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Life Sciences

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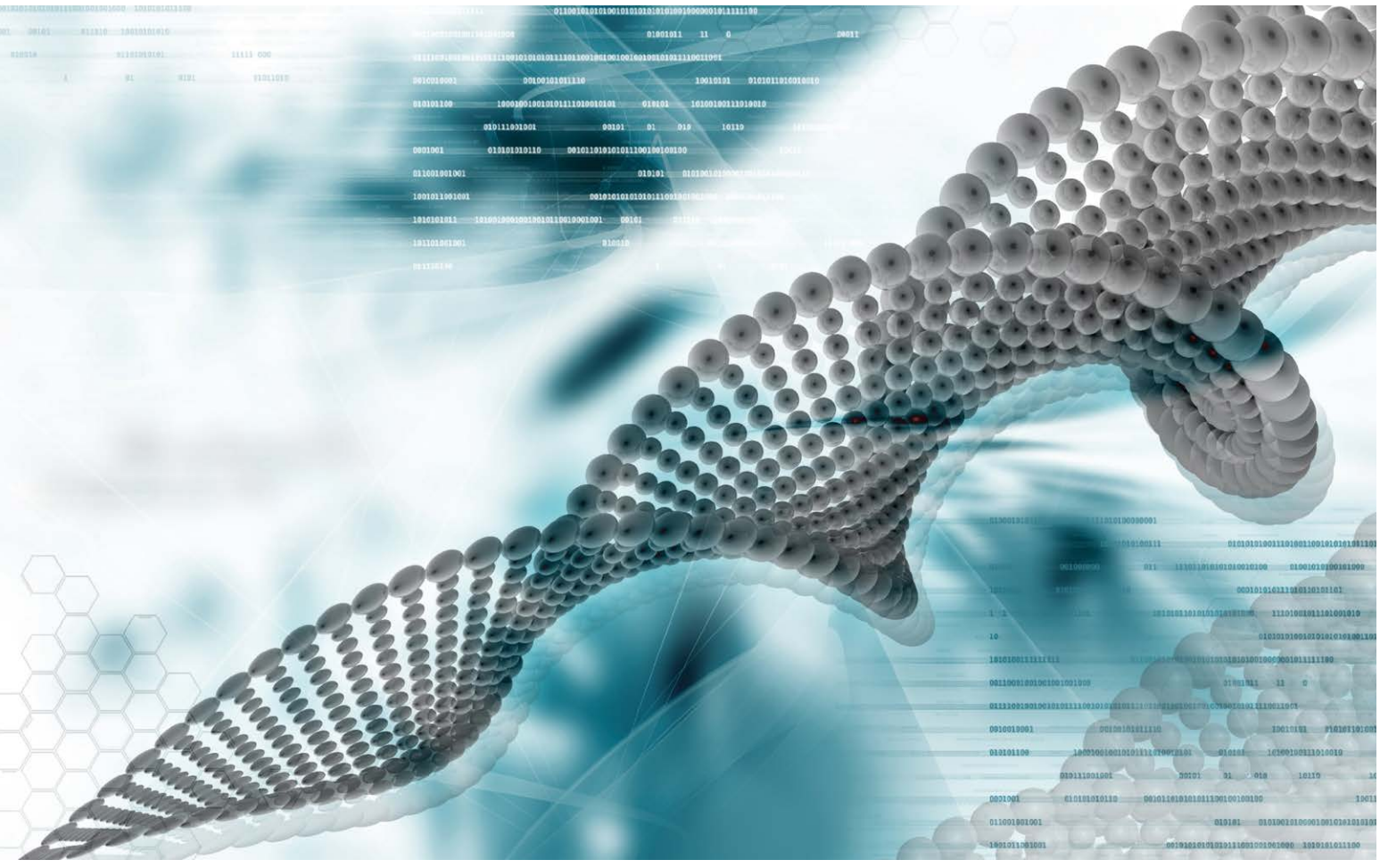

In this issue of Life Sciences Report you can read about important aspects regarding the processing and storage of patient data and the demands on complaining suppliers in public procurement cases. You can also learn about how to behave from a legal perspective in an open innovation environment and, when applying for a Supplemental Protection Certificate (SPC), which authorisation is the relevant first authorisation. These are just some of the interesting articles in the field of life sciences. Our guest contributor, Mr. Jonny Sågänger, editor for Läkemedelsmarknaden writes about his observations on transformation in the field of pharmaceuticals. 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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Exciting times

Exciting times – and possibly times of historical significance – for the life sciences in Sweden. As a journalist and editor of a niche editorial media service, I am privileged enough to get to reflect and review interesting and – to say the least – exciting developments in the industry in this country.

To say the editorial challenge is difficult is an understatement, but it is made easier by the fact that our media service Läkemedelsmarknaden is restricted to the pharmaceutical area, which together with medical technology and biotechnology is one of the three pillars of the life science sector.

What I have to do as an editor is keep up with a daily stream of press releases, political initiatives and the rest of what makes up "media noise". The idea is to select what we believe – with our knowledge of our readers and subscribers – to be relevant for our target groups. We also have to put together a jigsaw puzzle made up of a large number of news items, events and decisions – interesting in themselves – so as to try to get an overview, to understand the whole picture and to identify trends.

When "evaluating news", as it is called in journalism jargon, it is important to avoid falling into the classic trap of exaggerating the significance of any individual event. It is easy to end up falling into such traps because we, as people, can make the mistake of exaggerating the long-term significance of individual events – while at the same time having difficulty seeing and grasping the big picture when looking at a course of events. Put another way: sometimes we cannot see the wood for the trees.

At present there are several interacting elements that suggest that Sweden could actually get to sharpen its competitiveness as a national market in the global life science sector. Next to the asterisks in the list below you will find some of the events and developments in our time, which – according to Läkemedelsmarknaden's analysis – are going to be significant in terms of the vital force in work currently being done in the life sciences. This initiative is now being taken within Swedish trade and industry, the Swedish state, the academic world, within patient/user organisations and at a county council and regional level.

- The Social Democrat/Green Party government's decision to make life sciences one of the most prioritised areas for investment in growth, innovation and development, together with climate, energy and the environment. The first steps taken are ambitious, with the establishment of an Innovation Council and the re-cruitment of Anders Lönnberg as national co-ordinator for life sciences.

It continues to be something of a honeymoon period for the government and all the different players in the life science area. There has been a lot of heavy criticism, for example from the opposition Christian Democrats' trade and industry policy spokesperson Penilla Gunther, who believes the government's grant to amount to no more than "a bit of loose change to be divided among several players".

There comes a time after the honeymoon period when the surrounding world starts to demand to see results from the government's fine words and financial subsidies. We are not there yet, but there could be a crescendo of critical questions from the political opposition and from the life science players as soon as the most important political and business event in Sweden, the Almedalen week in July, and certainly the nearer we get to the next election.

- The establishment of a national committee for clinical research within the Science Foundation. The new committee – based in Gothenburg – has taken up the challenge of creating a national arena for clinical research with both great enthusiasm and a sense of purpose. Sweden's budding national arena for clinical research in the form of a country-wide node centre national committee for clinical research (incidentally, it is high time the committee hit on a good name and a catchy and simply communicable abbreviation!) and its six nodes around the country are a pragmatic and eagerly awaited attempt at creating a Swedish arena for pharmaceutical studies, pharmaceutical tests and other forms of research in the medical field. The vision is that pharmaceutical companies, people with different sickness diagnoses and other interested parties who want to, for example, run clinical studies in Sweden should be able to identify research subjects and establish easily and in one location on the Web what studies and tests are being carried out in the country. That is – if accomplished – without a doubt something that make Sweden attractive to international pharmaceutical companies. It should be possible to establish such a centre – at least one individual multinational pharmaceutical company has tried in vain to create just that type of online portal for clinical research in Sweden.

- Sweden is slowly but surely becoming more and more of an integrated health and medical services market for companies that introduce new medical therapies. By establishing what is known as the collaborative model, the New Therapies Board (NT-Rådet) expert panel and a number of other initiatives are creating opportunities for the 21 county councils and regions (who are paying) and the public authorities to coordinate their activities. It increases the speed of introductions, improves cost-effectiveness and minimises the risk of duplication of work in the time between a company getting marketing approval and patients being able to start being treated with the new product or service as a matter of course.

- AstraZeneca observed recently that the Swedish Dental and Pharmaceutical Benefits Agency was the quickest in the world to carry out a healthcare cost evaluation of one of the company's pharmaceutical products. With the increased speed of introductions of new therapies comes growth in the international pharmaceutical industry's interest in Sweden as an establishment nation for new products, at the same time as health and medical services staff have the satisfaction of working with the latest state-of-the-art and hopefully best tools in healthcare. This creates a positive spiral that means that Sweden's international competitiveness as a life science nation rises.

- AstraZeneca has invested heavily in Mölndal outside Gothenburg, which is currently one of the pharmaceutical company's three most important centres for research

and development. The establishment of an "airlift" between Cambridge and Gothenburg, making it possible for AstraZeneca's employees to switch to and fro between the two important research websites in order to advance and develop their skills and expertise.

- The Wallenberg power house's both stated and actual financial efforts to return Sweden to the absolute top of the world league where Swedish clinical research was 15–20 years ago. During a period of ten years the Knut and Alice Wallenberg Foundation is investing 1,7 billion Swedish kronor in research and development centres in Stockholm, Gothenburg, Lund and Umeå.
- Swedish legislation is about to be aligned with the EU's Unitary Patent system and Europe's new Unified Patent Court. The hope among advocates of the unitary system – there is plenty of strong criticism as well! – is that the new patent system should contribute to an increase in the pace of innovation and thereby growth in areas such as the life sciences. The Swedish government and its agencies have acted with foresight and vision, which has reaped the dividend that the Nordic-Baltic division of the Court is to have its seat in Stockholm. The working language will be English.

- The Social Democrat/Green Party government continues to finance the investments made by its predecessors in the non-socialist Alliance government through higher academic research, such as SciLifeLab in Stockholm. Research and science minister Helene Hellmark Knutsson said at the clinical conference on clinical research in Gothenburg earlier in April that she is almost convinced that there is broad cross-party parliamentary support for the size of finance package being put forward in the forthcoming research policy proposal.

- Several strong life science clusters are growing up around the country. The biggest investment to date has been in Stockholm-Solna where Hagastaden is emerging in a research-intensive environment with a focus on health and medical services and information and communication technology (ICT). Research on medicine and ICT brings together several ventures in medical research and digital health at Karolinska Institutet, KTH, Uppsala University and Stockholm University.

The ambition is crystal-clear. The initiative should make it obvious for international pharmaceutical companies, medical technology companies and other companies to choose between Boston, Cambridge and Stockholm-Solna when they make decisions about where to place collaborative projects and other life science activities.

These elements seem to be working broadly in a positive direction, i.e. they improve Sweden's chances of improving what is already a strong position as a life science nation. The negative elements are in the divided health and medical services structure that result when county councils and regions fail to co-operate in order to be able to make synergies by means of co-ordination. Swedish data and privacy legislation prevents Sweden from becoming champion of the world in the field of real world medical evidence, the data that shows the actual medical effect and cost-effectiveness that patients and taxpayers get from medicines and other treatments after they have passed the test and approval stage and are available on the market for health and medical services.

The editorial office for Läkemedelsmarknaden – and its sister publication Apoteksmarknaden – has a part to play in this development in terms of delivering, with a critical approach, editorial "need to know" news and analysis in our publications and with our seminars and other events – where we deliver "journalism on stage" – as regards life science in Sweden, the Nordic region and the EU.

My colleagues and I are fortunate to be able to carry out and develop editorial monitoring in what I consider to be a journalistic golden age. What we have are rapidly improving conditions for delivering fast news combined with in-depth detail. This is done by making the most of the opportunities the Web and digital distribution channels provide to us editors to direct our readers to relevant reports, surveys, political speeches, statistical summaries and other documents in their original form.

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[1] Läkemedelsmarknaden ("The Pharmaceutical Market") – and its sister publication Apoteksmarknaden ("The Pharmacy Market") – is a media service that primarily monitors economic, policy and legal issues concerning pharmaceuticals and the life science sector. We have been delivering daily news, detailed articles and analyses via our newsletter since 2002, as well as providing seminars, the professional network Pharma Network, training courses and other events.

See your doctor in the ”cloud” – click send and say aahhh!

The non-physical physical is an up-and-coming reality for many of us. That is, going to the doctor's surgery or – even more exotic – having a doctor coming to your house to give you a consultation and a prescription may soon be a thing of the past. No, in the future, like so many other things, you will be doing it on the Internet – a blessing for some, no doubt. Recent developments in this field have laid bare a number of issues including the processing and storage of patient data.

Processing of data

One issue is processing. The processing of data is regulated by the Data Protection Act, which implements directive 98/34/EC. Patient data is sensitive data that is regulated specifically by the Patient Data Act. This legislation limits access to patient data, basically stipulating a strict 'need to know' basis for access. The principle is that patients' data should not be made accessible unless the patient has given his or her express consent; nor should it be to a greater extent than necessary. Furthermore, it should be possible to vary the accessibility on the basis of the need a particular official may have for the information.

- There must also be efficient tools for follow-up and traceability of access. The identification of the user must comply with security restrictions.
- There should be technical "barriers", meaning that the user must make active choices in order to reach data about a particular patient.
- There should be tools to handle patients' requests.
- There must be procedures to handle secrecy-marked personal data so that the risk of sharing such data with an unauthorised person is minimised.

Storage in the cloud

The other issue is storage. It is, of course, tempting to use one of the available cloud services for storage of patient data. The Swedish Data Protection Agency has issued guidelines on the topic of cloud services generally.

First of all, when a data controller stores data in the cloud it relinquishes control of the data, but is still its controller. The cloud provider becomes a data processor. The data controller must therefore enter into an agreement whereby it gives instructions to the processor as to the processing of the data. Cloud providers often use standard agreements with predetermined user conditions, and appoint subcontractors – both of which you have to know or at least know about. The providers are typically reluctant to amend or alter these agreements – especially for small or medium-sized companies. You also have to consider that the data might be transferred to a third country. Mostly this is the U.S.A. and Google, for example, is party to what is known as the 'Safe Harbor list'. So that normally turns out all right.

But you have to do your homework. First, is the processing of the data, which is to be carried out by the cloud service provider, permitted under the Personal Data Act? Secondly, you have to carry out a risk and impact assessment to assess whether it is possible for you to appoint the cloud service supplier for processing of the personal data envisaged, what security level is appropriate and what measures need to be taken. Remember, the greater the privacy risks a particular element of personal data processing involves, the greater the requirements for security measures. Then, onward to the agreement!

Agreement with the cloud service provider

According to the Data Protection Agency the processor agreement shall

- prescribe that the processor is obliged to apply Swedish legislation with regard to the processing of personal data;

- prescribe that the processor is obliged to take appropriate security measures in accordance with Section 31 of the Personal Data Act;
- prescribe that the processor may only process personal data in accordance with the instructions of the controller of the personal data and thereby ensure that the processor does not process personal data for purposes other than those for which the processor has been appointed;
- ensure that the controller has knowledge of which other processors may come to process the personal data of the controller;
- ensure that the controller of personal data has the opportunity to monitor, in an appropriate manner, that the processor meets the requirements of the controller with regard to the personal data processing and actually takes appropriate security measures;
- ensure that there are technical and practical solutions for investigating suspicions that someone has had unauthorised access to personal data; and also
- ensure that the parties know what measures are to be taken upon the termination of the agreement so that the personal data processor does not have access to the personal data beyond that point in time.

Call your lawyer

With the Data Protection Authority's supervision of use of cloud services the standard agreements are getting better and better now – at least according to the Authority. But with patient data you have to be absolutely sure, and how do you do that? Well, you need to limit the scope of processing done by the processor. You also have to ensure that you can follow up the processing, e.g. check that the processor is following your instructions, ensure limitation of access and use of the data by and for the processor, and finally get information about the subcontractors the processor uses.

Do not forget your own processing. Make sure that the cloud service does not prevent you from complying with the requirements concerning patient data and make sure that your own safety measures are also adequate and in place.

And another thing: do not try to "heal yourselves". Read this sentence again and call your lawyer in the morning!

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Fair care?

The recently published edition of the Swedish Cancer Society Report for this year has reviewed target attainment by the county councils for some cancer diagnoses. Unfortunately the analysis points to a poor outcome: public healthcare is unable to meet the need. The report is also interesting to read in the light of recent debate on co-financing and self-financing of care.

There has been specific focus on self-financing and co-financing of life-sustaining treatment in recent times. The Swedish National Council on Medical Ethics (SMER) some time ago presented a report on self-financing and co-financing. Co-financing relates to the situation where a patient funds part of the medical care not covered by the publicly financed provision. SMER notes that co-financing already exists. This means that in some cases patients are able to choose a more expensive product and bear the additional costs themselves. This may be the case in connection with cataract operations or a more expensive hearing aid than covered by the publicly financed models. But this is also the way the market for generic medicines works, where the patient has the right to choose a more expensive alternative.

The issue come to a head when serious conditions such as cancers are involved. In recent times the issue of unequal access to the prostate cancer drugs abiraterone (Zytiga) and enzalutamide (Xtandi) has been the subject of public debate.

We know that new cancer drugs contribute to prolonged survival and improved quality of life. The Swedish Society of Medicine's delegation for medical ethics recently established that the right cancer medicine can prolong survival,

alleviate pain and generally contribute to an improved life situation in the form of fewer disease symptoms. In our work for the pharmaceutical industry we quite often observe that the Dental and Pharmaceutical Benefits Agency (TLV) has come to the conclusion that a particular medicinal product is not regarded as cost-effective and that the product has therefore been excluded from the pharmaceutical benefits scheme. The health service in turn tries to bypass TLV by making its own direct purchases in order to make it possible for the medicines to be provided and for patients to receive appropriate care. It has become evident in the debate that TLV has a too strict a financial approach and that the agency neglects the right to care according to need which is, in fact, one of the basic tenets of Swedish legislation. The cancer drugs Zytiga and Xtandi are estimated to cost around SEK 1000 per day of treatment and patient. It is not reasonable for patients with such a common cancer diagnosis as prostate cancer to be deprived of the most appropriate and modern treatment due to a relatively manageable increase in cost, particularly in view of the fact that the total cost of medicines has decreased in recent years.

It is naturally reasonable in this context to imagine that patients are willing to contribute to the cost of a more expensive drug treatment themselves, a wish that appears eminently understandable. Is it then right to deny patients what in reality is a better life on the grounds of what have been claimed in the debate to be reasons of equity?

This is obviously a highly complex issue. But it can also be questioned whether the prevailing system, with a somewhat parsimonious attitude to patients' right to contribute to their medical care is right and correct. Why should substitution of a generic medicine be regarded as more reasonable than the case where someone wants to receive the best cancer treatment, perhaps even life-saving better treatment? If the healthcare system, including TLV, cannot be organised in such away that it provides appropriate and modern care, I for my part consider that co-financing in many cases appears both humane and desirable.

Life Science Report has spoken to Magnus Pettersson, Country Manager, Astellas Pharma AB. He has made the following comments: With regard to co-financing, I will be thinking about the aspects of equity, solidarity and equality. Increased influence with more power for patients may look very different depending on place of residence. I can already see great regional differences between the county councils today in the way they choose to treat with these medicines. Prostate cancer is the disease of the ageing male. This leads to both age and gender perspectives and highlights the complexity of the other considerations to be taken into account by the authorities. When I draw comparisons with other countries I fail to see a mentality and tradition of "we'll sort it now and then solve it", primarily for the best of the patient. A 100% watertight solution need not be directly ready, but early access for patients would be desirable, during the time the process is under way. The need and wishes for co-financing would then diminish and quicker, more humane care would be the outcome.

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Time for new rules of evidence in public procurement cases – unreasonable demands on complaining suppliers

All contracting authorities are required to comply with the procurement rules when buying services and goods. The total value of public procurement contracts is approximately SEK 600 billion annually. The scope of public procurement spans everything from pencils to complex technical solutions. Accordingly, there is a great deal of variation in the requirements of different procurement documentation. The contracting authorities are therefore facing a varying task when checking that a tender meets all the requirements specified in the tender documentation.

When procuring medical devices, the contracting authorities often need products with advanced product features. In these situations, the contracting authority usually sets out extensive technical requirements that the products provided must meet. It is, of course, essential that the products procured actually meet these requirements. Failure to comply with the requirements could bring devastating consequences at a later date when the products are used on patients.

We have noticed that the contracting authority is often content with a confirmation from the bidder that its products meet the requirements in the procurement tender documentation. This confirmation is often made in the tender by simply ticking a box that says "yes, the product complies with the requirements" or by providing a description of the product.

A recurring situation is that a bidder who has not been awarded the contract initiates proceedings to have the procurement process reviewed on the basis that the winning bidder's product does not meet the requirements set out in the procurement documentation. In these situations, the court must decide whether or not the winning bidder's product does meet those requirements.

This situation occurred in the following case. A county council procured a specific medical device. The winning bidder had confirmed in its tender that its product met a specific technical requirement and had also provided a description of how the requirement was met. Another bidder initiated court proceedings and claimed that the winning bidder's product in fact did not meet that specific requirement.

In support of its claim, the claimant presented various product studies that explained why the winning bidder's product did not meet the requirement. Furthermore, a detailed explanation was submitted as to why the winning bidder's confirmation was not valid.

The Administrative Court dismissed the claimant's application based on the fact that the winning bidder had "stated that it complied with current mandatory requirements" and that the winning bidder had "satisfactorily explained how the requirement was fulfilled".

After the agreement between the county council and the winning bidder was signed, the winning bidder issued a safety notice. According to the notice, the products that had been called into question in the court proceedings did not meet the requirements set out in the procurement documentation. The question thus arises as to how the Administrative Court could have come to the conclusion it did. In the above example, and in similar situations, the court must decide whether a product meets a certain requirement. In this regard, the issue regarding burden of proof is of significance.

The first issue that the court must consider is which party should bear what is known as the burden of proof, i.e. which party should provide the evidence supporting a particular claim. Neither the procurement legislation nor the administrative procedural legislation contains any provisions on how the burden of proof should be allocated in this situation. So what have the courts stated? Initially it should be noted that there is no precedent from the Supreme Administrative Court. However, the Administrative Court of Appeal has touched on the issue in some cases.

One quotation that has been repeated in judgments from both the Administrative Courts and Administrative Courts of Appeal is from the Administrative Court of Appeal in Gothenburg in Case No. 6092-13 where it stated: "Should a court order rectification, a complaining supplier must clearly have proved that the contracting authority has misjudged a bid or considered irrelevant matters. As regards claims which by nature are such that it is not possible to assess their reliability without any technical or other particular expertise, it is the supplier's responsibility to prove its claims by means of expert evidence or otherwise."

This implies that the burden of proof lies entirely on the complaining supplier. In practice, this means that a contracting authority's obligation to check a tender is considerably restricted and may be limited to confirming that a box has been ticked. A supplier who questions whether the ticking accurately reflects reality must produce substantial evidence to support this.

Furthermore, the above quotation does not offer any guidance as to what evidence the complaining supplier must submit. Our experience is also that it is difficult for the complaining supplier to obtain substantial evidence, especially since it is the product owner who has possession of the relevant product information.

Our opinion is that this allocation of the burden of proof makes unreasonable demands on complaining suppliers. Furthermore, we believe that the consequence of this could be that contracting authorities may procure defective products. There is also a risk that any judicial review will be close to illusory.

Equally, we understand that contracting authorities' procurements are regularly reviewed and that it would be administratively unmanageable for the authorities to produce full proof that the products procured meet specified requirements as soon as proceedings have been initiated.

We therefore propose that the burden of proof should be allocated equally between the complaining supplier and the contracting authority. Should the complaining supplier show that there are grounds for its claim, the burden of proof should be transferred to the contracting authority, which must then demonstrate that it acted properly in accepting the product.

Such "transferable" burden of proof also has support in legal precedent. The Administrative Court of Appeal in Jönköping stated in Case No. 1667-14 that the evidence adduced by the complaining supplier suggested that "there was at least reason to question whether the [winning bidder's] product met the current mandatory requirement". In that situation, the court considered that the contracting authority had to provide support of its decision to accept the product. We are convinced that a transferable burden of proof would benefit the quality of the procurement contracts awarded and that at the same time the administrative burden on contracting authorities during the reviews would be kept at a reasonable level.

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How do you behave from a legal perspective in an open innovation environment?

Companies and organisations invite one another either unilaterally or on a reciprocal basis into their innovation processes, often to complement their own R&D departments and other internal resources. The thinking is that fresh new ideas and the involvement of more players can quicken the process towards a finished product or a solution to a problem whilst at the same time costs are kept down.

The word "Open" in OI should not be misunderstood as meaning that all rights produced or resulting from these processes or collaborative efforts are necessarily free for each and every participant to use. "Open" in this context should rather be understood as meaning that whoever initiates or owns the project, rather openly invites others to collaborate. The threadbare phrase "Look before you leap" is highly relevant when it comes to OI. It is important not to be blinded by the undeniably huge potential advantages, but to consider the risks involved in OI as well.

In the below, we provide a few tips as to what to consider from a legal perspective as a participant or initiative taker in OI.

- How is the right to and use of knowledge and expertise/technology the parties involved are already familiar with, or bring to the project, to be regulated? This is often referred to as "background information". How much of this information can be shared?
- Are the participants free to share the information or the ideas they contribute to an OI project – are they bound by existing rights or loyalties, e.g. already registered intellectual property rights, employment or confidentiality agreements? Is the information or idea considered a company's trade secret?

- Is there an awareness of the other participants' actual objective in participating – what are their aims and purposes?
- How is the situation to be dealt with if a participant delivers something that comprises the same invention as another participant has already developed or is in the process of developing, but has not yet patented or protected in some way? Publication or other disclosure may interfere with such protective measures.
- How are the intellectual property rights of something that is produced/created in or as a result of processes or collaborations in OI (often referred to in English as "foreground information") to be protected, and who is entitled to register or claim those rights?

It is not possible to provide general solutions to the above challenges; they are often dependent on the particular circumstances prevailing, on the aims and purposes of the OI project in question and on the participants. It is fair to say, however, that before the process begins the areas above should have been considered and, ideally, regulated. This can often be perceived by innovators and entrepreneurs as a wet legal blanket that risks jeopardising the whole project and the environment of open innovation they were seeking. Experience suggests, however, that when an innovation has been produced, it is difficult to agree as to how it should be managed. Tentatively, it is not necessary to regulate everything in detail in advance – that may risk creating problems that may in the end turn out to be illusory – but overall and "in principle" solutions should be in place. The participants deserve, on the one hand, to be aware in advance of the lay of the land and have the opportunity to plan their participation accordingly, and, on the other hand, to have such a clear map that, when an innovation or an outcome of commercial interest emerges/is created within the OI framework, they know what roads are open to them – how they should act, who should act and how ownership and potential earnings will be distributed and regulated. If this does not happen, there is a risk that potential hostage situations can be created, making it impossible to put the outcome to use and forcing inequitable solutions or disputes.

In conclusion, totally irrespective of whether it is decided that "Open" in an OI project should mean that nothing created in the project is to be protected in terms of intellectual property rights, third party rights and one's own right to act in the market, (referred to in English as freedom to operate) should be checked and ideally secured. This in order to avoid conflicts involving situations where the outcome/what is created in, or results from, the processes or collaborations in OI is infringing someone else's intellectual property rights.

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Can special approvals also be marketing authorisations? – when does the SPC clock actually start ticking?

It is not always clear, when applying for a Supplemental Protection Certificate (SPC), which authorisation is the relevant first authorisation. For veterinary medicinal products there are several possible routes to authorisation to market. The EFTA Court recently clarified community law as regards the first marketing authorisation according to the SPC regulation. This judgment may be important for future applications for SPC protection and in invalidity proceedings against SPCs.

Supplemental Protection Certificates, or SPCs, can provide a prolonged period of protection for medicinal products of up to five years following the expiration of a patent. The reason for granting this additional protection period is to compensate for the delay to the commercial exploitation of the invention, which is commonly caused by the clinical trials and processes required for establishing the medicinal product's safety and efficacy – in the end this is needed to obtain the mandatory marketing authorisations required to put the product on the market.

Similarly to patent rights, SPCs can be declared invalid by national courts if the application granted did not in fact meet the conditions required for granting an SPC. One argument used in such invalidity proceedings is that the SPC application was based on a marketing authorisation that *was not the first* authorisation to put the product on the market (with the consequence that the SPC protection period was prolonged unlawfully) and that the SPC in question must thus be declared invalid.

However, in the context of an SPC it is not always clear which authorisation should be considered the first marketing authorisation. For veterinary medicinal products, there are various authorisations and means of obtaining permission to put a product on the market. There are a number of authorisations or permissions besides the regular marketing authorisation – for example, for special or extraordinary situations where different requirements might apply.

Should all of these sometimes temporary or conditional authorisations be seen as the relevant first "SPC-qualifying" marketing authorisation? This is a pertinent question, both for rights holders and competitors, which up until recently has remained in the dark.

In early April this year the EFTA Court shed some light on the uncertainty in a judgment in its case No E-16/14 (Pharmaq AS vs. Intervet International BV). The proceedings in the referring national (Norwegian) court concerned a Norwegian SPC for a vaccine against viral pancreatic disease in salmonid fish. The claimant had previously lost a patent dispute against the SPC-holder, in which the court found

that the claimant's medicinal product (also a vaccine against pancreatic disease in fish) fell under the scope of the patent that was the basis for the SPC in question. After having lost the patent infringement case, the claimant sought a court declaration that the SPC was invalid, inter alia due to the SPC not having been based on the first marketing authorisation – the SPC-holder had been supplying its product under a "special approval exemption" and under an "exceptional authorisation" prior to the marketing authorisation referred to in the SPC. The claimant thus argued that the SPC marketing authorisation was not the first authorisation to place the product on the market.

In these national proceedings, the District Court of Oslo referred questions regarding the interpretation of the EC regulation No 1768/92 (the SPC regulation) to the EFTA Court. One of the central issues was which permissions or authorisations were to be considered as the relevant marketing authorisations under the SPC regulation.

The EFTA Court initially found that administrative authorisation procedures, as set out under Title III in directive 2001/82/EC, are the relevant marketing authorisation in relation to an SPC. Such administrative procedures include testing of the safety and efficacy of the medicinal product, the result of which must accompany the application for marketing authorisation – which is the reason for granting the additional protection period in the first place.

The EFTA Court then considered in particular two kinds of special authorisation forms and whether these constituted marketing authorisations as regards an SPC. These were 1) a special and conditional approval based on article 26(3) of directive 2001/82/EC granted under specific circumstances and where the approval is conditional upon specific procedures concerning inter alia safety and incident reporting, and 2) a special provisional permission based on article 8(1) of directive 2001/82/EC granted in the event of serious epizootic diseases.

As regards the first authorisation form – the special and conditional approval – the EFTA Court noted that such authorisations require specific procedures, particularly concerning the safety of the medicinal product, notification to authorities of any incidents and actions to be taken upon any incidents. The EFTA Court thus found that approvals according to article 26(3) of the directive constitute relevant marketing authorisations and can be considered "first" marketing authorisations in the context of SPCs.

In contrast, the EFTA Court noted that the second authorisation form – the permission to supply medicinal products under article 8(1) of directive 2001/82/EC – rather constitute an exemption to the authorisation scheme set out in that directive. Such a provisional permission, the EFTA Court noted, does not require safety and efficacy testing as for marketing authorisations and it does not entitle the producer to market the product, but only to supply it to the extent necessary to combat the disease in question. Therefore, the second form of special permission does not as such constitute a relevant marketing authorisation in the context of SPCs. Thus, only certain kinds of the permissions or authorisations available – which include testing for safety and efficacy according to Title III of directive 2001/82/EC – may form a basis for an SPC. Which of all available national permissions and authorisations should be considered as such marketing authorisations is, however, up to the national courts to decide, based on the merits in each case.

Consequently, according to the judgment of the EFTA Court, the "SPC clock" does not necessarily start ticking at the first permitted use on the market – but rather at the first authorisation which has been subject to safety and efficacy measures, in accordance with Title III of directive 2001/82/EC. Upon several different uses and authorisations for a product, it is thus just as important to choose the right marketing authorisation when applying for an SPC as it is to base your argument on the relevant authorisation in any invalidity proceedings.

Court decisions from the EFTA Court are of course not binding within the EU and it remains to be seen whether the judgment from the EFTA Court will be followed by the European Court of Justice. Nevertheless, the EFTA Court judgment provides relevant and useful arguments for any future SPC proceedings.

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Pharmaceutical products for animals, automated dose dispensing of pharmaceuticals and pricing of orphan medicinal products

The Pharmaceutical and Pharmacy Inquiry's remit was to review certain issues concerning pricing, availability and market conditions in the pharmaceuticals and pharmacies area. The Inquiry's final report, presented in December 2014, deals with the parts of the remit that concern trade in pharmaceutical products for animals, automated dose dispensing of pharmaceuticals and pricing of orphan medicinal products.

Remit

The Inquiry was instructed to:

- analyse and submit proposals on how to improve availability of pharmaceuticals for animals;
- analyse and submit proposals that could lead to favourable conditions for effective competition in the field of automated dose dispensing of pharmaceuticals; and
- if deemed necessary, propose a separate pricing model for orphan medicinal products.

Pharmaceuticals for animals

The Inquiry doses not present any major suggestions regarding pharmaceuticals for animals. It has analysed whether pharmacies that only sell pharmaceuticals for animals should be allowed. The Inquiry considers that the present obligation on the part of all retail pharmacies to provide all prescribed pharmaceuticals for animals should remain in place. As specialisation has proved possible within the framework of the current regulations for retail pharmacies, the Inquiry sees no reason to create any special regulatory framework for pharmacies that only sell pharmaceuticals for animals. Requirements on pharmacies' stock-keeping have been considered but are deemed to be difficult to implement. The Inquiry considers that the possibility should not be introduced for veterinary practices to acquire pharmaceuticals directly from wholesalers beyond the current rules concerning vaccines and serums. This kind of structure is deemed to risk resulting in a lack of sales for retail pharmacies. Further, the Inquiry has decided not to propose that certain non-prescription pharmaceuticals for animals be sold at places other than retail pharmacies.

The Inquiry's analysis indicates that compliance with the cascade principle in the prescription of pharmaceuticals is relatively good. However, it considers that the supervisory agencies need better data to be able to monitor prescriptions. The Swedish Board of Agriculture, the county administrative boards and individual veterinarians should be given access to information on individual veterinarians' prescriptions by the Swedish eHealth Agency. This is expected to contribute to better compliance with, and monitoring of, the cascade principle.

Automated dose dispensing

Automated dose dispensing means that pharmaceuticals are repacked into dose bags that are labelled with information about the patient and the pharmaceutical product contained in the bag.

Automated dose dispensing is procured by the county councils. The pharmaceuticals are paid for in the same way as regular outpatient pharmaceuticals. The county councils pay the dose providers for dose dispensing – known as the 'dose payment'. The substitution rules in the pharmaceutical reimbursement system also apply to automatedly dispensed pharmaceuticals, but they are difficult and expensive to apply. The Inquiry's conclusion is that the pharmaceutical reimbursement system should continue to apply to automatedly dispensed pharmaceuticals, but that the substitution regulations should be adapted to doses. The main proposal is that a player involved in automated dose dispensing may substitute

automatedly dispensed pharmaceuticals, but does not have to do so. A special pricing model should be applied, based on the lowest substance prices that the generic substitute would result in. Dose pharmacies should be allowed to negotiate the purchase price. If it is not considered possible to implement the Inquiry's main proposal, an alternative may be to draw up a separate list intended to be used for the substitution of automatedly dispensed pharmaceuticals.

The proposals for a new pricing model are expected to mean more savings for the public sector than at present. For the few dose dispensing players currently in the market, the proposals means that they would have the right to negotiate the purchase price for pharmaceuticals to be used for automated dose dispensing.

Orphan medicinal products

Orphan medicinal products are intended for patients with rare and serious illnesses and are defined as such under a special EU Regulation (141/2000/EC).

There are applications for inclusion in the Swedish reimbursement system for orphan medicinal products that have been approved by the Dental and Pharmaceutical Benefits Agency, but in some cases applications have been rejected because the cost was considered too high.

The Inquiry proposes that for certain pharmaceuticals that cannot be subsidised in the regular procedure, a possibility should be introduced to subsidise them under a special procedure. This would mean that the Dental and Pharmaceutical Benefits Agency, together with the county councils and the company concerned, would agree on more detailed terms for the subsidy decision.

For the Dental and Pharmaceutical Benefits Agency to take such an initiative, a pharmaceutical product must meet certain set criteria in terms of patient numbers, characteristics of the illness, long-term/lifelong treatment and lack of other relevant treatment.

Furthermore, the Agency's decision would be linked to special terms. These would be, for example, follow-up requirements of various kinds, time limits, repayment due to lack of effect, renegotiation times for pricing and volume limits. The number of pharmaceutical products affected by the proposal is estimated to be only two to three per year.

It is suggested that most of the proposals should enter into force on 1 July 2016. We will be following this closely.

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European transparency going live

The European Federation of Pharmaceutical Industries and Associations' (EFPIA) Code on the Disclosure of Transfers of Value from Pharmaceutical Companies to Healthcare Professionals and Healthcare Organisations (the Disclosure Code) has now gone live, and member companies in 33 countries within Europe have started to collect data for publication in 2016.

Self-regulation to meet public demand

The collaboration between the pharmaceutical industry and healthcare is constantly increasing and it is essential that the industry interacts regularly with healthcare professionals (HCPs) and Healthcare Organisations (HCOs) to improve patient care and treatment. Collaboration and partnerships between HCPs and HCOs and industry are subject to strict regulation and require all parties to respect high ethical standards.

In recent years there has been growing public interest in the pharmaceutical industry's relationships with HCPs and HCOs. The public want to ensure that such relationships do not influence clinical decisions and that HCPs can be trusted to recommend, administer or purchase appropriate care and treatments based solely on clinical evidence and experience.

In the US, the Sunshine Act was implemented in 2010 to bring transparency to financial relationships between physicians, teaching hospitals and the pharmaceutical industry. In Europe, the pharmaceutical industry implemented the voluntary Code to enhance transparency by enforcing the disclosure of payments to HCPs and HCOs and thereby meeting the demand from the public and creating greater trust.

The Disclosure Code

By 31 December 2013, each of the EFPIA's member associations should have implemented the Disclosure Code and transposed the provisions into its national code. The

Disclosure Code sets out the minimum standards that apply to all EFPIA member associations in all member states. Member associations have a right to deviate from the Disclosure Code where it conflicts with applicable national law or regulation. The provisions of national codes may therefore deviate from the Disclosure Code.

Member companies are bound by the relevant EFPIA member association's national code in each European country in which they operate (whether directly or through their relevant subsidiary). If the Disclosure Code has not been transposed into national code, member companies will be required to comply with the Disclosure Code when operating in such country.

From the beginning of 2015, EFPIA member companies have started to collect data on all transfers of value to HCPs and HCOs. The Disclosure Code imposes obligations to disclose transfers of value to HCPs and HCOs, commencing with reporting in 2016 on transfers of value for the calendar year 2015.

All EFPIA member companies are required to disclose payments and other transfers of value made to HCPs and HCOs in certain categories. The transactions disclosed may, for instance, consist of a consultancy fee for an HCP speaking engagement or a grant to an HCO.

Disclosures are made based on the national code of the country where the HCP or HCO receiving the payment or transfer of value has its principal practice, which applies regardless of whether the transfer of value occurs within or outside that country.

It is a condition of EFPIA membership that member associations adopt all EFPIA codes in full, and that member companies comply with the national codes (even in those countries where they are not a direct member of the relevant member association).

If a member company breaches the applicable code, the member association of the country where the HCP or HCO receiving the transfer of value has its principal practice will sanction the company in question, in accordance with local rules.

Data Privacy

Member companies must comply with applicable data protection and other laws, which may impose certain limitations on their ability to make disclosures on an individual basis. In each case and prior to any disclosure, data privacy requirements must be checked at national level (i.e. the jurisdiction of the HCP or HCO receiving the payment or transfer of value) by the member company. Companies are encouraged to obtain consent from HCPs and HCOs prior to disclosure.

A Data Protection Directive was adopted in 1995 to harmonise national provisions on protection of individuals in processing and free movement of personal data within the European Union. The directive was implemented in all EU countries. Each country currently has its own national data privacy requirements based on the directive. In 2012, the European Commission proposed a major reform of the EU legal framework on the protection of personal data. The new EU Data Protection Regulation, currently being drafted, will apply at a pan-European level. As the draft legislation stands, it would allow fines of up to EUR 100 million or 5 per cent of turnover, whichever is greater.

Considerations and work to be completed

Implementation is at different stages across Europe and the pharmaceutical industry faces challenges in ensuring consistency of information and integrating data at a corporate level. Meanwhile, HCPs are concerned about the impact on privacy and on the public perception of their profession.

Member companies have been putting a lot of time and effort into preparing for implementation. Information continues to be gathered, but there is still considerable work to be completed during 2015 in order for member companies and national associations to comply with the Disclosure Code and national codes. Among the most critical components will be addressing data privacy issues and obtaining consent from healthcare providers to disclose their information.

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Can the granting of applications for trademarks be predicted now?

When registering a trademark for a new product, or when preventing others from registering a trademark similar to yours, several different factors need to be considered. We have previously reported that OHIM has almost always been consistent with the ruling that if the mark has an identical beginning and end, the two marks are considered to be similar. Furthermore, OHIM has also been quite consistent with the opinion that the most important part of the trademark is constituted by the letters at the beginning of the mark, with the explanation that the consumer normally attaches more importance to the first part of trademarks. OHIM has therefore been quite consistent in finding a likelihood of confusion between marks with identical beginnings. But is this the only critical issue in determining the likelihood of confusion? In class 5, where pharmaceutical preparations are registered, this assumption does not always apply since many of the marks have some kind of conceptual meaning or start with a prefix deriving from the preparation's active substance. An overall assessment must therefore often be made.

In the case MENOCHRON vs. MENODRON (case T-473/11, 28 April 2014) it was found that the trademarks differed in length and rhythm of pronunciation but had an enhanced degree of visual similarity. Both trademarks were registered in classes 3 and 5 and the goods were found to be identical. As a result of this, the differences in pronunciation were reduced and the application was therefore refused. The identical beginning and end of the trademarks seems to have been critical to this outcome, together with the fact that the goods were identical.

However, the indication now that similarity at the beginning of a word is not crucial for determining the likelihood of confusion. In the case of GEPRAL vs. DELPRAL (case T-493/12, 24 September 2014) both trademarks were applied for prescription drugs in class 5. The court stated that the trademarks would be distributed in the same distribution channels but that the attentiveness of costumers in respect of medicines is high. However, they also stated that it was of decisive importance that the therapeutic indication of the products were different and the products were not in com-

petition or interchangeable with one another. The products were therefore considered similar but only to a low degree. Subsequently the court stated, in accordance with its previous practice, that the relevant public pays particular attention to the beginning of a word. However, in this case they found that "Ge" and "Del" were only slightly different visually, which dissimilarity the relevant public was not likely to spot. Although the goods only had a low degree of similarity, the visual and phonetic similarities could lead to the relevant public believing that the medicines came from activities that were economically linked. The application was therefore refused.

We believe that there is very little similarity between "Ge" and "Del" either visually or, more especially, phonetically. The identical ending therefore seems to have been critical to the outcome. This is even more vital to the decision as the court stated that there was only very low similarity between the products in question.

As we have stated before, it is not possible to predict whether or not the Board of Appeal or the General Court will find two trademarks similar. As it now seems as though there is an opening to not only finding a trademark in the life sciences sector similar if the beginning and end are identical, Setterwalls will continue to follow closely the outcomes of subsequent trademark applications with different beginnings but identical endings tried by OHIM.

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Have you amended your agreements containing licensing of technology rights?

The transitional period granted for technology transfer agreements ended on 30 April 2015. This means that all patent and licensing agreements, including supply and distribution agreements containing licensing of technology rights, have to comply with the new 2014 EU Tech Transfer block exemption instead of the old 2004 block exemption. There are new limitations introduced in the 2014 block exemption that have to be addressed with regard to existing agreements. If your agreements contain provisions regarding the points below, it is advisable to consult legal expertise.

Sales restrictions

It is no longer permitted to restrict a licensee's sales in an exclusive territory or for a customer group reserved for another licensee.

Restrictions of technology application

The licensee may no longer be obliged to produce with the licensed technology rights only within particular fields of use or markets.

Exclusive licenses within a territory

Obligations on the licensor not to license the technology to another licensee in a particular territory is no longer possible. Licensors and licensees should review their current stock of agreements containing licensing of technology rights in order to ensure that they comply with the above amendments to EU competition law. If you would like to know more, please contact us for assistance.

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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 statements from clients *"This is a great team, which is well equipped to assist pharmaceutical companies. The lawyers have the right attitude and the appropriate legal competencies. They fulfil all requests and requirements, and I am very happy with their support."* and *"These lawyers are excellent - they are always available when I need them, and present their knowledge in an understandable way, so we can make good decisions for our business."* Setterwalls' Life Sciences group is top ranked by Chambers Europe 2015

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.

Practise areas

Aviation
Commercial
Corporate
Dispute Resolution
Employment & Labour Law
Energy & Commodities
Environment
Equity Capital Markets
EU & Competition Law
Financial Markets
Infrastructure & Construction
Insolvency & Restructuring
Insurance & Reinsurance
Intellectual Property Rights & Marketing Law
Life Sciences
M&A
Private Client
Private Equity
Public Procurement
Public Sector
Railway
Real Estate
Real Estate M&A
Shipping
Sports & Entertainment
Tax
Technology, Media & Telecom
Transportation

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