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Sweden

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Abstract

This chapter provides an overview of the model for pricing and reimbursement of pharmaceuticals in Sweden, including brief notes on reimbursement of medical devices.

In 2002, Sweden abandoned the reference price system for pharmaceutical reimbursement used since the 1990s, which is still widely adopted in European countries, and instead introduced a value-based pricing and reimbursement scheme. Thereby and since, to a large extent Sweden has led the way on value-based pricing for pharmaceuticals. The main features of the value-based model are the use of cost-effectiveness analysis for determining the reimbursement status of pharmaceuticals, and mandatory substitution for the lowest-cost generic alternative within the reimbursement scheme. The use of cost-effectiveness analysis in reimbursement decisions aims to relate and balance the reimbursement price to the social value of the pharmaceutical, but does not necessarily result in (or intend to result in) the lowest possible price.

The 21 Swedish regions are responsible for the funding of in-patient pharmaceutical expenditure, and the costs are covered by taxes.

Costs for out-patient pharmaceuticals included in the reimbursement scheme are formally financed by the regions but are almost exclusively covered by state grants. Patients only pay a limited part of the price for such pharmaceuticals, and a patient's maximum costs during a year are subject to high-cost protection.

Market introduction/overview

Swedish healthcare involves the state, regions and municipalities. The state is responsible for the overall health and medical care policy, while the regions are responsible for providing healthcare.

The Ministry of Health and Social Affairs (Sw. *Socialdepartementet*) is responsible for issues concerning the welfare of society by implementing the objectives set by the Swedish Parliament and the Government. Several independent agencies answer to the ministry.

According to the Health and Medical Services Act (2017:30) (Sw. *hälso- och sjukvårdslagen*) ("**HSL**"), healthcare aims at good health and healthcare on equal terms for the entire population. Furthermore, care should be given with respect to the equality of all human beings and to the individual's dignity. Those who have the greatest need for care shall be given priority.

Manufacturing of pharmaceuticals and medical devices is one of the largest industries in Sweden and accorded a high priority by the Swedish Government. For 2021, Sweden continues to be the EU innovation leader according to the European Innovation Scoreboard.

During 2021, the Swedish pharmaceutical market had a turnover of SEK 53.5 billion, an increase of roughly 2% compared to 2020. In 2021, close to 208 million pharmaceutical packages were sold in Sweden. Approximately 52% of these packages were prescription pharmaceuticals, while approximately 42% were non-prescription pharmaceuticals.

The Swedish pharmacy state monopoly was abolished in 2009. Since then, the number of pharmacies has increased by almost over 500. Currently, there are over 1,400 out-patient pharmacies in Sweden and the industry is dominated by five pharmacy chains. In addition to out-patient pharmacies, there are hospital pharmacies, dose-dispensing pharmacies and distance pharmacies providing their services online. Since the deregulation, pharmacies have increased their opening hours. This, as well as the emergence of e-commerce, has contributed to improved accessibility on the pharmaceutical market in Sweden.

Pharmaceutical pricing and reimbursement

Regulatory classification

Legal framework

Being an EU Member State, Sweden's legal regulatory framework for pharmaceuticals is to a large extent based on relevant EU directives and subject to EU regulations. The national legislative basis for regulatory issues (including marketing authorisation and substitutability), supervision and enforcement of pharmaceuticals in Sweden is primarily stipulated in the Medicinal Products Act (2015:315) (Sw. *läkemedelslagen*) and the Medicinal Products Ordinance (2015:458) (Sw. *läkemedelsförordningen*) and, for medical devices (including *in vitro* medical devices), in the Act (2021:600) and the Ordinance (2021:631) of supplementary provisions to Regulation (EU) 2017/745 and Regulation (EU) 2017/746. The Medicinal Products Act and the Medicinal Products Ordinance are based on Directive 2001/83/EC. There are also regulations and guidelines issued by the Swedish Medical Products Agency ("**MPA**").

The legal framework concerning the granting of marketing authorisation of a pharmaceutical differs from the framework concerning pricing and reimbursement. While the former is based on EU rules as described above, the latter is substantially regulated at a national Swedish level, with little influence from the EU.

The Swedish Dental and Pharmaceutical Benefits Agency ("**TLV**"), which is an expert state agency, decides if and to what extent a pharmaceutical shall be reimbursed, according to the Pharmaceutical Benefits Act (2002:160) (Sw. *lag om läkemedelsförmåner m.m.*) ("**PBA**") and the Pharmaceutical Benefits Ordinance (2002:687) (Sw. *förordning om läkemedelsförmåner m.m.*) ("**PBO**"). The TLV also issues regulations and general guidance.

In addition, Sweden has a system for substitution of generically equivalent pharmaceuticals. The MPA decides which pharmaceuticals shall be substitutable (generic substitution) at pharmacies and publishes a list of groups that include such products.

The basic principles for substitution are that products containing the same active substance in the same amount, and that are otherwise medically equivalent, shall be substituted to the cheapest pharmaceutical within the reimbursement scheme. The system demands that pharmacies dispense the least expensive generic product available to the patient, regardless of the prescribed product, unless the prescribing healthcare professional has opposed substitution for medical reasons in writing or the dispensing pharmacist opposes the substitution. The patient may also refuse substitution if he or she is willing to pay the price difference between the prescribed medicine and the generic alternative.

Prescription (out-patient) vs. requisition (in-patient)

The procedure and regulations for pricing and reimbursement of pharmaceuticals primarily depends on whether the specific product is a *prescription pharmaceutical (out-patient)* or a *requisition pharmaceutical (in-patient)*.

Prescription refers to when a pharmaceutical is prescribed to a patient and dispensed to the patient by an out-patient pharmacy. The price of prescription pharmaceuticals included in the reimbursement scheme is determined by the TLV, while the pricing of prescription pharmaceuticals outside this system are set freely (see below).

Requisition, on the other hand, refers to the requisition of pharmaceuticals by and to healthcare professionals, to be administered to patients in institutional or non-institutional healthcare. Institutional care refers to treatment given to patients in a hospital or in another type of institution, and non-institutional care refers to any other treatment of a patient that is not defined as institutional. Requisition pharmaceuticals that are to be provided to publicly owned healthcare providers are procured and priced pursuant to public procurement procedures carried out by the Swedish regions. Privately owned healthcare providers who perform healthcare on behalf of the Swedish regions can make call-offs from these agreements unless they want to arrange their pharmaceutical supply on their own.

It is possible for a specific pharmaceutical to be subject to both prescription and requisition. In such case, two different systems of regulation will apply – which can lead to different pricing of the same product.

Prescription-only vs. non-prescription pharmaceuticals

Pursuant to Chapter 4 of the Medicinal Products Act, a pharmaceutical will, in connection with being granted a Swedish marketing authorisation, be classified either as a prescription-only or a non-prescription pharmaceutical. The MPA will decide the classification for the pharmaceutical depending on its intended use and characteristics. A prescription-only pharmaceutical must be subject to either prescription or requisition in order to reach the patient. Non-prescription pharmaceuticals, on the other hand, do not require prescription or requisition; however, nothing prevents non-prescription pharmaceuticals from being prescribed or requisitioned.

Products eligible for reimbursement

The general rule is that only prescription-only pharmaceuticals are eligible for reimbursement under the reimbursement scheme, as set forth in Section 15 of the PBA. However, pursuant to Section 17 of the same act, and further by the PBO, TLV has been authorised to issue regulations regarding the prerequisites for non-prescription pharmaceuticals being eligible for reimbursement. According to the TLV regulation TLVFS 2003:2, regarding non-prescription pharmaceuticals in accordance with the PBA, (last amended by TLVFS 2012:3), non-prescription pharmaceuticals may be eligible for reimbursement. As at the date of this chapter, non-prescription pharmaceuticals eligible for reimbursement include, e.g., certain allergy pharmaceuticals and pharmaceuticals for skin and stomach problems. In addition to pharmaceuticals, there are also other products that are eligible for reimbursement (see below). Further, such pharmaceuticals and other products must be prescribed by healthcare professionals in order to be reimbursed.

As stipulated in Section 18 of the PBA, only some medical devices are eligible for reimbursement. Medical devices eligible for reimbursement, called consumables, only include products used: (i) in connection with stoma; (ii) to induce a pharmaceutical into the human body; and (iii) for self-monitoring of medication. Stoma consumables are covered by the same rules regarding reimbursement as pharmaceuticals in general with a co-pay

component, while consumables used to induce pharmaceuticals, and for self-monitoring of medication, are entirely reimbursed and are free of charge for the patient.

In addition, food may, under certain circumstances, be eligible for reimbursement. According to Section 20 of the PBA and as further regulated in Sections 6 and 7 of the PBO, foods that have been prescribed to a child (aged below 16) may be reimbursed provided that the child suffers from any of the specific conditions stipulated in the PBO.

Who is/are the payer(s)?

Pricing of out-patient pharmaceuticals included in the reimbursement scheme is regulated and the cost of such pharmaceuticals dispensed in pharmacies to patients is to a large extent indirectly financed by the state. The patient pays some of the costs for subsidised prescription pharmaceuticals, but according to the PBA, a patient's maximum costs are subject to high-cost protection valid for 12 months at a time, starting from the date of the first purchase. As at the date of this chapter, the maximum amount is SEK 2,400 (approx. €230). The high-cost protection is calculated based on the base amount set out in the Social Insurance Code (2010:110) (Sw. *socialförsäkringsbalken*). The patient pays a full price up until a maximum amount (as at the date of this chapter, SEK 1,200), after which the following discount scheme comes into effect:

- Between SEK 1,220 and SEK 2,290, the patient pays 50% of the actual cost of the pharmaceutical.
- Between SEK 2,291 and SEK 4,255, the patient pays 25% of the actual cost of the pharmaceutical.
- Between SEK 4,256 and SEK 5,889, the patient pays 10% of the actual cost of the pharmaceutical.

All children under the age of 18 are offered free prescription pharmaceuticals and medical devices included in the reimbursement scheme. The purpose of this is to reduce inequality of children's health between groups in society with different financial conditions. Also, prescribed contraceptive pharmaceuticals included in the reimbursement scheme are free for all women under the age of 21.

As stated above, the prices for requisition pharmaceuticals used in publicly owned institutional and non-institutional healthcare are negotiated in public procurement processes. Prices for requisition pharmaceuticals used in privately owned institutional and non-institutional healthcare will depend on whether the healthcare provider has made call-offs from regional agreements or procured them independently.

For publicly financed healthcare, a patient pays the applicable patient fee for the healthcare, which includes the cost for any requisition pharmaceuticals.

What is the process for securing reimbursement for a new pharmaceutical?

TLV decides on the basis of the PBA if and to what extent a pharmaceutical shall be reimbursed after an application by the manufacturer. For a pharmaceutical to be covered by the reimbursement scheme, a written application shall be submitted to TLV. The company applying for reimbursement is responsible for demonstrating that the pharmaceutical meets the applicable legal requirements. In the application, the applicant shall state the requested price of the pharmaceutical and provide reasoning and adequate documentation to support the requested price (see below how the price is determined), e.g. a health economic analysis.

An application is granted if the pharmaceutical is eligible for reimbursement and all the material requirements in the PBA are fulfilled, and if TLV finds that the requested price is justified in consideration of the value that the pharmaceutical brings to society in terms of improved health (i.e., if the pharmaceutical is cost-effective and brings marginal benefit to the market).

Medical devices that are eligible for reimbursement are subject to the same reimbursement rules as pharmaceuticals, provided that the devices are to be used by patients and prescribed by a healthcare professional. However, the rules regarding substitution of pharmaceuticals do not apply to medical devices.

For further reading and more detailed instructions on the application process, TLV has issued a handbook for companies who wish to secure reimbursement (Sw. *Handbok för företag vid ansökan om subvention och pris för läkemedel*) (diary number 1871/2021).

Decisions made by the MPA, TLV and other governmental authorities can be appealed to the Swedish Administrative Courts. The Administrative Procedures Act (1971:291) (Sw. *förvaltningsprocesslagen*) governs the procedure of such appeals. Decisions and judgments from the Administrative Courts may, subject to granting of leave to appeal, be appealed to one of the Administrative Courts of Appeal, whose decisions and judgments may further be appealed to the Supreme Administrative Court. Proceedings in the Administrative Court system are primarily conducted in writing; however, oral hearings are possible if requested by a party or if the court finds it appropriate.

Appeals of decisions by authorities (e.g., the MPA and TLV) are submitted directly by the company to the authority that took the decision. The main rule is that the appeal must be submitted so that it is received by the authority no later than three weeks from the date on which the appellant received the decision, or it may be inadmissible. Should the authority not amend the decision, the appeal will be forwarded to the relevant Administrative Court. If all formal requirements of appeal are fulfilled, the Administrative Courts are authorised to assess an appealed decision in its entirety. The main possible outcomes in court are either: rejection of the appeal; material change of the appealed decision; or referral of the case back to the authority for reassessment in accordance with statements of reason from the court. It is possible to claim that the court should issue an interlocutory order regarding the appellant's claims (in full or in part), to be in effect during the court proceedings. However, it should be noted that it is relatively unusual for reimbursement decisions to be appealed.

How is the reimbursement amount set? What methodology is used?

As stated above, the main rule is that only prescription-only pharmaceuticals may be included in the pharmaceutical reimbursement scheme. In general, all pharmaceuticals, including non-prescription pharmaceuticals, may be reimbursed and included in the reimbursement scheme, provided that the conditions stipulated in the PBA are fulfilled. According to the PBA, the requirements for a prescription-only pharmaceutical to be included in the reimbursement scheme are that: (i) the costs of using the pharmaceutical appear reasonable from a medical, humanitarian and socioeconomic perspective; and (ii) there are no other available pharmaceutical(s) or treatments, which, when balancing the intended effect and potential harm, are deemed significantly more suitable.

TLV shall determine whether the price requested by the applicant is reasonable by making a total assessment, taking into consideration three ethical principles of healthcare that are included in the HSL to guide priority-setting in Swedish healthcare. These ethical principles are:

(i) the human dignity principle, which implies that the care should be given with respect to the equality of all human beings and with consideration of the individual's dignity;
(ii) the needs and solidarity principle, which entails that the person with the greatest need for healthcare shall be given priority; and
(iii) the cost-effectiveness principle, which means that one should strive towards a reasonable relationship between cost and effect, measured in improved health and an increased quality of life, when considering different activities and measures.

In order to estimate the cost for the use of the pharmaceutical, TLV requires information regarding the relevant patient group and volume; for instance, the number of patients that will need the pharmaceutical and for how long. Furthermore, TLV considers whether there is a risk that the pharmaceutical will be used outside a potential limitation of the reimbursement, which would risk being a usage that is not cost-effective.

A decision on reimbursement is thus based on value, which is often described in terms as applying value-based pricing of pharmaceuticals. In reality, prices can be freely set under a value-based price ceiling. There are only a few countries that apply value-based pricing of pharmaceuticals. Instead, most EU countries apply international reference pricing in some form. To summarise, TLV attempts to find a reasonable balance between the cost of the pharmaceutical compared to the effect/value of the pharmaceutical, measured in improved health and increased quality of life.

There are two main types of reimbursement: general; and restricted reimbursement. In the case of general reimbursement, the pharmaceutical is eligible for reimbursement for its entire approved area of use, while restricted reimbursement means that the pharmaceutical is included in the reimbursement scheme only for a certain area of use or a specific patient group. TLV may grant a restricted reimbursement if the pharmaceutical is only considered to be cost-effective for a limited and specific group of patients. TLV may also stipulate special conditions for a reimbursement decision (conditional reimbursement), e.g. that the applicant, after some time, must present new data on the use of the pharmaceutical in the healthcare system.

There are no further statutory laws at the legislative level specifying the criteria applied by TLV when taking a decision on a subsidy and price. Instead, TLV provides more detailed guidance through regulations and general advice.

In 2003, TLV issued general guidelines (TLVAR 2003:2, last amended by TLVAR 2017:1), which are intended to guide pharmaceutical companies that plan to apply for subsidy and pricing of a pharmaceutical. Furthermore, the guidelines include instructions of how a health economic analysis should be conducted, according to TLV. The guidelines are worth considering in the planning and implementation of health economics studies to be used in upcoming applications for subsidy and pricing.

TLV's practices on the conditions for determining the subsidy and price have over time been developed by the Administrative Courts.

How are pharmaceutical prices set? What is the relationship between pricing and reimbursement?

There are various pricing procedures for pharmaceuticals; for example, through decisions by TLV, the regions' procurement procedures, or free pricing. The pricing of products differs in out-patient and in-patient treatment.

Out-patient care

In out-patient care, the difference between the price of a pharmaceutical and the reimbursement received by the manufacturer is the patient's co-payment (see section 'Who is/are the payer(s)?'above).

TLV determines the pharmacies' trade margin for pharmaceutical products included in the reimbursement scheme, which means that the pharmacies' purchase price ("**AIP**") as well as selling price ("**AUP**") are regulated.

The regions and pharmaceutical companies may enter into managed entry agreements, which may be taken into account by TLV when deciding on reimbursement. So far, such agreements have been seen as a tool to ensure cost-effectiveness and reduce the increasing costs for new pharmaceuticals by way of flat rebates. However, the 2022 agreement between

the Swedish regions and the Swedish Government concerning financing of pharmaceuticals provides for a halt of new rebates agreement with regions *outside the three-party negotiation process*, and includes a mechanism intended to disincentivise the regions from entering into new such agreements outside the three-party negotiation process.

Furthermore, the pharmacies have a limited right to negotiate pricing of pharmaceuticals that differ from the price of pharmaceuticals determined by TLV, a right that mainly extends to parallel imported pharmaceuticals.

The pricing of non-prescription pharmaceutical products can generally be set freely. Prices are, however, regulated for non-prescription pharmaceuticals that are included in the reimbursement scheme, and the patient makes a co-payment for those pharmaceuticals (as described above). It should be noted that most non-prescription pharmaceuticals are not included in the reimbursement scheme, and the patient pays the entire cost for these pharmaceuticals.

As part of the general generic substitution, Sweden has a "product of the month" system for substitutable products. The product of the month within the groups of substitutable products is decided by TLV and appointed through a monthly auction. The substitution is, in principle, mandatory and, consequently, the pharmacies are obligated to dispense the least expensive pharmaceutical product included in the reimbursement scheme that is available on the market, regardless of the prescribed product. The "product of the month" system promotes price competition, and it can be noted that during the years 2014–2021, Sweden's pharmaceutical prices in the "product of the month" system were the lowest in Europe or among the lowest.

In-patient care

The prices for in-patient pharmaceuticals within the publicly owned healthcare are set in the regions' public procurement processes, which are regulated by the Public Procurement Act (2016:1145) (Sw. *lagen om offentlig upphandling*). However, prices for requisition pharmaceuticals used in privately owned institutional and non-institutional healthcare will depend on whether the healthcare provider has made call-offs from regional agreements or procured them independently.

In publicly financed healthcare, the patient only pays the applicable patient fee for the in-patient treatment concerned and, except for a flat fee, the full cost of the pharmaceuticals used in in-patient case is borne by the regions.

Issues that affect pricing

Generic substitution

As described above, the MPA approves pharmaceuticals with regard to their quality, safety and efficacy. Furthermore, the MPA decides which pharmaceuticals shall be substituted at the pharmacies and publishes a list of groups that includes such products. The basic principles for substitution are that the products contain the same active substance in the same amount and are otherwise medically equivalent. All pharmaceuticals, whether or not included in the reimbursement scheme, are subject to substitution, if there is an equivalent pharmaceutical in the reimbursement scheme. The pharmacies are obligated to dispense the least expensive pharmaceutical that is available on the market. Physicians and pharmacists at the pharmacies may only decline substitution on medical grounds, as stipulated in Section 21 of the PBA. The purpose of this substitution system is to safeguard the lowest possible cost for both the patient as well as the society and is applied rather strictly in practice.

Price ceilings

Generic substitution leads to lower prices due to competitive market forces, which may result in significant price differences between generic substitutes arising. In this situation,

TLV may decrease the maximum accepted AUP within the reimbursement scheme by setting a lower price ceiling for substitutable pharmaceuticals. This is mainly relevant for branded original pharmaceuticals that have lost their patent protection.

Each month, TLV analyses prices and sales volumes in order to find product groups where the criteria for setting a price ceiling are met. When the prices of a group of substitutable generic pharmaceuticals have dropped by at least 70% of the price that the pharmaceuticals had before generic competition entered the market, and when generic competition has been ongoing for at least four months, TLV sets a price ceiling. The price ceiling may not enter into force until at least six months after the introduction of generic competition within the substitution group.

The new fixed price ceiling is normally 35% of the highest price in the relevant substitution group when generic competition arose. Setting the price ceiling in this way reduces the differences in price between substitutable generic pharmaceuticals within the reimbursement scheme, but it also has the effect of further decreasing costs in addition to the cost-decreasing effect of generic substitution itself, by forcing a lower price of original pharmaceuticals within the reimbursement scheme. After TLV has determined a price ceiling, pharmaceutical companies have the option of either applying for a new price that meets the set price ceiling or withdrawing from the reimbursement scheme.

Price reduction after 15 years

Certain rules apply for the pricing of some older pharmaceuticals approved for reimbursement (see TLV's regulation TLVFS 2014:9, last amended by HSLF-FS 2018:30). Based on these rules, TLV may reduce the price of pharmaceuticals by 7.5% when they have been on the market longer than 15 years. The 15-year threshold is based on the date of first marketing authorisation in each relevant so-called substance/form group. This means that TLV can decide to reduce the price of pharmaceuticals that have recently been approved for reimbursement if the first marketing authorisation in the same substance/form group is older than 15 years. TLV's decisions to reduce the price can be appealed to the Administrative Courts (see section 'What is the process for securing reimbursement for a new pharmaceutical?').

Policy issues that affect pricing and reimbursement

According to Statistics Sweden (Sw. *Statistiska Centralbyrån*), the population in Sweden will continue to increase within all age groups. The percentage increase is greater in the older age groups. In addition to the increasing number of elderly, immigration constitutes the largest demographic change and primarily increases the population that is of working age.

A recently reported public inquiry appointed by the Swedish Government (see further 'Emerging trends' below), *inter alia*, concluded that shared resources available for financing pharmaceuticals are insufficient to meet all needs and, therefore, priorities must be set. As the population grows, gets older and suffers from more chronic diseases, while innovation within the pharmaceutical industry increases and pharmaceuticals become more expensive, the need for priorities will also increase. These issues are likely to affect pricing and reimbursement policies, at least in the long term.

Emerging trends

The Swedish Government has a major focus on the pricing and reimbursement of pharmaceutical products and, in 2016, the Swedish Government appointed a public

inquiry to investigate and analyse the current system of funding, subsidising and pricing of pharmaceutical products. It is the first review since 1998 when the cost responsibility for pharmaceutical products benefits passed from the state to the regions. Since the introduction of the value-based pricing and reimbursement scheme system, the conditions in the healthcare system have changed, as well as the types of pharmaceutical products that reach the market. Patients, companies and regions have described the current system for financing, pricing and reimbursement of pharmaceutical products as complex, difficult to grasp and, in some respects, not sufficiently transparent.

The public inquiry was concluded in December 2018, and the final report was submitted to the Swedish Government in January 2019 (SOU 2018:89). The inquiry proposes several changes to the current system, including increased responsibility for regions to fund pharmaceuticals (with a decreased responsibility for the state). A new special subsidy to support the use of drugs within certain areas, e.g. cell and gene therapies, has been proposed. The inquiry also proposes several new responsibilities for existing competent authorities, with the purpose of increasing the state's ability to facilitate a more equal and cost-effective use of pharmaceuticals across the country, while making new innovative drugs and therapies available to patients quicker.

The inquiry report has been heavily criticised by several important and influential parties on the market. Among these are the Swedish Association of the Pharmaceutical Industry, which is of the opinion that the inquiry must be fundamentally reworked, and large patient organisations that believe the inquiry focuses too heavily on costs and moving funds between different parties, without paying sufficient attention to patient needs or enabling timely access to new treatments (which was an express objective of the inquiry). Time will tell whether the inquiry report will result in any governmental bill for new and amended legislation. As at the date of this chapter, no governmental bill has been presented.

In 2014, a three-party negotiation process involving the regions, TLV and the pharmaceutical company in question were introduced. The three-party negotiations are intended to facilitate a more dynamic process for pricing and reimbursement assessments of pharmaceuticals, as well as facilitate access to new, innovative treatment options for patients while maintaining a general price control and price reduction for the society. The public inquiry report mentioned above (SOU 2018:89) proposes a few changes and clarifications of the three-party negotiation process, including that the framework for such negotiations should be more comprehensively regulated by law. Managed entry agreements are used to an increasing extent and now encompass products with a total annual turnover of approximately SEK 4 billion. More than half of the sales of newly introduced unique drugs are covered by managed entry agreements. The public inquiry report proposes changes to the organisation for managed entry agreements, including, e.g., the launch of a new regional joint public authority. This new authority would, in order to increase transparency and legal certainty, etc., among other things, take over the responsibilities of the current New Therapies Council (Sw. *NT-rådet*), which is a group of experts that supports the regions on matters concerning new drug therapies, including making recommendations on the use of new drug therapies, with the aim of enabling equal drug treatment for patients throughout the country.

As mentioned above, in June 2020, certain amendments to the PBA entered into force, enabling the substitution of prescribed pharmaceuticals not included in the reimbursement scheme, to equivalent cheaper pharmaceuticals that are included in the reimbursement scheme. As a result of these amendments, TLV initiated a reassessment of several reimbursed pharmaceuticals, to either adjust medicines subject to restricted reimbursement and make them generally reimbursed, or in some cases harmonise reimbursement restrictions within

specific substitution groups (regarding general and restricted reimbursement, respectively, see section 'How is the reimbursement amount set? What methodology is used?', under 'Pharmaceutical Pricing and Reimbursement' above). In April 2020, several decisions by TLV entered into force, adjusting the reimbursement status for approximately 680 pharmaceuticals. The intention with the legislative amendment and TLV's reassessments was, *inter alia*, to enable more patients to receive their prescription drugs within the benefits scheme and subject to high-cost protection.

Furthermore, TLV was, in 2020, assigned by the Swedish Government to develop models for health economic assessments, and to analyse viable payment models for gene and cell therapies, so-called Advanced Therapy Medicinal Products ("**ATMP**"), and TLV reported its conclusions in May 2021 through the report 'How shall we value and how shall we pay?'. The report addresses, among other things, combination products (including pharmaceuticals and diagnostics combinations) and the room to include new value factors in the models to capture the type of uncertainties that are particularly common for ATMPs. In the report, TLV expresses its willingness to explore outcome-based payments models, a type of managed-entry agreement that seldom is applied in Sweden. TLV concludes that it sees outcome-based models as a tool to bridge value differences and to reduce payor risk, where TLV envisions payments tied to value realisation over time. Although deferred payment models for ATMPs may offer financing benefits for payors, TLV concludes that it does not see it as a viable in a Swedish context. The report also argues for the benefits in allocating at least partial responsibility for the financing of ATMPs on the national government.

In 2021, TLV was instructed by the Swedish Government to implement cost-reducing measures on pharmaceuticals included in the pharmaceutical benefits scheme, as well as to ensure an improved price dynamic and good access to pharmaceuticals in Sweden. The result of the work carried out by TLV in this matter is to be presented in June 2022. The Swedish Government's intention is that the cost-reducing measures will save the state and the regions at least SEK 800 million during a four-year period, as a result of price changes, three-party negotiations and side agreements.

Successful market access

For successful market access in Sweden, it is crucial to obtain an understanding of the Swedish value-based pricing model and the considerations involved in assessing applications for the inclusion of pharmaceutical products in the reimbursement scheme. This is true for marketing of original drugs, generics and parallel imports alike. An understanding of the model will also facilitate effective participation in public procurement by the regions for in-patient use.

The three-party negotiations with the regions and TLV are a natural path for a large share of new pharmaceuticals to the reimbursement scheme and the Swedish market. Given the dynamic nature of the process, careful preparations are essential and access of in-house or external experience with experience of the three-party process will be key.

It is worth noting that reimbursement and pricing decisions within the reimbursement scheme by TLV are appealable decisions that can be tried by the Administrative Courts (see above 'What is the process for securing reimbursement for a new pharmaceutical?'), and there are generally no restrictions against resubmitting an application to TLV (e.g., including a more comprehensive health economic analysis) for a second-round evaluation.

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