmation can usually be obtained between three and six weeks after filing with the Swiss Federal Tax Administration and usually between three and twelve weeks after filing with the cantonal tax authorities, whereas this varies largely between the different cantonal tax authorities.

The preparation and completion of a spin-off usually takes 6–12 months.

6. Acquisitions of Public (Exchange-Listed) Healthcare Companies

6.1 Stakebuilding

In Switzerland, it is common to acquire a certain stake in a public company prior to making a public tender offer. The stakebuilding can take place as a private transaction or through trades on the exchange.

Whenever the relevant shareholder reaches or exceeds a threshold of 3, 5, 10, 15, 20, 25, 33⅓, 50 or 66⅔% of votes in the company through an acquisition of shares (or falls below such thresholds as a result of a sale of shares), the relevant shareholder has to notify the company and the exchange. These thresholds apply to stakebuilding in (i) companies having their corporate seat in Switzerland and having all or parts of their participations listed on a Swiss stock exchange, as well as (ii) companies having their corporate seat abroad, but having all or parts of their participations primarily listed on a Swiss stock exchange. The notification obligation also applies when shares are bought or sold in concert and when converting participation certificates or profit participation certificates into shares, when exercising convertibles or option rights, and for other changes of the capital of the company and exercise of sale options.

The notification duty is triggered by the creation of the right to acquire or dispose of the equity securities – ie, upon conclusion of the binding transaction. In the event of capital increases or decreases, the duty is triggered by the publication in the Swiss Official Gazette of Commerce. The indication of an intended acquisitions or disposal or similar proposals do not trigger the notification duty as long as there are no legal obligations to execute the transaction imposed on any of the parties.

When the notification duty is triggered, the beneficial owners of the equity securities (the parties controlling the voting rights) have to be disclosed. In addition, in the case of parties acting in concert, the aggregate participation, identity of all members of the group, the type of acting in concert, and the representative have to be disclosed as well. The purpose of the acquisi-

tion and the buyer's intention with respect to the company do not need to be disclosed.

If a party publicly announces that it considers a public tender offer without the legal obligation to submit such offer, the Swiss Takeover Board ("*Übernahmekommission*") may at its discretion request the potential offeror either to publish a public tender offer within a certain deadline ("put up") or to publicly declare to abstain from submitting an offer or from stakebuilding in excess of the threshold triggering a mandatory offer (see **6.2 Mandatory Offer**) within six months ("shut up").

6.2 Mandatory Offer

Under Swiss public takeover laws, once a direct or indirect shareholding of 33⅓% is reached, a mandatory offer has to be submitted. This obligation also arises when the threshold is reached by acting in concert.

6.3 Transaction Structures

A public company in Switzerland can be acquired through a public tender offer, a statutory merger, a share deal through which a controlling shareholding is acquired or an asset deal whereby the assets and liabilities of the operational business are acquired. In general, the two typical transaction structures are a public tender offer or a statutory merger. Whereas the public tender offer structure is usually seen in an international setting (in case a (reverse) triangular merger does not work) involving a listed Swiss entity, statutory mergers are more frequently used in domestic private M&A transactions. Public tender offers are governed by the Swiss Financial Market Infrastructure Act and the relevant ordinances thereto. Statutory mergers are governed by the Swiss Merger Act.

6.4 Consideration; Minimum Price

In voluntary offers, the acquisition may be structured as a cash or stock-for-stock transaction or a combination thereof. In public tender offers, it is mandatory to offer a cash consideration where a stock-for-stock exchange offer is made.

In mergers, a cash compensation is possible and common either as a combination of shares and cash (in which case the cash compensation must not exceed $\frac{1}{10}$ of the fair market value of the shares), a right to choose between shares or cash compensation or by stating in the merger agreement that only a cash compensation is offered.

The price offered in a public tender offer has to comply with a strict minimum price rule. The price has to be equal or higher than either (i) the stock exchange price which corresponds to the volume weighted average price (VWAP) during the 60 trading days' period before the preliminary announcement or the offer prospectus or (ii) the highest price paid by the bidder (or any person acting in concert with the bidder) during the 12-month period before the preliminary announcement or the offer prospectus, which takes into account all agreements concluded during that period independent of the closing of such transaction.

Contingent value rights are not a common feature in public M&A transactions in Switzerland.

6.5 Common Conditions for a Takeover Offer/Tender Offer

Offer conditions are permitted for voluntary offers if:

- the bidder has a justified interest;
- the satisfaction of a condition cannot be (substantially) influenced by the bidder; and

- the bidder has to pay a compensation due to the type of the condition, it has to implement all reasonable measures to ensure that the condition is satisfied.

The following types of conditions are common in Swiss public M&A transactions:

- conditions to secure the acquisition of control (minimum acceptance levels);
- conditions to protect the substance of the target company, including material adverse change clauses; and
- conditions to secure the completion of the transaction, such as approvals by authorities, amendments to articles of incorporation, entry in the shareholders' register and/or control over the board.

Where a bidder is subject to a mandatory offer (see **6.2 Mandatory Offer**), offer conditions are limited to regulatory approvals and registration as shareholder in the share register.

6.6 Deal Documentation

In Switzerland, it is common to enter into a transaction agreement between the bidder and the target company in connection with a takeover, which is supported by the board of directors of the target company.

The transaction agreement would typically contain the following undertakings of the target company.

- Co-operation undertakings with respect to access to information, publication of financial statements, notice of relevant events/violation of covenants/actions threatening the completion of the transaction.
- Non-solicitation of other offers (no-shop undertakings).

- Future management structure.
- Information obligation with respect to competing offers or related inquiries.
- Joint press releases.
- Obtaining a fairness opinion.
- Fulfilment of specific offer conditions.
- Reasonable best efforts to solicit the tender of the shares.
- Compliance with takeover regulations.
- Convocation of shareholders' meeting to elect new board members appointed by the bidder.
- Registration of the bidder in the share register after completion.
- Conduct of business undertakings.
- Payment of a break fee if certain covenants, laws, regulations or conditions are violated.

It is also common to include representations and warranties in a transaction agreement, which are normally limited to fundamental representations and warranties (due incorporation, accuracy of information, valid issuance of shares, no violation of any contractual or constitutional obligations).

For mergers, it is mandatory to enter into a merger agreement between the merging entities and the Swiss Merger Act prescribes a mandatory minimum content. There are no specific obligations of the target company and it is not common to provide any representations and warranties.

6.7 Minimum Acceptance Conditions

Minimum acceptance conditions prescribing that the bidder (after the expiry of the offer period) directly or indirectly owns a certain number of target company shares are permitted and common in voluntary public tender offers (see **6.2 Mandatory Offer**). In principle, a threshold of 66⅔% of outstanding target shares is usually accepted by the Swiss Takeover Board. How-

ever, there is no specific control threshold for minimum acceptance conditions as long as such thresholds are not unreasonably high. Based on case law of the Swiss Takeover Board, the following general rules apply, subject to a case-by-case analysis:

- thresholds of 50% are reasonable for partial offerings;
- thresholds of 66⅔% or less are in principle reasonable;
- thresholds of 66⅔% or more are only reasonable in specific situations; and
- thresholds of 90% are reasonable for holding offerings.

With a 66⅔% majority, a shareholder is able to control all important decisions of a Swiss target company according to Swiss law, unless the articles of incorporation stipulate different voting thresholds.

6.8 Squeeze-Out Mechanisms

If a bidder does not achieve a shareholding of 100% after a public tender offer, it may squeeze out the remaining minority shareholders. The squeeze-out mechanism depends on the ownership threshold.

- If the bidder already holds more than 98% of the voting rights, the squeeze-out can be effected through court proceedings. The bidder would file a respective squeeze-out request within three months after the end of the additional offer period. The shares of the minority shareholders will be cancelled upon court order against a compensation payable by the bidder and re-issued to the bidder. Subsequently, the board of directors of the target company may request the delisting of the shares of the company. Often the delisting

process is already initiated in parallel to the squeeze-out procedure.

- If the bidder holds more than 90% but less than 98%, the squeeze-out can be effected through a statutory squeeze-out merger. In this case, the bidder (or one of its affiliates) is merged with the target company. This requires the entering into a merger agreement between the merging companies, approval by the general meeting of shareholders of both companies, a report by the board of the merging companies outlining the reasons for the merger, a report by a Swiss qualified auditor reviewing the merger documentation and a filing with the commercial registers where the two companies are registered. Following registration of the merger, the transferring company will be deleted from the commercial register and the minority shareholders will receive a cash compensation. The adequacy of the compensation can be challenged during a period of two months from publication of the merger in the Swiss Official Gazette of Commerce.

6.9 Requirement to Have Certain Funds/ Financing to Launch a Takeover Offer

Upon publication of the offer prospectus in connection with a public tender offer, the bidder must confirm that the funds required to finance the takeover will be available on the settlement date. Under Swiss public takeover laws, an independent review body (auditor) has to confirm the availability of the necessary funds. In the case of debt financed offers, the executed financing documentation (and not only a term sheet) should be available as the financing banks will issue their commitment letters only under such documentation.

The permissibility of conditions and covenants in the financing documentation are admissible but

limited and need to correspond to the offer conditions. Offers conditioned to obtaining financing are not permitted as the financing documentation has to be available in executed form already at the time of publishing the prospectus.

There is no certain funds requirement in a statutory merger.

6.10 Types of Deal Protection Measures

To secure the support of a transaction, the bidder and the target company may enter into a transaction agreement and agree on deal protection measures. Typical deal protection measures are as follows:

- the undertaking of the board of directors of the target company to support the deal;
- non-solicitation provisions; and
- matching rights and break fees.

These measures are all subject to the fiduciary duties of the board of directors of the target company and, therefore, must not be overly restrictive. Break-up fees and reverse break-up fees are generally limited up to the amount of coverage of reasonable costs incurred on the level of the bidder. Punitive break fees are not admissible and transaction agreements have to contain a break right in case a better competing takeover offer is announced.

6.11 Additional Governance Rights

If a bidder cannot obtain 100% ownership of a target company, there are a number of statutory governance rights depending on the exact shareholding.

- A shareholding of more than 50% allows the bidder to pass shareholders' resolutions unless Swiss law or the constitutional docu-

ments of the company prescribe a qualified majority.

- A shareholding of 66% allows the bidder to pass resolutions requiring a qualified majority (eg, delisting).

In addition, Swiss law recognises the following governance instruments.

- Super voting shares or preference shares granting preferential dividend and liquidation entitlements.
- Transfer restrictions on the shares issued, allowing the board of directors (and indirectly the bidder through the relevant board representatives) to reject new shareholders (eg, competitors).
- Veto rights at board level.

6.12 Irrevocable Commitments

In Switzerland it is common to obtain irrevocable commitments from key shareholders of the target company to support the transaction, either through tendering their shares into the offer or selling their shares before the offer is announced.

The nature of these undertakings depends on whether the underlying agreement contains any conditions with respect to the success of the offer. Such conditions allow the shareholder to withdraw from the tender or sale if a better competing offer is announced at a later stage. In absence of such condition, withdrawal would not be possible.

Depending on the exact timeline, the details of the agreement have to be disclosed in the offer prospectus and the price paid affects the minimum offer price (see **6.4 Consideration; Minimum Price**).

6.13 Securities Regulator's or Stock Exchange Process

Mandatory and voluntary public tender offers are reviewed by the Swiss Takeover Board prior to publication of the offer. The review by the Swiss Takeover Board has to be completed within “a short period of time” and normally takes around three weeks. As part of the review, the Swiss Takeover Board verifies whether the terms of the offer are in compliance with Swiss law. This includes:

- compliance with the best price rule;
- the conditions of the offer;
- the fairness opinion on the offer price; and
- the provisions of the transaction agreement with the target company.

Prior to the publication of the offer, the bidder normally publishes a pre-announcement. The publication of a pre-announcement is not mandatory but common. The offer prospectus has to be published within six weeks from the pre-announcement. The timeline for the tender offer is determined by the bidder and disclosed in the pre-announcement or offer prospectus based on the deadlines set forth in the Ordinance of the Swiss Takeover Board (see **6.14 Timing of the Takeover Offer**).

If a competing offer is announced during the offer period, the shareholders are free to choose between the earlier offer and the competing offer. To enable this free choice, the Swiss Takeover Board would consult the parties involved and co-ordinate the timelines of both offers. In particular, it may determine a maximum offer period and limit the deadlines for amendments of the offers.

6.14 Timing of the Takeover Offer

Under Swiss takeover laws, the general offer period is at least 20 business days and a maximum 40 business days. The offer period may be shortened by the Swiss Takeover Board upon request of the bidder where the bidder already holds a majority of voting rights and the report of the board of directors is published in the prospectus.

The offer period may be extended up to 40 business days if an extension has been reserved in the offer. A longer extension requires the approval of the Swiss Takeover Board and is granted if this is justified by superseding interests.

In the past, an extension has been granted while administrative proceedings were pending with the Swiss Administrative Supreme Court, to review the launch of a partial offer during an ongoing primary offer and for synchronisation with a foreign public tender offer. It is also possible that an extension is granted if regulatory/antitrust approvals are not obtained prior to the expiry of the offer period.

7. Overview of Regulatory Requirements

7.1 Regulations Applicable to a Healthcare Company

Several activities in the healthcare sector are subject to healthcare regulation, on the cantonal level and/or the federal level. Switzerland has implemented specific regulation on the following activities/topics:

- manufacturing, trade and distribution of medicinal products and medical devices;
- narcotics;
- transplant medicine;

- genetic testing;
- reproductive medicine;
- human research;
- stem cell research;
- biological safety;
- tobacco;
- chemicals;
- radiation protection;
- non-ionising radiation and sound;
- protection from sound and lasers;
- transmitted diseases;
- cancer registration;
- COVID-19; and
- electronic patient dossiers.

In addition, healthcare institutions, healthcare professionals and sickness insurance companies are subject to specific regulation.

Depending on the relevant topic, either cantonal authorities, the Federal Office of Public Health (FOPH) or the Swiss Agency of Therapeutic Products (Swissmedic) are competent for the supervision and for the granting of the relevant permits and approvals.

The duration of proceedings required to obtain the necessary permits and approvals depends on the specific case and usually on the complexity of the matter.

7.2 Primary Securities Market Regulators

The primary securities market regulators for public M&A transactions in Switzerland are the Swiss Financial Market Supervisory Authority FINMA and the Swiss Takeover Board.

7.3 Restrictions on Foreign Investments

There are limited restrictions on foreign investments in Switzerland, and currently these only exist in the banking/financial services and real estate sectors. In 2023, the Swiss government

published its revised proposal for foreign direct investment (FDI) regulations. According to the proposal, a governmental authorisation may be required for the acquisition of certain Swiss healthcare targets (domestic university hospitals and general hospitals with centralised care, companies that are active in the research, development, production or distribution of drugs, medical production or distribution of medicinal products, medical devices, vaccines or personal medical protective equipment), provided that certain turnover thresholds are reached and only if the intended acquirer qualifies as foreign state investor.

7.4 National Security Review/Export Control

In principle, there is no national security review of acquisitions in Switzerland. Currently, Switzerland has restrictions in place against 26 countries and certain organisations, which restrict the transfer of goods and payments and also include certain notification obligations. The applicable restrictions need to be assessed on a case-by-case basis at the moment of a transaction.

7.5 Antitrust Regulations

Swiss antitrust regulations have to be taken into account whenever two (or more) previously independent companies merge, in the case of transactions where a company acquires direct or indirect control of one (or more) previously independent companies or two or more undertakings acquire joint control over an undertaking which they previously did not jointly control.

A merger control notification obligation is triggered if (i) the companies concerned have a joint turnover of at least CHF2 billion worldwide or a turnover of at least CHF500 million in Switzerland, and (ii) at least two companies have an individual turnover of at least CHF100 million.

Irrespective of the turnover, a notification obligation is triggered if one of the companies involved in a transaction has held a dominant position in the Swiss market and the takeover/business combination concerns either the same market, an adjacent market or an upstream or downstream market.

The notification has to be made to the Swiss Competition Commission and the obligation is triggered at signing and must be made prior to completion of the transaction.

7.6 Labour Law Regulations

Generally, Swiss labour law regulations in connection with M&A transactions are rather lenient. There is no involvement of employees and/or works councils in public takeover offers. In the case of a statutory merger or an asset deal constituting a business transfer, the employees (or the employees' representative body) have to be informed about the reason and (legal, economic and social) consequences of the transaction. Where it is intended to implement measures that affect the employees concerned, the employees need to be consulted on those measures and they can comment and propose alternative measures. Employees are also granted the right to reject the transfer of their individual employment relationship, in which case the employment would be terminated. However, employees, or the employees' representative body (if any), do not have a binding vote on the transaction itself.

7.7 Currency Control/Central Bank Approval

There is no currency control regulation or approval by the Swiss National Bank for M&A transactions.

8. Recent Legal Developments

8.1 Significant Court Decisions or Legal Developments

There are a number of legislative reforms that (could) have an impact on healthcare M&A transactions in Switzerland. Some are already in force, while others are still being debated in the legislative process.

The medtech community is still affected by the refusal of the European Union to recognise the Swiss Medical Devices Ordinance and the Swiss Ordinance on In Vitro Diagnostic as equivalent to the Regulation (EU) 2017/745 on medical devices and the Regulation (EU) 2017/746 on in-vitro diagnostic medical devices. As a consequence, Switzerland, from an EU perspective, continues to qualify as third country, leading to stricter regulatory requirements for Swiss medtech companies.

As part of the Swiss corporate law reform, which came into force on 1 January 2023, new legal provisions have been introduced that provide opportunities for flexible structuring of M&A transactions. In particular, interim dividends are now explicitly permitted under Swiss law. They allow the avoidance of “cash for cash” payments so that the liquidity management after the acquisition can be improved. Additionally, a capital fluctuation band can now be introduced allowing the board of directors to increase or reduce capital within a certain range. This enables the board of directors to issue shares as acquisition currency.

Additionally, the revised Swiss data protection law came into force on 1 September 2023. One of the main goals of the new law was to achieve the compatibility with EU law (GDPR). The compliance of the target company with the newly

introduced law should be observed and also the data disclosure during the transaction process should take the new data protection act into consideration.

The Swiss Cartel Act is currently being revised. Although it is not yet clear what specific provisions will be included, the core element of the revision is the modernisation of Swiss merger control. It is planned to adapt an internationally accepted standard of review for business combinations, namely by replacing the qualified market dominance test by the significant impediment to effective competition test (SIEC test). This would result in a lower threshold for regulatory intervention. Swiss merger control proceedings are expected to be more time consuming and burdensome due to the increased role of economic evidence. This is likely to have an impact on the larger transactions in the healthcare sector.

Finally, the Swiss government published its revised proposal for foreign direct investment (FDI) regulations. According to the proposal, a governmental authorisation may be required for the acquisition of certain Swiss healthcare targets (domestic university hospitals and general hospitals with centralised care, companies that are active in the research, development, production or distribution of drugs, medical production or distribution of medicinal products, medical devices, vaccines or personal medical protective equipment), provided that certain turnover thresholds are reached and only if the intended acquirer qualifies as foreign state investor.

9. Due Diligence/Data Privacy

9.1 Healthcare Company Due Diligence

Publicly listed companies are allowed to provide due diligence information as long as the provi-

sion of such information (i) is in the best interest of the company, and (ii) complies with applicable law and contractual obligations, in particular with insider trading rules, ad hoc disclosure obligations, confidentiality undertakings, data privacy obligations and the principle of equal treatment of shareholders. The permissibility of any disclosure of due diligence information must be analysed on a case-by-case basis in relation to the specific information, bidder and intended transaction and its implications for the company.

Before any confidential information is disclosed, the company should ensure that the bidder has entered into appropriate non-disclosure undertakings and that the due diligence information is only disclosed on a limited and a need-to-know basis. Information that is sensitive from a commercial or antitrust perspective should be disclosed to clean teams only.

The company has no general obligation to provide due diligence information to potential or actual bidders. However, if a company has provided or will provide to actual or potential bidders due diligence information, all actual (but not other potential) bidders have a right to receive the same information.

The level of healthcare due diligence depends on the specific IP portfolio. Generally, a company may be allowed to disclose IP information that is already public in the relevant IP registers. However, particular attention should be taken in relation to trade secrets and other commercially valuable confidential information. In healthcare companies, such information is likely to qualify as insider information and therefore may not be disclosed in connection with a due diligence.

9.2 Data Privacy

Any processing of personal data of Swiss data subject must comply with the provisions of the Swiss Federal Data Protection Act (DPA).

Generally, it is noted that, on the one hand, the processing must be based on one or several reasons provided for in the DPA. In the context of a due diligence exercise, the seller and the buyer usually may rely on the legal basis of safeguarding their legitimate interests. On the other hand, the seller and the buyer must comply with the general principles that apply to any processing of personal data:

- the processing of personal data must be made in good faith and must be proportionate;
- personal data may only be used for the purpose(s) specified at the time of its collection; and
- both (i) the fact that personal data is being collected and (ii) the purpose of the processing must be apparent to the relevant data subject – moreover, the data must be accurate and data security must be ensured.

Finally, specific requirements apply for transfers of personal data abroad and for the processing of particularly sensitive personal data.

10. Disclosure

10.1 Making a Bid Public

A requirement to launch a public tender offer applies if the target's shares are listed on a Swiss stock exchange and more than 33⅓% (or a higher threshold up to 49% as stipulated in the target company's articles of incorporation) of the voting rights are acquired by the bidder (mandatory bid), unless there is an opting-out clause. Other-

wise, a bid will usually only be made public after parties have reached a definitive agreement. The offer is made public by way of an offer prospectus. In the scenario of a hostile bid, a bidder may publicly announce the intention of an acquisition of a target's shares. In such case, the hostile bidder may be required to announce a public offer under the "put up or shut up" rule.

10.2 Prospectus Requirements

The publication of a prospectus is required by any person making a public offer for the acquisition of securities or seeking the admission of securities for trading on a trading venue. Provided that information exists which is deemed equivalent in terms of content to a prospectus in connection with shares offered in a stock-for-stock takeover, a prospectus may not need to be published. A similar exception applies in connection with a merger, spin-offs and the likes, again provided information exists that is deemed equivalent in terms of the content of a prospectus.

10.3 Producing Financial Statements

In a stock-for-stock transaction, bidders need to disclose financial statements for the last three years of the company for which stocks are being offered.

Companies listed on a stock exchange and larger undertakings must prepare financial statements in accordance with a recognised financial reporting standard.

10.4 Disclosure of Transaction Documents

The prospectus for a public tender offer needs to be submitted to the Swiss Takeover Board for review and clearance.

11. Duties of Directors

11.1 Principal Directors' Duties

In general, the directors of a Swiss company:

- have a duty of loyalty towards the company;
- must always pursue the company's best interest with due care; and
- apply equal treatment to all shareholders (so-called fiduciary duties).

These fiduciary duties apply in the event of a business combination and other forms of M&A transactions.

There is no general definition of what constitutes the "best interest of the company". In recent years, Swiss scholars have discussed whether such definition includes only the shareholders' interests (shareholder approach) or whether the interests of other stakeholders must also be considered (stakeholder approach). Despite these discussions, in business combinations, a company's interests should not only encompass value growth and fair shareholder compensation but also the interests of other stakeholders. The directors have discretion to weigh these different interests in a way they deem appropriate.

The principle of equal treatment of the shareholders must always be observed, as long as they do not contradict the company's best interest. For Swiss companies whose shares are at least partly listed in Switzerland, the Swiss takeover rules already take this principle into account (eg, by stipulating the best price rule so that all shareholders may sell their shares for the same price). The Swiss takeover law further stipulates the principle of equal treatment of different bidders. Extensive exclusivity agreements with individual potential buyers, not allowing the board of the target company to negotiate with other

potential buyers, may likely be unlawful in light of this principle.

11.2 Special or Ad Hoc Committees

Swiss listed companies often establish a special or ad hoc committee in the context of M&A transactions. The establishment of such a committee is a way to avoid conflicts of interest but can also be beneficial to streamline the transaction process. Even if certain tasks might be delegated to the special or ad hoc committee, important strategic decisions (eg, granting due diligence to a party or the decision to defend the company) must be passed by the full board, excluding the principal directors with conflicts of interest.

11.3 Board's Role

Prior to the launch of a public takeover offer of the buyer, the board is actively involved in the negotiations with potential buyers. It is the task of the board of the target company to review the proposal of a potential buyer. At this stage, the board is guided by the issue of whether it is in the best interest of the company to continue the takeover process. If the board concludes that the offer is not in the best interest of the company, it may abandon the negotiations. However, if the board decides to continue with the process, the shareholders will have the final decision on whether to accept the offer.

The Swiss takeover law further specifies the role of the board of a listed target company as soon as a public tender offer has officially been made. In particular, the board must prepare a report for the shareholders setting out its position in relation to the offer. Furthermore, the board is not allowed to enter into legal transactions that might significantly alter the assets or liability of the company (eg, the sale or acquisition of assets representing more than 10% of the total assets

or contributing more than 10% to the profitability of the company). This limits the possibilities to take defensive measures at this stage. However, certain defence measures might still be taken by the board, such as actively looking for a “white knight” (always under consideration of the principle of equal treatment of different bidders), PR communications or convening an extraordinary shareholders’ meeting to decide on defence measures.

Shareholder litigation challenging the board’s decision to recommend a particular transaction is not common in Switzerland. However, qualified shareholders (holding at least 3% of the voting rights of the target company) may be parties to proceedings before the Takeover Board and are eligible to challenge its rulings. There are some past cases where qualified shareholders challenged the rulings of the Takeover Board.

11.4 Independent Outside Advice

It is common for the board to obtain financial, legal or other advice in the context of an M&A transaction. This allows the board to ensure the availability of sufficient expertise and to act with due care.

The Swiss Takeover Board imposes the obligation to obtain a fairness opinion if not at least two members of the board of the target company are free of conflicts of interest. However, obtaining fairness opinions is also customary in business combinations where no conflicts of interest exist as they allow the board to legitimise its position when rejecting or recommending acceptance of a public tender offer.

Trends and Developments

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Deal Activity and Market Insights *Deal activity in 2023*

In general, M&A activity in Switzerland has seen an overall decrease in 2023. However, M&A activity in the Swiss healthcare sector has remained strong and increased in 2023 compared to the previous year, both in terms of number of deals and value.

Private equity and venture capital investors have been particularly active in healthcare M&A. In 2023, more than 50% of the M&A deals in the Swiss healthcare industry involved either private equity or venture capital investors. Whereas in the past, private equity investors mainly focused on healthcare service providers, their focus shifted in 2023 towards investments in pharmaceutical and medtech companies. In contrast, venture capital investors continued to focus on the Swiss biotech sector. Beside private equity and venture capital, larger pharmaceutical companies were heavily involved in the Swiss M&A market: the three Swiss pharmaceutical companies Roche, Novartis and Lonza were involved in almost half of the ten largest M&A deals by value in the Swiss healthcare industry.

Multifaceted healthcare industry in Switzerland

The Swiss healthcare industry consists of a wide variety of companies in terms of sectors, size, stage of development, activities and organisational structure. Healthcare targets range from early-stage start-ups, through numerous small and mid-market companies, to large, fully integrated pharmaceutical companies. This variety of targets results in high diversity in terms of deal structuring, including in terms of scope of due diligence, sophistication of deal documentation, compensation (including, increasingly, earn-out provisions), governance and protection.

Investments in early-stage start-ups are usually minority equity investments in which new preferred shares are issued through a capital increase. It is common to thereby grant to the new investors preferential rights with respect to dividend and liquidation proceeds, anti-dilution protection, and information and governance rights.

In certain sectors, in particular pharmaceuticals, biotech and medtech, early-stage financing may be secured by entering into development and licensing agreements with pharmaceutical companies and later exiting by sale to private

equity or strategic investors. Where only certain products are targeted by an investor's interest, asset deals by way of carve-out may be implemented.

Outlook

Besides the overall slowdown of the economic growth in Switzerland, 2023 has been marked by numerous challenges, including high inflation, rising interest rates, the strength of the Swiss franc, turbulence in the financial sector and ongoing wars. However, with an increase in the number and value of deals compared to 2022, M&A activity in the Swiss healthcare industry remains strong. The outlook for M&A activity in the Swiss healthcare industry through 2024 remains positive. An increase in transaction activity is expected assuming more certainty with respect to the economy and regulatory landscape.

Key Drivers in Swiss Healthcare M&A

Digitalisation

The use of new technologies is a key driver of M&A activity in the Swiss healthcare industry. Digitalisation and the emerging new fields of applications of artificial intelligence (AI) are driving companies to acquire respective capabilities.

Between 2018 and 2023, almost half of the Swiss transactions by healthcare providers were directly or indirectly linked to digitalisation. Diagnostic labs, medical suppliers and technology companies in the field of ophthalmology were particularly targeted. Additionally, it is recognisable that hospitals are trying to achieve digital innovation through M&A transactions, eg, in the area of healthcare ICT. This enables hospitals to meet current challenges such as budget restraints and staff shortages. Potential applications include remote patient monitoring and care, but innovation may also be required for

an efficient use of newly introduced electronic patient records.

Large pharmaceutical companies have recognised possible applications of AI to accelerate innovation and transform drug discovery and development. Pharmaceutical companies still appear to be focusing on collaborations and partnerships to assess the potential of AI applications rather than acquiring or building in-house capabilities. In fact, the proportion of M&A activity related to expanding AI capabilities in drug discovery is still relatively small, but has increased in recent years. Increased experience and confidence in the use of AI is likely to have additional positive impact on M&A activity in the healthcare sector.

Investments in R&D-focused companies

R&D plays an important role in the healthcare industry. A well-balanced R&D pipeline with respect to new drugs and medtech products is essential for companies' long-term success. It is therefore not surprising that M&A activity is often driven by investments in R&D-focused companies, especially in Switzerland, where many attractive R&D-focused companies are available as potential targets.

With the renowned Federal Institutes of Technology in Zurich (ETH) and Lausanne (EPFL), Switzerland is home to many start-ups in the biotech and medtech sectors. The ETH has traditionally been very strong in the fields of biotech and pharmaceuticals. In 2023 alone, eight start-ups in these fields were founded as ETH spin-offs. Spin-offs with ETH, EPFL or other Swiss universities are usually subject to specific contractual arrangements with such academic institutions and these institutions may hold equity or have rights to acquire equity in spin-offs.

A particular feature of M&A transactions involving R&D-focused companies is the widespread use of earn-out clauses, especially when the companies are at a relatively early stage. The earn-out is usually a performance-related, variable purchase price component, which is paid in addition to a fixed base price. The performance indicators can be defined by the parties. Financial performance indicators, such as net income or operating cash-flow, are frequently used. This way, the earn-out depends on actually generated revenues and can thus compensate for uncertainties with regard to future returns.

Portfolio optimisation

In the last few years, there was a recognisable tendency for fully integrated pharmaceutical companies to focus on their core business and to divest non-core assets. For example, Novartis has completed its spin-off of its generics and biosimilars business Sandoz in 2023 as part of its strategy to fully focus on its core competencies in the field of innovative medicines. The proceeds from these divestments will then be used for the expansion of the core business, eg, through respective M&A transactions. Large pharmaceutical and life science companies are expected to continue following this strategy in the years to come.

Regulatory and Other Developments

Swiss adaption to the European regulation governing medical devices

Since the Mutual Recognition Agreement between the European Union (EU) and Switzerland was not updated in 2021, Switzerland is now considered a “third country” under the EU regulations. Thus, Swiss registrations/authorisations are not recognised in the EU any more, and vice versa. The Swiss Federal Council tried to mitigate the negative consequences of this non-recognition by aligning the Swiss legisla-

tion on medical devices and in vitro diagnostics with the European Union Medical Devices Regulation (MDR) and In Vitro Diagnostics Regulation (IVDR) and imposing certain additional measures. For example, medical devices with an EU conformity assessment (CE marking) are unilaterally recognised in Switzerland. These legislative developments may be relevant to M&A activity in the field of medical devices. For example, if a non-European company acquires a Swiss manufacturer of medical devices with the respective authorisation(s) under Swiss law, this does not suffice for the target to be recognised as manufacturer or distributor in the EU. The appointment of an authorised representative or other authorisations may be necessary under EU regulation for such purpose. Generally, Swiss medtech companies have addressed this topic in a timely manner and implemented the measures required to be compliant under EU law.

Revision of the Swiss Data Protection Act

On 1 September 2023, the new Swiss Data Protection Act (revDPA) came into force. The aim of the revDPA was, on the one hand, to modernise Swiss data protection law and, on the other hand, to bring it into line with EU law, in particular with the EU General Data Protection Regulation (GDPR). Companies that were already compliant with GDPR had only minimal adaptations to implement under the revDPA. The revDPA may be relevant in the context of Swiss healthcare M&A if the business of a target company involves processing of Swiss personal data or generally processing personal data in Switzerland. It is noted that the transfer and processing of personal data in the context of a due diligence exercise may trigger obligations and restrictions under the revDPA.

Failure to comply with the revDPA may result in criminal sanctions against the individuals involved.

EU Artificial Intelligence Act (EU AI Act)

Artificial Intelligence (AI) is making its way into the healthcare sector, in particular in the area of pharmaceuticals where AI is used in research and development, including for better processing of large amounts of data and quicker evaluation of different combinations of active ingredients. In medical treatment, AI increasingly comes into use in medical devices, either as standalone software or integrated into hardware components.

On 8 December 2023, the EU Commission published a draft of the AI Act, the first-ever legal framework on AI that aims to provide AI developers, deployers and users with clear requirements and obligations regarding specific uses of AI. Like the GDPR, the AI Act will have an extraterritorial reach and will not only be applicable to a Swiss company that makes an AI system available in the EU market but will also apply if the output generated by the AI system of a Swiss company is used in the EU. Once it is formally adopted, it is expected to be fully applicable after two years.

There is currently no specific AI systems regulation in the Swiss legal system. On 22 November 2023, the Federal Council has instructed the Federal Department of the Environment, Transport, Energy and Communications to prepare a report on the possible regulatory approaches to AI systems for Switzerland that are particularly compatible with the EU AI Act and the Council of Europe's AI Convention, which should create the basis to issue a concrete mandate for an AI regulatory proposal in 2025.

Foreign direct investment screening

Currently, Switzerland does not have any general foreign direct investment (FDI) screening mechanisms in place. However, certain regulatory requirements apply to certain industries and sectors, for example, banking and real estate. Several additional business activities require a governmental licence, and the licensing conditions include specific requirements regarding foreign investors. Examples of such business activities are aviation, telecom, radio and television, and nuclear energy.

Mid December 2023, the Federal Council adopted the dispatch on a new Investment Screening Act. Under the new draft legislation, investment screening is intended to only apply when a foreign state-controlled investor takes over a domestic company that operates in a particularly critical area, such as health infrastructure. This means that the takeover of Swiss hospitals and companies active in the research, development, production or production or distribution of medical products, devices or other equipment by a foreign state-controlled investor would need an approval subject to reaching certain turnover thresholds. The proposal is still subject to the approval of the Swiss parliament.

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