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Life Sciences

REPORT

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In this issue of our Life Sciences Report you can read about new EU directives on public procurement, proposals on pricing and availability of pharmaceuticals and the revised agreement concerning collaboration between the industry and the health service, to mention just some of the interesting articles in the field of life sciences. Our guest contributor, Mr. Anders Blanck, Director General for LIF, the trade association for the research-based pharmaceutical industry in Sweden, writes about health technology assessment of hospital drugs. And don't forget, you are always welcome to contact us at Setterwalls to take a more in-depth look at these and other issues.

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Health technology assessment of hospital drugs: inequality, lack of transparency, and undue waiting

The Swedish Agency for Health and Care Services Analysis (*Vårdanalys*) is a relatively new government agency, with the mission to strengthen the position of patients and users by analyzing health care and social care services from the perspective of patients and citizens. It has just presented a report that in one swift move has positioned the authority as a key player in the Swedish health care debate.

It is a matter of considerable political discussion whether or not Sweden has too many government authorities. In particular, the multitude of analyzing and evaluating agencies has been the subject of pointed criticism from the opposition. Vårdanalys is one of the latest entrants, and if there is a change in government this coming fall, its future is not at all clear. Be that as it may: the agency has already made its mark, and more is certainly to come if they are allowed to continue.

The report *"Värdefullt men inte fullvärdigt – Om nyttan med hälsoekonomiska bedömningar av klinikläkemedel"* (Vårdanalys 2014:4) is the result of a government remit to evaluate the project for health technology assessment of medicines used in hospitals. The project in question ("*Klinikläkemedelsprojektet*") has been active since 2010 with the pricing and reimbursement agency TLV in the lead. It is this project that Vårdanalys has now, in turn, evaluated.

The picture painted in the Vårdanalys report is not a pretty one. Patients who could benefit from a given hospital medicine are left waiting for a protracted period of time. It is not clear when a decision will be taken, there is no information about on which ground the decision will be taken, and to make matters worse the result is likely to be different depending on in which county the patient is resident. Briefly, the result is inequality, lack of transparency, and undue waiting.

Vårdanalys makes a suggestion to cut through the present long-winded, bureaucratic process when it comes to truly life-saving drugs. They should have a "fast lane" to decision.

Vårdanalys has great respect for the underlying reasons for health technology assessments of all medicines. But they see serious weaknesses in organization and working methods in the project on hospital medicines. Their verdict is that these weaknesses must be addressed when the government decides whether the project on HTA analysis of hospital medicines should be made permanent.

HTA analysis is basically a good thing, but the lack of transparency and legitimacy is serious. And furthermore, this smaller project – in *Vårdanalys*' view – has shown problems in how Swedish health care generally manages to handle questions regarding priorities and equality.

Vårdanalys' report is like a breath of clean air in its clear, dispassionate analysis; albeit slightly depressing.
Is it really this bad?
On balance: Yes it is.

Lack of transparency is not just a matter for patients to lament. Pharmaceutical companies are like all other companies: clear rules and transparent systems are the basis for sound company decisions. Where there is lack of clarity there is uncertainty, and uncertainty breeds less willingness to invest. This does not bode well for Sweden's health care system, for its patients – nor for the pharmaceutical industry in Sweden.

Sweden is well on the way to muddle through to a situation where it is no longer a country which embraces innovation. Rather, it is gradually building ever higher obstacles for innovation and new medicines – cloaked in the well-meaning goal of economic control of potentially "galloping cost increases". This fear, common as it is, does not have much basis in the actual statistics. Sweden's overall costs for medicines is not "galloping", quite the contrary. Medicine sales are flat over the last decade, in spite of numerous new medicines being authorized. And new medicines are used to a lesser and lesser extent – a result we see as stemming directly from the ever growing bureaucratic overload for evaluation on many different levels; a process that takes longer and longer to make decisions and which inherently seems to have the basic assumption that older medicines are generally better.

LIF see the developments on the Swedish market for pharmaceuticals as deeply worrying. There are elements of growing problem awareness among stakeholders, primarily on the national level. There is also a very clear political willingness to focus on Life Science innovation *on the general level*, something which we very much welcome of course. But connecting the dots seems to be very difficult: innovation in pharmaceuticals needs a welcoming environment, a "market" that is willing to use and evaluate the new products, otherwise Life Science R&D will not start to grow again in Sweden. And LIF see *Vårdanalys*' report as a serious and well-reasoned analysis, from a reputable government agency, which hopefully will help in turning the trend.

Because it is not just words on a paper, right? We can only hope that it will have real impact; that the powers that be will listen and take action. Because it is about real patients and real needs.

Guest contributor
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Läkemedelsindustriföreningen (LIF) is the trade association for the research-based pharmaceutical industry in Sweden with about 80 members and associate companies who represent approximately 80 percent of the total sales of pharmaceuticals in Sweden.


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NASDAQ Transportation
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Listings increasing in the Life Sciences sector in 2014

More than 20 companies in the healthcare and pharmaceutical sector are planning to apply to become publicly listed in Sweden in 2014. This is a significant increase on recent years. Several of the companies are heading for NASDAQ OMX Stockholm, both the main market and the growth market First North.

NASDAQ OMX Stockholm

NASDAQ OMX is the largest authorised securities exchange in Sweden and is the principal market on which shares, bonds, derivatives and other securities are traded in the country. Sweden also has a small exchange, the Nordic Growth Market (NGM), where small and medium-sized businesses can choose either a regulated listing on NGM Equity or an unofficial launch on Nordic MTF. Companies can also list on AktieTorget (another Swedish multilateral trading facility (MTF)).

NASDAQ OMX Nordic is the combined offering from NASDAQ OMX exchanges in Helsinki, Copenhagen, Stockholm, Iceland, Tallinn, Riga, and Vilnius. The Nordic list is a combined market comprising both large and medium-sized companies across three segments: small, mid and large cap. NASDAQ OMX Nordic also provides First North, which is NASDAQ OMX's European growth market, designed for small and growing companies. Many large and established companies began their journey on First North and later went on to launch on the NASDAQ OMX regulated main market.

Pipeline

According to Scandinavia's largest business daily Dagens Industri, Adam Kostyál, Senior Vice President NASDAQ OMX, predicts there will be 25 new listings on NASDAQ OMX Stockholm by 1 July 2014, 10 of which will be on the main market and 15 on First North.

The forecast of approximately 10 listings on the main market should be compared to the number of launches between 2007 and 2013. Only two companies listed in 2013, none in 2012, five in 2011, three in 2010, none in 2009, three in 2008 and six in 2007.

The key factor, according to Kostyál, is that the valuation have reached levels at which equity holders consider a stock market launch to be equally or more attractive than selling the company. Another issue, says Kostyál, is the importance of advisers in preparing companies for their new life on the exchange, with legal advisers and managers having a particularly vital role. In addition, recently listed companies have enjoyed a successful start on the exchange and, according to Kostyál, the seven companies listed so far in 2014 have seen their shares rise by 29 percent compared to a 1 percent increase in the index.

Life sciences listings

Kostyál says that interest in launching on the NASDAQ OMX has come from many different industries, but that it has been greatest in the medtech and life sciences sector, as well as the real estate sector.

Recipharm AB, one of Europe's leading pharmaceutical contract development and manufacturing organisations (CDMO) and a mid-cap company in the healthcare sector, is one of three companies to list on the NASDAQ OMX Stockholm main market so far this year.[1] First day of trading was 3 April 2014.

According to the website nyemissioner.se, the following life sciences companies are planning a listing on the NASDAQ OMX Stockholm main market in 2014 and 2015: Bactiguard Holding AB, Cederroth AB, InDex Pharmaceuticals AB, C-RAD AB, Episurf Medical AB, Enzymatica AB, ApoPharm Holding AB, SciBase AB, Intervacc AB and Diaverum AB. So far in 2014, the following life sciences companies have been listed on First North: Scandi-Dos AB (first day of

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[1] Setterwalls was legal adviser to Recipharm and its founders in connection with the listing of Recipharm on NASDAQ OMX Stockholm.

trading 11 April 2014), Doxa AB (first day of trading 7 April 2014) and Brighter AB (first day of trading 14 March 2014). According to the website nyemissioner.se, six more life sciences companies plan to list on First North in 2014.

The listing process

The Swedish public listing process is similar to that in other European jurisdictions.

For a company with no prior listing that is making a public offering of shares in connection with its listing, the process will normally take between four and six months and usually includes the following steps:

- Engagement of managers and legal counsel (and any other advisers).
- Initial discussions and meetings with NASDAQ OMX about the listing process.
- Appointment of an examiner (an accountant) by NASDAQ OMX.

  The examiner carries out an investigation which forms the basis for the decision of the Listing Committee ("Bolagskommittén" in Swedish). The purpose of the investigation is to determine whether the company satisfies the listing requirements. The examiner also reports on the suitability of the company's internal reporting systems.
- The company needs to consider issues such as:
  - Publicity guidelines and "black-out" period.
  - Lockup arrangements or other restrictions on current shareholders and management.
  - Placing agreement.
  - Stock lending arrangements.
  - Any internal restructuring required.
  - Overallotment/greenshoe option.
  - Offers by existing shareholders to sell shares in connection with the listing.
  - Changes to employee incentive arrangements.
- Information gathering and a due diligence investigation performed by legal counsel.
- Drafting of the prospectus. The prospectus, which is often prepared by the legal advisers, should contain all the information required to enable an investor to make an informed assessment of the company's operations and financial position and the rights attached to the securities in question. The examiner appointed by NASDAQ OMX follows this work and provides comments on the content of the prospectus.
- Filing of the prospectus (in Swedish) with the Swedish FSA for registration and approval.
- Approval of the listing application by the Listing Committee. Approval is based on the recommendation of the examiner appointed by NASDAQ OMX.
- A press release is issued, stating main terms of the offering and where the prospectus is available and where it may be obtained by the public.
- Book closure followed by pricing, allocation and execution of the placing agreement.
- Filing and registration of the shareholder or board resolution on the new issue of shares, as applicable, with the Swedish Companies Registration Office.
- The manager subscribes for the shares as set out in the placing agreement. Delivery of borrowed shares, if any, to the manager for delivery to investors.
- Signing of NASDAQ OMX's Rule Book for Issuers.
- Listing – trading in the shares starts.
- Start of stabilisation measures, if any. The EU Regulation on stabilisation measures (2273/2003/EU) permits a manager to undertake measures to stabilise the price of shares in connection with an offering of shares, provided that certain conditions are satisfied.
- Exercise of overallotment/greenshoe option to cover any short positions not already covered by stabilising purchases.

Conditions for listing and considerations for the process in Sweden

NASDAQ OMX has established certain fundamental requirements for companies applying for listing on the exchange. These demands include the company having to undergo a legal examination carried out by an external attorney prior to listing and continual listing requirements. These include meeting NASDAQ OMX's requirements regarding the general suitability of the board of directors and management, procedures for financial reporting, adoption of an information policy, implementation of routines for how information is to be disseminated and requirements for the board of directors, senior management and auditors elected at the shareholders' meeting to have basic knowledge of the rules and regulations on the stock market.

Listed companies must have their shares registered in, and their share register maintained by, the computerised book-entry share registration system administered by Euroclear Sweden AB.

Sweden has implemented the Prospectus Directive, the relevant rules of which are set out in the Trading Act.

Swedish limited liability companies cannot indemnify persons who acquire shares or other securities of the company in an IPO or a new issue of shares for damages resulting from errors or inadequate disclosures in the prospectus. Damages may, however, be sought from the board of directors of the company if the losses for which damages are sought are the result of wilful or negligent behaviour by the board members.

The board is less exposed to prospectus liability claims if the company has engaged well-reputed legal and financial advisers. In larger offerings it is customary to request the auditors to provide a comfort letter in respect of the financial information included in the prospectus.

In Sweden, it is market practice to make the prospectus and application forms, once approved and/or registered by the Swedish FSA and duly published, available online, both on the company's and the manager's websites. Under the Trading Act, a listed company is required to post the prospectus on its website. Before making a prospectus available online, the company should, however, seek legal advice and take measures to avoid targeting the public in certain other jurisdictions.

Concluding remarks

Several healthcare and life sciences companies are planning to list on NASDAQ OMX Stockholm and First North, as well as on unofficial lists such as AktieTorget. Some companies that are already listed are considering moving, for example to the main market from First North or Aktietorget. When preparing to list or switch to a different exchange, companies need to also ensure that they are aware of and will comply with the legal requirements for listed companies. Legal advisers play a significant role in preparing companies for their new life on the stock exchange, where they face an extensive package of new rules and regulations that apply to public companies.

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M&A in Life Science and technology

These days, nearly all M&A transactions are technology driven. Previously, risk assessment was more on operational issues but there has been a shift towards risk assessment of technology. This affects legal advice in M&A especially if you are in transactions with immature technology which often is the case in Life Science. To succeed you need to understand the technology and recent developments. What is going on and why?

For example, in Life Science M&A you need to understand that when a patent expires the price of the product generally drops by 80 per cent and an original player therefore may need to find emerging markets in order to compensate by differentiation or they may need to refurnish the product pipeline. Strategic buyers may also be looking for transition to new products and faster return on investments.

The core technology-driven deals (typically Life Science start-ups) are often done through licensing and extensive escrow protection rather than through purchase of shares or assets. Clinical trials are where this happens since that is where the first large chunk of big money is needed.

At the same time, smaller companies also have access to venture capital these days so the game has slightly changed. In some European countries there is now plenty of money in the market for Life Science investments and it is not only strategic players who are taking part in acquisitions.

As a transaction lawyer, how do I help our clients make sure that they get what they want in these deals? One frequent challenge is work performed by third party. In such context you should ensure unrestricted ownership and ability to use core technology. Verify the title chain and go as far back as possible. In this context you often need to encourage the target to make changes to existing contracts before signing any deal. A hive-down might help but cannot fix the title chain, so stay alert. Another risk is that the patent is voidable which, for example, could be the case if the target's proud professor has been travelling to conferences and showing slides before the patent was filed. These things tend to be difficult to analyse in full before signing.

Sleeping dogs do exist. Your fear is that having incorporated what you bought, developed it into a block-buster, someone says they have a right to the patent or product. Normally representations and warranties do not help much since customary warranty periods do not exceed two years from closing and are capped.

As a parallell, if it is an IT M&A transaction, and in particular if it is in a cloud industry, you also need to look at open source issues. Tests like Blackduck are not hard to do but analyzing them is another thing. Has the code been distributed to someone else? Has it been modified? Also here, problems generally show up much later than warranty periods. The Cloud is also a hot topic, and here data protection is key. Look at where the service providers are located. Most of the providers are located in the States since there is not so much restrictions as in Europe. These things are only examples of M&A becoming increasingly tech driven in all sectors.

So how do you act as a buyer in this competitive environment? Obviously you need to take some risk to be able to do M&A. But you should never take direct title risk. From experience, if you are buying, the seller's reaction to your findings is often far more interesting than the findings themselves. There are ways to fix things but if you have a seller whose reaction is to refuse to understand the problem, then you should be ready to walk away if it is a direct title risk.

One common technique to seek some kind of protection is to establish milestones for further payments of the purchase price. Here the practice is different in IT deals where both milestone payments and earn-outs are less frequent com-

pared with Life Science deals. In IT, earn-outs could work if the product is really isolated but not if it's intended to be merged with another product-offer in the market. In general a very small portion of global M&A have earn-outs these days.

If used, earn-outs are where you really need proper drafting. In Life Science M&A earn-outs are typically used when a product is in an early stage. The use of earn-outs is declining due to the dynamics behind it, for example that the drafting can never cover all events and a buyer normally has nothing to lose in questioning an earn-out well after closing. He or she may use a variety of arguments. Many deals therefore have milestones instead, which could be approval by public authorities, certain sale levels etc. As a seller you will need covenant protection that the buyer will try to reach the milestones and protection if the buyer in its turn divests the assets. Normally the latter should, if you're acting for the original seller, be covered by an obligation for the new buyer to stand guarantor.

All in all, modern M&A requires that you understand the hurdles technology world behind. It is not advisable to simply move standard "operational asset M&A-techniques" straight over to modern M&A.

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Does supply from a third party fall under the Bolar exemption?

Medicinal products take a long time and huge effort to develop. It is estimated that the cost of bringing a new product to the market exceeds on average half a billion US dollars. Patent protection is vital for originators in order to recover some of the spending for research and development invested in new medicines.

There are, however, exemptions from the exclusivity granted to the patent holder. One is the use of an invention for experiments relating to the invention itself. Patent law promotes the development of new inventions. However, the exemption for such experimental use is supposed to be narrowly interpreted (and is obviously interpreted and implemented in different ways within the EU).

Closely related to the exemption for experimental use is the so called Bolar exemption. The Bolar exemption stems from the development in the US and later on the Hatch-Waxman Act. In short – and in this context – the Hatch Waxman Act states that it is not an infringement to use a patented invention for uses related to the development and submission of information to the FDA.

Within the EU, the corresponding Bolar exemption is regulated by EU Directive 2004/27/EC (amending inter alia. the EU Directive on Medicinal Products for Human Use). The Directive establishes that conducting the *"necessary studies and trials with a view to the application of [a marketing authorization] and the consequential practical requirements shall not be regarded as contrary to patent rights or to supplementary protection certificates for medicinal products"*.

There are different interpretations among the member states of the EU as to which acts are exempted from infringement. It is likely that a party wishing to carry out trials necessary to obtain marketing authorization for a generic product, may manufacture the product relying on the Bolar exemption. It is not clear, however, if third parties supplying patented substances to the generic industry for the use in obtaining marketing authorization also may refer to the same exemption.

Recently a dispute between the Polish company Polpharma, a manufacturer of the active ingredient solifenacin succinate, and Astellas Pharma, the proprietor of a European patent for solifenacin succinate, highlighted the question of supplies from a third party in national proceedings in Poland and Germany (Düsseldorf court).

Polpharma advertised the active ingredient on its website and in journals. In parallel, Polpharma had also supplied Hexal in Germany with solifenacin succinate. Polpharma asserted that the supply had been made subject to the condition that Hexal must use the active ingredient only for the purpose of conducting the studies required to obtain marketing authorization, i.e. in accordance with the Bolar exemption.

The Düsseldorf court considered that third party supply is only exempted in accordance with the Bolar regulation under limited and narrow conditions, emphasizing the role of the supplier as a part of the tests and studies carried out by the customer under the Bolar exemption. The court held that these conditions were not met and that it was not necessary to refer the question to the CJEU. The Polish court seems to have come to the same conclusion.

However, the Oberlandesgericht Düsseldorf decided that clarification from the CJEU is required and referred a number of questions to the CJEU concerning the scope of the Bolar exemption, including if the exemption applies to acts by which a third party, for purely commercial reasons, supplies to a manufacturer of generic products a patent-protected active substance.

Although the Bolar exemption aimed to harmonise the position in the EU member states, the implementation of the Directive into national law seems to differ. It is also said that the UPC has narrowed the approach to interpretation of the Directive. The referral to the CJEU is of importance for the pharmaceutical industry and the outcome is awaited with great interest.

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New EU directives on public procurement – how will procurement of Swedish health care be affected?

On 11 February 2014, the Council of the European Union adopted a package of new public procurement directives (the "Directives") made up of two directives replacing the Public Sector Directive (Directive 2004/18/EC) and the Utilities Directive (Directive 2004/17/EC) and a new directive on concessions. The Directives mark the most significant reform of public procurement law since 2004, when the current directives were adopted.

The new Directives support economic growth and deficit reduction by making the public procurement process faster, less costly and more effective for businesses and procurers alike. The general EU procurement principles will not be changed and the new rules have a similar overall structure as the existing rules. However, the rules are promoted to have a greater degree of flexibility which will enable better commercial outcomes.

The Directives must be incorporated into the Swedish legislation within two years. Mr. Eskil Nord has been appointed as a special investigator; delegated to provide suggestions on how the Directives should be implemented in Sweden and his report shall be submitted later this year. The question is, thus, how the new Directives will affect the Swedish health care.

Procurement of Swedish health care

Health care services are currently classified as B-services and are not subject to the directive controlled area within the Swedish Public Procurement Act. Nevertheless, health care services are covered by the general EU procurement principles (the principles of equality of treatment, non-discrimination, proportionality, transparency and mutual recognition). In Sweden, procurement of B-services is regulated in Chapter 15 of the Public Procurement Act. The rules in this chapter are in many respects similar to those stipulated in the existing directives.

Since 2009, Sweden's county councils and municipalities also have the opportunity to introduce systems of choice (*Sw. valfrihetssystem*) for health care services and social services. It is optional for municipalities to introduce systems of choice, but mandatory for county councils within the primary health care.

Regarding procurements of pharmaceutical products, medical devices and other health-related services and products, these are often (depending on the value) subject to the directive controlled area within the Public Procurement Act.

The Directives impact on Swedish health care

Will the Swedish public procurement legislation within health care be affected by the new Directives? The answer is yes. As a general starting point, we can assume that the framework of the Swedish system of choice will remain in one way or another. Conversely, healt h care services, classified as B-services, will be affected as the division of A and B-services will be abolished according to the Directives.

Furthermore it should be noted that, according to the Directives, health care services are deemed inappropriate for the application of the regular procedures for the award of public service contracts. Since the rules of the procurement procedures available in Chapter 15 of the Public Procurement Act are similar to those stipulated in the directives, the procurement rules for these services have to be changed. However, the Directives clearly state that procurement of health services with a value of, or exceeding, EUR 500,000 must be in accordance with the fundamental principles of transparency and equal treatment.

The procurement of pharmaceutical products, medical devices and other health-related services and products will

also be affected by the general changes when the Directives are implemented. As mentioned earlier, the changes will lead to more flexible and simple procurement procedures and better market access for small and medium sized enterprises. Moreover, the allocation criteria will be changed, implementing possibilities for the purchasers to consider the mandatory regulations in social, labor and environmental law as well as life cycle costs of products or services, i.e. purchasers' costs such as acquisition of raw material, environmental costs and cost for removal.

As a final point, innovative products and services are vital to research and development within health care. Through the Directives, a new procurement procedure will be implemented: innovation partnership. This procedure will allow public authorities to call for tenders to solve a specific problem without pre-empting the solution, thus leaving room for negotiations between the authority and the bidding companies to find the most appropriate answer. Contracting authorities will have access to this procedure when a need for the development of an innovative product, service or works and the subsequent purchase of the resulting output cannot be met by solutions already available on the market. Innovation partnership is deemed to simplify the already existing procedure competitive dialogue procedure (*Sw. konkurrensprägladd dialog*). According to the Swedish Competition Authority, only 25 out of almost 20,000 Swedish procurements in 2012 were carried out as competitive dialogue procedure. Hopefully innovation partnership will be used in a further extent as it is vital with innovation within health care. However, the prosperity of innovation partnership will, in the end, depend on the purchasers' organization, capacity and resources to structure the procurements and to draft the agreements.

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Pricing and availability of pharmaceuticals

The Government decided as early as June 2011, to appoint a special investigator to conduct a review of certain matters relating to pricing, availability and market conditions within the pharmaceutical and pharmacy area. The Committee is called The Pharmaceutical and Pharmacy Inquiry (S 2011:07) and has presented several reports.

The Committee's first interim report on the pricing and availability of pharmaceuticals, which included a proposal to introduce international reference pricing, led to a large number of comments in the round of referral in early 2013. LIF, the research-based pharmaceutical industry in Sweden, suggested that the proposals would not signify any improvements on Swedish patients' access to medicines and that the pressure on pharmaceutical companies would become so significant, that the proposals to revitalize the Swedish pharmaceutical research could threaten to collapse before they even got started. It was also pointed out that the combination of "a variety of differentiated price-reducing steps bring to mind restraining measures that the crisis-ridden countries across Europe are forced to implement. If the proposal is implemented, Sweden will indirectly capitalise on the difficult economic situation in countries like Greece, Spain and Portugal."

The Government's bill

In March 2014, the Government presented a bill called Increased Availability and More Appropriate Pricing of Pharmaceuticals (Government Bill 2013/14: 93) to parliament.

According to the proposal, the decision on subsidy will continue to be based on the ethical platform, but the value-based pricing should be evolved to ensure that pharmaceuticals are cost effective throughout their life cycle and, if possible, increase the cost-efficiency in new introductions and reassessments of pharmaceuticals.

The Government's focus is to ensure a "reasonable price range throughout the life cycle of a medicinal product". International reference pricing is currently not relevant. LIF has managed to avoid the international reference pricing by voluntary price reductions on older original pharmaceuticals.

Few actual suggestions on pricing in the bill

The bill provides few actual proposals. The development of value-based pricing is largely put on the Dental and Pharmaceutical Benefits Agency, TLV. This means that it is still unclear what the development of value-based pricing will signify in practice. Some conclusions that may be worth noting are set out below.

- The Government wants more dynamic pricing and discusses TLV's opportunities to coordinate price and volume components within the framework of its decisions. The decision on how to proceed is assigned to TLV.
- The Government is discussing how the reassessment of earlier reimbursement decisions could be carried out

more efficiently. One suggestion is that TLV could limit the number of pharmaceuticals in a therapy group during the reassessment and give companies the opportunity to submit new prices based on the limited offer.

- It is indicated that TLV, when reassessing, has the opportunity to compare the price level in Sweden with prices in other countries. This provides a form of international reference pricing.
- As regards the so-called confidential agreements between the industry and the county councils, the Government proposes that the framework for cooperation in this area eventually need to be revised once the ongoing judicial proceedings are completed.

The only actual proposal in the pricing area is that regulations regarding the conditions for changing the price of a medicinal product within the reimbursement system could be established for medicinal products provided that there has been 15 years since the product was approved for sale, or if there are accessible generic substitutions marketed to pharmacies in Sweden.

Other proposals in the proposition

In this context, it is worth mentioning that the bill comprises several proposals that are aimed at increasing the availability of pharmaceuticals such as:

- More clearly defined negotiating rights regarding the purchase price of certain pharmaceuticals for outpatient pharmacies.
- Opportunity to replace prescribed parallel imported pharmaceuticals with less expensive originals.
- Obligation for authorized retailers to provide the relevant "product of the period".
- Sanctions for a pharmacy and a marketing authorization holder that does not follow the rules on substitution and provision of the "product of the period".
- Where a pharmacy is not able to fulfil its supply obligations directly, it must inform the consumer in which pharmacies the drug or product is available.
- An opportunity for pharmacists to oppose substitution (known in Swedish as "*farmaceutkryss*").
- The Swedish eHealth Agency is to submit information to TLV as well as to the Swedish Medical Products Agency to enable the follow-up of substitution and supply obligation.

The proposals are to apply from the 1 July 2014, except in respect of farmaceutkryss, which becomes effective on 1 January 2015.

Conclusion

LIF has stated that any change in the model of pricing and reimbursement for pharmaceuticals has to be made concrete in actual proposals by the Government and prepared in an open political process before being implemented.

It is a challenging assignment for the Government to achieve a realistic balance between the public cost control and the refund of the investments and other efforts of the pharmaceutical companies. However, it is essential that the pricing model is predictable for all parties. It is, therefore, an evident problem that the Government has announced that new rules will apply that could be of crucial importance for the introduction of new pharmaceuticals on the Swedish market, without declaring the meaning or consequence of these.

We therefore still call for the Government's concrete proposals on the future model of pricing and reimbursement of medicines. We are monitoring the development closely.

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Pharmaceuticals for Special Needs

The Pharmaceutical and Pharmacy Inquiry has delivered its third interim report, "Pharmaceuticals for Special Needs" (SOU 2014:20).

The report deals with questions concerning:

- management and pricing of pharmaceuticals against infectious diseases;
- management and pricing of licensed pharmaceuticals;
- pricing of extemporaneous pharmaceuticals.

The report, which comprises few proposals, has thus far received a mixed reaction. Notably, the Swedish Pharmacy Association has been critical of the report on the basis of its proposal as to licensed pharmaceuticals.

Pharmaceuticals against infectious diseases

The majority of pharmaceuticals prescribed pursuant to the Communicable Diseases Act (2004:168) have been reviewed in accordance with the Pharmaceutical Benefits Act (2002:160) and given a price by the Dental and Pharmaceutical Benefits Agency (TLV). To avoid lack of clarity in the pharmacies' pricing, the Inquiry is now proposing that it be made clear that the provisions in the Pharmaceuticals Benefits Act regarding price and the right of the pharmacies to negotiate on price is also to apply when the pharmaceutical has been prescribed under the Communicable Diseases Act.

The Inquiry's assessment is that pharmaceuticals against infectious diseases that have not been reviewed under the Pharmaceutical Benefits Act could be subjected to a health economic evaluation within the framework of the clinical pharmaceuticals project conducted by the TLV.

At present, there is a lack of simple ways to monitor which pharmaceuticals – and associated costs – may come into play in fighting infectious diseases. To improve opportunities for monitoring and facilitate invoicing of county councils by pharmacies, the Inquiry proposes that the eHealth Agency should mediate these invoices (as in the case of pharmaceuticals covered by the pharmaceutical reimbursement system).

Licensed Pharmaceuticals

Each year, the Medical Products Agency grants about 68 000 applications for licences. Currently, it is the pharmacies that apply for a license, i.e. permission to sell a non-approved

pharmaceutical, while it is the prescriber who explains the reasons why it is needed.

The Inquiry has considered whether another party, such as the prescriber, should apply for the licence. Following a review of the pros and cons of the various alternatives, the Inquiry has concluded that the system of applications from pharmacies should be retained. This is justified by the fact that the licence, as mentioned above, constitutes a sales permit.

Today, the pharmacies pay a fee for each licence application made. This means that it can be costly for the pharmacies to sell a licensed pharmaceutical. But nor does the Inquiry propose changes to the fees.

When Apoteket AB ran all the pharmacies, patients could collect a licensed pharmaceutical from any pharmacy of their choosing irrespective of which pharmacy applied for the licence at the Medical Products Agency. In connection with the re-regulation of the market, this possibility ended, which led to poorer availability. This is because a licenced pharmaceutical now has to be picked up from a pharmacy in the same chain as the pharmacy that made the application. The Inquiry has found that a system could be created in which a decision on a license could apply at all pharmacies. This may, however, mean that it will be necessary to reconsider the way in which the Medical Products Agency's work on applications is financed.

A further proposal concerning licensed pharmaceuticals is that they should be automatically covered by the pharmaceutical reimbursement system except in cases where the TLV has made a special decision on this. It is deemed to be inappropriate for TLV to undertake a value-based assessment when a new licensed pharmaceutical is to be prescribed and it is a matter of urgency for the patient to get access to this drug.

Extemporaneous Pharmaceuticals

Extemporaneous pharmaceuticals are pharmaceuticals manufactured for a specific patient and are exempted from the requirement of approval. Extemporaneous pharmaceuticals also exist in the form of stock preparations (with or without a national licence) when they are manufactured in larger volumes to meet an expected need.

For extemporaneous pharmaceuticals, the TLV has set a list of rates showing the payment that the manufacturer is allowed to charge for the raw material and the work needed to produce a certain kind of preparation. In the case of stock preparations (with or without a national licence), the manufacturer applies to the TLV for a price for the stock preparation concerned.

The Inquiry has analysed the current practice for pricing and has considered whether another model for pricing could be applied to extemporaneous pharmaceuticals. The Inquiry has not found any more practical alternative and proposes that the current method should be retained. However, current practices should be regulated by statute so as to clarify the requirements that apply.

The future

The interim report is the third from the Pharmaceutical and Pharmacy Inquiry. The report will now be circulated for comments.

It is proposed that the suggested legislation, which above all applies to the management of the flow of information in the matter of prescriptions, pharmaceuticals and prices, is to enter into force on 1 January 2016.

The final report will contain proposals for orphan medical products, medicine dose dispensing service, and trade with pharmaceuticals for animals and will be presented no later than 30 October 2014.

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The pharma, medtech, lab-tech industry continues to lead the fight against corruptive business practices

The research-based pharmaceutical industry, Swedish Medtech, Swedish Labtech and the Swedish Association of Local Authorities and Regions have adopted a revised agreement concerning collaboration between themselves and the health service.

This agreement aims to achieve greater transparency but also a more moderate conduct in the collaboration between the industry and their counterparts in the health service. There has also been a call for more clarity with regard to each party's responsibilities in connection with, for instance, training activities for health care personnel.

In direct relation to this, the so called 50/50 rule which enables a pharmaceutical company to finance 50 % of the participating personnel's costs for travel, room and board will no longer apply after 1 January 2015. Consequently, the company will no longer have to document approval from the employer concerning participation in such an activity.

The agreement applies not only to employees but also to senior officers in the organization. The industry's ability to offer modest meals is clearer as well as the industry's opportunities and obligations to offer product and service information; sponsoring of meetings arranged by the industry, the health service or third parties. It also clarifies what applies in relation to market surveys, public procurement and donations.

The agreement covers not only the pharma industry but also the medtech and labtech industry. It is incumbent on each party to ensure compliance by its members and to implement a self-regulatory system for this purpose. The parties will review the rules once a year and revise and amend them if necessary.

The agreement entered into force on 1 January 2014. It is to be ratified by each regional authority in the months to come.

Five core principles

There are five core principles for collaboration between the industry and the healthcare sector. The principles of Benefit – collaboration should always be based on the activities of health service and on the needs of the patients. An activity must be clearly connected to the company's business operations. A mutual benefit perspective must be applied. Transparency – Collaboration should always be open and transparent in accordance with the agreement, applicable legislation, codes of conduct and policies.

Proportionality – The obligations of a party in a collaboration must be proportionate to the other's. All forms of compensation should be proportionate, reasonable and correspond to the market value of the service performed Moderation – All activities sponsored by a pharmaceutical company should be permeated by moderation. This means that the benefit must not be such that it may influence the behavior of the recipient. The collaboration must not result in undue influence and must not jeopardize the independence of the health service.

Documentation – all forms of collaboration between the industry and the health service where any form of compensation for costs occurs, regardless if it accrues to an individual employee or groups of employees or at an operative level must be documented through decisions, contracts or agreements. Records and relevant documents, for instance invoices, must be kept.

General rules which should always be observed

The basic rule is that a company may not offer benefits contrary to the agreement or its intentions and employees in the health service may not request such benefits. In relation to meetings arranged by, or in collaboration with, companies the company may offer modest meals. Such hospitality may include alcohol provided it is moderate and alcohol can only be served in connection with meals. Spirits should never be offered. Non-alcoholic beverages should always be offered. Recreational activities may not be financed by a company or requested by health service employees. Travel arrangements should, where possible, be arranged in economy class. Travel time may not exceed the length in time of the meeting. It is not permitted to bring along a spouse, partner or friend. The venue selected for the arrangement should be reasonable in relation to the purpose of the meeting. Leisure resorts in season and places known for their exclusivity should be avoided, as well as locations hosting or in the vicinity of major international events. Arrangements outside Sweden including the Öresund-region (Denmark) may only be chosen if a majority of the participants come from other countries than Sweden.

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Facts and figures

Setterwalls has a proud history spanning over 130 years. During that time we have always been cutting edge. That is as true today as it ever was. Setterwalls has undergone substantial expansion over the past 10 years, both in terms of the number of lawyers and practice areas. Setterwalls' dynamic growth and the firm's participation in several high-profile cases and transactions have pushed the firm to its prominent position in the Swedish legal services market. We are now one of the largest law firms in Sweden, employing more than 190 lawyers at offices in Stockholm, Göteborg and Malmö.

Setterwalls is organized into practice groups and trade and industry oriented teams but Setterwalls' lawyers try not to think in compartments. Each problem will have unique features; each client individual goals. So the firm is committed to pulling together multidisciplinary teams from across the firm to find the best solutions in the areas where its clients' businesses encounters the law. Setterwalls provides legal services to all the players in the international pharmaceutical sector as well as manufacturers of medical devices; public authorities and suppliers of health foods. Our clients also include companies within the innovative and speciality pharmaceutical industry.

Setterwalls' is frequently involved in IP litigation and related matters, competition law and public tenders, regulatory issues, commercial legal work and transactions.

With a *"Sizeable team spread across the firm's Stockholm, Gothenburg and Malmö offices. Offers specialised support in all areas of the life sciences sector including IP, regulatory and transactional advice"*, Setterwalls' Life Sciences group is top-ranked by Chambers Europe 2014.

The Life Sciences group has substantial experience in dealing with authorities and has managed a number of important lawsuits in court for our pharma clients, not only concerning patents and trademarks, but also regulatory issues. Our team is a multi-disciplinary team bringing together the experience and expertise from all offices and with in-depth knowledge of the sector.

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Equity Capital Markets
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Financial Markets
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Life Sciences
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