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In this issue of *Life Sciences Report* you can read about the review of the system for funding, reimbursing and pricing of medicines as well as the new clinical trials regulation and the two new regulations for medical devices. We also provide you with an overview of the European Commission's nuanced approach in determining the market for pharmaceuticals in competition cases. Our guest contributor, Jan Heidebrandt, Manager, Compliance and Regulatory at Swedish Medtech, writes about the new regulations for medical devices. Enjoy your reading, and feel welcome to contact Setterwalls' Life Science group for more information.

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Guest contributor Mr. Jan Heidebrandt

New legislation for all medtech products finally ready!

Swedish Medtech is the trade association for all medical technology, or 'medtech', companies with operations in Sweden. Swedish Medtech's vision is for Sweden to be an attractive country for medtech companies, that with value based innovations increase patient safety and create a sustainable care and welfare.

Medtech encompasses a very wide range of technologies and products. Examples include different kinds of implants, wound dressings, pacemakers, medical software and all imaging equipment in hospitals.

Medtech products are often highly complex and their development often requires expertise from a number of fields. Medtech consequently has its own specific regulation detailing what is required to launch a product onto the market.

Until now, three EU directives have regulated what is required for the market launch of a medtech product. These are now being replaced by two EU regulations that have been negotiated over a number of years.

Friday 5 May saw the publication of the long-awaited MDR and IVDR regulations in the EU's Official Journal. IVD stands for in vitro diagnostic medtech products, and MDR, or Medical Device Regulation, covers the vast majority of all medtech products. These regulations will come into force on 25 May. There will then be a transitional period of 3 years for the MDR and 5 years for the IVDR.

This means that both the old medtech product directives and the new regulations will exist in parallel until May 2020 for medtech and until 2022 for IVD. In addition, some changes will be subject to even longer transitional periods, such as the introduction of Unique Device Identification (UDI), which involves the marking of products with a barcode or datamatrix. The introduction of these identification requirements first applies to products in higher risk categories.

In certain cases, parallel regulations will mean manufacturers can choose which rules apply when they release a product onto the market. The co-existence of two systems will place very high demands on both notified bodies and authorities.

In Sweden, the Swedish Medical Products Agency will establish the details regarding the application of the new regulations for the first six months following the introduction of the regulations. This is estimated to be completed by the end of November. Other authorities such as the Swedish Health and Social Care Inspectorate and the National Board of Health and Welfare will be affected by the new regulations.

Only then will we know all the details of the situation in Sweden. There may be important strategic considerations for companies regarding the timing of certificate renewal and choice of regulatory system.

There are also lots of technical systems to be finalised and groups to be appointed, as required under the new regu-

lations. This includes Eudamed, the EU medical device database, and the Medical Device Coordination Group (MDCG) needs to be appointed.

So there is extensive secondary legislation and regulation that now needs to be established both at EU and member state level.

Notified bodies also have to register and gain certification under the new regulations. It is generally assumed that not all of them will do this. There are already waiting periods for access to notified bodies and longer processing times than before. This situation will get worse.

The new regulations pose a number of potential challenges, such as changes in risk classifications for a number of product groups, including medical software. An entirely new risk classification is being introduced for IVD, along with requirements for the use of notified bodies.

The introduction of UDI will mean companies have to think about their product range in a different way.

The current directives also include requirements on clinical data and clinical assessment. Such requirements will increase and change to some extent.

The MDR makes it possible for individual countries to decide if they want to permit the reuse of single use products. It has been said, however, that Sweden will not allow the reuse of single use products.

It will be an interesting autumn as the situation becomes much clearer, after which the work of the Swedish Medical Products Agency on the application of the new regulations will be completed.

Jan Heidebrandt, Manager, Compliance and Regulatory at Swedish Medtech.

Review of the system for funding, reimbursing and pricing of medicines

In November 2016, the Swedish Government decided to appoint a commission of inquiry to conduct a thorough review of the present system of funding, subsidising and pricing of medicines. It is the first since the rules came into force 15 years ago. The inquiry chair is Toivo Heinsoo, former director of Stockholm County Council.

A two-part remit

The overall aim of the review is to bring about a long-term sustainable system that enables economically efficient use of medicines. This, in turn, is to contribute to modern and equal care.

In the Terms of Reference for the Inquiry (Dir 2016:95), the Government notes that the present system of funding, reimbursement and pricing is both complex and difficult to comprehend. There is a need, among other things, for a clearer distribution of responsibilities between central government and county councils, predictable processes and favourable conditions for research and innovation. Most people active in the area would probably agree that this is the case.

There are two parts to the remit. The issue to be investigated first is the distribution of responsibilities between central government and county councils with regard to the funding of medicines. An analysis is thereafter to be made and proposals are to be presented for the reimbursement and pricing of medicines, adapted to the proposed funding model.

Background

At present, a single medicinal product can be used in outpatient care where it is prescribed, but also be requested by hospitals. Medicines dispensed on prescription are priced by the Dental and Pharmaceutical Benefits Agency (TLV), while medicines used in hospitals are subject to a procurement process. The price for the same medicine differs in these cases. The present reimbursement and pricing system is based on a central government responsibility for funding medicines in the benefits scheme and the county councils being responsible for funding medicines used in inpatient care. As patients can now often administer advanced medicines themselves at home, the boundary between medicinal products used in outpatient and inpatient care has become blurred.

In addition, the pharmacy market has been re-regulated, medicinal products are being developed for small groups of patients and medicines are being omitted from the benefits scheme. The pricing system has been adjusted on several occasions to cope with the challenges and changes the system has faced over the past 15 years. TLV has initiated three party negotiations between the county councils, the pharmaceutical companies and the agency. These negotiations have led to a number of 'risk-sharing agreements' between the companies and the county councils. The process is, however, resource-intensive for both the county councils and the companies. It is has also been accused of inadequate transparency, predictability and legal certainty.

The remit

In relation to the *funding model*, the inquiry is to analyse, among other things:

– Whether the current system with a special government grant for medicines in the benefits scheme is appropriate, or whether it should be changed.

– Whether there is a continued need to divide medicines into outpatient medicines and inpatient medicines or some other form of division.

– Whether there may be a need for a change in distribution of responsibilities between central government and county councils in relation to the funding of new effective medicines.

– The need for equalisation of costs between the county councils with regard to medicines.

The remit also covers *consumables*. The proposals in this part of the remit are also to take account of the need for an adequate range of products to be ensured and for there to be scope for new and effective products.

In addition, proposals are to be made for a *reimbursement and pricing system*. The chair of the inquiry is to:

– Evaluate access to and actual prices of medicines in Sweden in relation to other comparable countries.

– Analyse what consequences the pharmacies' right to negotiate has on the reimbursement and pricing system and, if necessary, propose measures to deal with any adverse consequences.

– Analyse and, if appropriate, present proposals for some form of price control for all publicly funded medicines.

– Propose a reimbursement and pricing system that creates good and equal access to and use of effective medicines in Sweden, without resulting in increased costs in comparison with the present system.

Final report in December 2018?

Under the Terms of Reference, the chair of the inquiry is due to present an interim report containing an overall problem description and a description of the orientation of continued work by 1 November 2017. The final report is to be delivered by 1 December 2018.

The inquiry has been given a difficult remit. There are several stakeholders, and various aspects need to be considered. It is crucial that the inquiry proposals ensure that Swedish patients have early access to new medicines. The system must also provide an incentive for pharmaceutical companies to develop new treatments, i.e. for innovation. In addition, everyone stands to benefit from a stable and transparent system.

The remit is very important and extensive, and it is questionable whether the timetable can be met.

We will monitor this carefully.

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The New Clinical Trials Regulation

The way clinical trials are conducted in the EU will undergo a major change when the Clinical Trials Regulation comes into force in 2018. This Regulation harmonises the assessment and supervision processes for clinical trials throughout the EU, via an EU portal and database. The new process, simplified in several aspects, is intended to enable the initiation of clinical trials in different Member States simultaneously.

Background

A major decline in the number of clinical trials in several European Union (EU) Member States is expected to be reversed with the implementation of a new EU Regulation on clinical trials[1]. The purpose of the Regulation is to promote innovation by simplifying and speeding up the authorisation process as well as by increasing access to information about clinical trials and their results. A harmonised authorisation process is intended to ensure the rights, safety, dignity and well-being of the individuals who participate in a clinical trial, and to ensure that the data generated is reliable and robust.

Today, all clinical trials performed in the EU are governed by the Clinical Trials Directive[2]. The purpose of the Directive was to simplify and harmonise the administrative regulations on clinical trials in the EU. However, the regulations were only partially harmonised, since the Directive was implemented differently in different Member States through national legislation. The Directive has been criticised for impeding the development of clinical trials in the EU. The costs, the number of employees needed for application proceedings, and the length of the proceedings have all increased following the implementation of the Directive in national legislation.

The new Clinical Trials Regulation was adopted on 16 April 2014 and entered into force on 16 June 2014. Since then, it has been uncertain when it would become applicable; application being dependent on the completion of an EU web portal and database developed by the European Medicines Agency (EMA). However, the EMA has recently confirmed that it is currently on schedule to introduce the new EU portal in October 2018. When the Regulation becomes applicable, it will replace the Directive and national legislation that was put in place to implement the Directive.

The Regulation foresees a transitional period of three years from the date of application of the Regulation. From October 2018 to October 2019, applicants may submit their clinical trial applications either under the new Regulation using the EU portal and database, or under the Directive using the EudraCT database. From October 2019 to October 2021, only clinical trials authorised under the Directive will continue to be governed by that Directive. Any trials authorised under the Directive and still on-going in October 2021 will, from then on, be governed by the Regulation.

The new Clinical Trials Regulation

The new clinical trials legislation has taken the legal form of a Regulation. EU regulations are not incorporated into domestic law. Instead, they are binding and directly applicable in Sweden and other Member States, just like national legislation, which ensures that the rules are identi-

1. REGULATION (EU) No 536/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 16 April 2014 on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC

2. DIRECTIVE 2001/20/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use

cal throughout the EU. The Clinical Trials Regulation will therefore further harmonise the manner in which Member States authorise and supervise the conduct of clinical trials.

The purpose of the Regulation is to create an environment that is favourable for conducting clinical trials, with the highest standards of patient safety, for all EU Member States. The Regulation governs all investigation in relation to humans with the objective of ascertaining the safety or efficacy of medicinal products. Both commercial and non-commercial clinical trials are covered, including academic research. However, the Regulation does not apply to non-interventional studies, where patients are treated with pharmaceutical products in accordance with normal clinical practice.

EU web portal and database

The most important instrument that comes with the Regulation is an EU web portal and database to be used throughout the EU. All communication between the sponsor of the clinical trial and the concerned Member State will take place through the web portal. The database will serve as a source for information to the public, since all information entered into the portal will be stored there. The Regulation gives the EMA responsibility for setting up and maintaining the portal and database.

All information from clinical trials registered on the portal will, as a general rule, be public through the database. This includes the main features of the trial, e.g. the objectives, design, methodology, statistical considerations and organisation of the clinical trial, its title, the investigational medicinal product, the clinical trial population and number of subjects, and subject inclusion and exclusion criteria. Other public information includes the decision of the relevant authorities, substantial amendments, the end date of the trial, the summary of the results of the clinical trial, and, where the trial was used to obtain marketing authorisation, the clinical study report.

However, some information is excluded from publication. This includes personal data of subjects, commercially confidential information, confidential communication between Member States, and the supervision of the conduct of a clinical trial by Member States. Commercially confidential information is defined by the EMA as information whose publication might prejudice the commercial interests of individuals or companies to an unreasonable degree.

Application

The current system in Sweden requires separate applications to be submitted to the Regional Ethics Committee (Regionala etikprövningsnämnden) and the Medical Products Agency (Läkemedelsverket). For proceedings conducted under the Regulation's provisions, however, the application is submitted only once, and coordinated through the web portal. In contrast to the current procedure, the EU portal will also enable applicants who wish to conduct a multi-jurisdictional study in the EU to submit one single application dossier to the EU portal for trials in all Member States.

An application for authorisation to conduct a clinical trial can concern authorisation for a new trial as well as authorisation to extend an authorised clinical trial to another Member State or to make substantial amendments to an already authorised trial.

Assessment

The Member States in which the applicant wishes to conduct the clinical trial concerned coordinate their procedures regarding the application in accordance with the Regulation, after receiving the application dossier through the portal. Participation of ethical committees in the assessment is governed by the national legislation in the Member State concerned, and the ethical review is performed in accordance with the time frame of the Regulation. The Member States assess whether the application is valid and put together two different assessment reports.


Clinical Trials

The first report contains documentation which in a multi-jurisdictional study is the same for all Member States. One Member State is the reporting Member State responsible for the assessment and for drawing up the assessment report, taking into consideration any communication from other Member States concerned. The report includes the assessment of whether the study is a low-intervention clinical trial, the anticipated therapeutic and public health benefits of the trial, and the risks to the subject.

The second report is based on assessment of the clinical trial of each Member State for its own territory. This report includes, for example, assessment of compliance with requirements for informed consent, compensation and recruitment of subjects.

Decision

When each Member State concerned has made a decision on the clinical trial based on the assessment reports, the decision is communicated in a single decision for each Member State through the EU portal. The decision can be either that the clinical trial is authorised, that it is authorised subject to conditions, or that authorisation is refused.

All steps in the application process are governed by time limits. This means that a clinical trial could, at least in theory, commence in all 28 Member States at the same time, no later than 90 days after the application was submitted and approved.

Special provisions

The Regulation includes simplified rules for trials where the medicinal products have marketing authorisation and are either used in accordance with the terms of such authorisation or their use is evidence-based and supported by published scientific evidence.

The Regulation also sets forth conditions that need to be met in order to protect subjects and provisions on informed consent to participate in the clinical trial. Special provisions concern clinical trials on minors, incapacitated subjects, pregnant or breastfeeding women, and clinical trials in emergency situations.

Furthermore, the Regulation includes provisions on the conduct of a clinical trial and how safety reports concerning serious adverse events and reactions should be submitted.

There are provisions on the manufacture, import and labelling of investigational medicinal products and auxiliary medicinal products. The sponsor's and investigator's obligations are regulated, and it is stated that the Member States must make sure there are systems for compensation in place for any injury suffered by a subject.

What's to come

Several Swedish legislative instruments and other regulations that describe the work of the Medical Products Agency and the Regional Ethics Committee need to be adapted to the new Regulation. The Swedish Government has submitted a proposal[3] for the changes needed, including amendments to the Medical Products Act[4] and the Public Access to Information and Secrecy Act[5]. The changes have not yet been decided, however. We will monitor developments closely.

For companies interested in sponsoring clinical trials, the EMA has announced that sponsors of trials of medicinal products may participate in training in how to use the EU portal and EU database. Training sessions will be made available by the EMA during the second half of 2017 for the version of the system that has been built at that point. Further training will be made gradually available as additional functionalities are developed and added to the EU portal and the EU database. We encourage sponsors to take the opportunity to try out the EU portal and database, in order to be prepared for the extensive changes which it is anticipated will become applicable as from next year.

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3. Ds 2016:11
4. Läkemedelslag (2015:315)
5. Offentlighets- och sekretesslag (2009:400)

Two new regulations for medical devices

Two new regulations for medical devices enter into force in 2017. The purpose of the new regulations is to promote cross-border trade and innovation and to strengthen patient safety. The first regulation concerns medical devices which is to replace Directive 90/385/EEC on active implantable medical devices and Directive 93/42/EEC on medical devices. The second regulation is concerning in vitro diagnostic medical devices.

The new regulations are directly applicable in all the Member States and are expected to enter into force during the second quarter of 2017. The new rules for medical devices will not need to be applied until three years later. The rules for *in vitro* diagnostic medical devices will not need to be applied until 5 years after the regulation has entered into force. As a result, current Swedish rules will be re-written, and in many cases repealed and replaced by the new rules.

However, for those of you who are affected by the new rules it is a good idea to start taking account of the changes now so that the implementation process is not as noticeable in your organisation. A broad summary of the new rules follows below.

Scope

Under the rules contained in the regulations, requirements will be set not just for manufacturers of the medical devices concerned but also, for example, for distributors, importers and authorised representatives. All medical device companies may be affected, but it is in vitro diagnostics (IVD) companies in particular that will need to adapt, partly because significantly more of these companies will need to make use of a notified body. The changes will also mean that some new products are covered by the regulatory framework, for example syringes prefilled with human collagen, dermal fillers and coloured contact lenses for cosmetic purposes.

Increased requirements and increased review

Implementation of the new rules will lead to increased review of medium- and high-risk devices. Among other things, the changes will mean that responsibility for evaluation falls on the Member States and the European Commission. The changes will also mean increased requirements for quality management and market follow-up. In addition to this, the requirements also increase for clinical data for the CE-marking of medical devices and for clinical follow-up after the device has been placed on the market.

The changes also result in further requirements to be met by distributors, as they have to check, for instance, that the device bears the CE-marking, that the declaration of conformity has been prepared, that the manufacturer's information has accompanied the device and that the importer fulfils specified requirements. In addition, there are requirements for larger companies that manufacture medical devices to have a person with regulatory expertise within the organisation.

A coordination group for medical devices will be set up for the purpose of improving coordination between the national supervisory authorities. This is to ensure that only safe devices circulate on the EU-market.

Notified bodies

Notified bodies are to issue certificates for medium- and high-risk products before they are introduced on the market and check safety and performance when they have been placed on the market. In addition, notified bodies can make unannounced inspections and carry out physical checks or laboratory tests on devices.

The four risk classes for medical devices are still to apply, but the risk classification is to be adapted to technical development and experience from vigilance and market surveillance. For class I devices the manufacturers have to take responsibility themselves for the assessment of compliance. If the class I devices have a measuring function or are sold in sterile conditions, however, a notified body must inspect the device. With regard to devices in classes IIa, IIb and III, a notified body has to take part in inspection to a suitable extent in relation to the risk class. Devices in class III must be approved by the notified body before being placed on the market.

Traceability

The traceability of medical devices is to be improved. Among other things, a system for unique device identification (UDI) is to be introduced. UDIs are to be stored by the healthcare system and used for example in the event of accidents to identify manufacturers. Manufacturers and importers are therefore to provide their devices with a unique device identification, register themselves in a central EU database and be able to specify who has supplied a device and to whom they have supplied a device. However, it will not be up to the Member States themselves to assess whether distributors are to be registered.

Importer is understood to mean the operator who imports the products into the EU-market, and not the operator who imports articles within the EU. To enable importers to be contacted, importers have to state their name, registered office and address on the device or packaging or other accompanying documents.

In addition, manufacturers of implants have to provide the patient with information regarding device name, serial number, UDI, name and address of the manufacturer, warnings, precautions, expected product life and other information needed to enable the device to be used safely.

Reconditioning of certain disposable products

The proposal makes it possible for certain disposable products to be reconditioned. However, it is up to the Member States themselves to decide whether to permit such reconditioning. In the event that reconditioning is permitted, this is regarded as manufacturing of new devices, and the reconditioner therefore has the same obligations as a manufacturer.

Expansion of the European Database on Medical Devices, EUDAMED

The European Database on Medical Devices, EUDAMED, for medical devices is to be expanded to provide access to information, among other things, on use of medical devices available in the EU. Economic operators, notified bodies and sponsors will also gain access to the information they are considered to need to fulfil their obligations. The general public are also to have access to adequate information about devices and operators through this database, which is to contribute to greater transparency and safety.

We are, of course, here to answer any questions you might have.

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The Swedish Supreme Court takes a stance in the calculation of damages for a wrongful preliminary injunction

While the use of a preliminary injunction (PI) can be an invaluable tool for an intellectual property rights (IPR) holder to maintain its position on a market by preventing other actors from infringing the IPR during the infringement proceedings, the PI can also cause significant harm to the alleged infringer. PIs are granted early in the proceedings, based on a preliminary assessment of the facts and arguments. The full proceedings may often be concluded several years later and, on closer scrutiny, it will sometimes be the case that the PI should not have been granted, for example because the underlying IPR was invalid or because there was never any infringement. To strike a balance between the interests of the alleged infringer and the IPR holder, the IPRED Directive requires EU member states to ensure that the alleged infringer is compensated for any injury caused by a wrongful PI.

Claims for such compensation rarely reach the courts, as they are normally settled between the parties. Recently, however, the Swedish Supreme Court had the opportunity to shed light on several issues related to a claim for compensation for damages caused by a wrongful PI.

Background to the case

The parties to the dispute before the Supreme Court were referred to as Hela Pharma and Cederroth. In 2006, Hela Pharma was the sole supplier of a nutrition supplement in liquid form under the trademark "Mivitotal". Early 2006, Cederroth launched a similar product under the trade mark "Multi total". Hela Pharma sued Cederroth for trademark infringement. On 1 March 2006, the district court granted a PI, whereby Cederroth was prohibited from using the trade mark "Multi total" for nutritional supplements. The PI was in force for almost 4 years, until 26 February 2010, when the court of appeal held that "Multi total" did not in fact infringe the trademark "Mivitotal". Hence, the court of appeal lifted the PI.

Subsequently, Cederroth initiated an action for damages against Hela Pharma and claimed compensation in the amount of approx. SEK 26 million for lost profits incurred over the period 1 March 2006 to 31 December 2010 as a result of the PI.

Grounds for liability

The Supreme Court confirmed that the IPR holder is strictly liable for any damage caused by a wrongful PI and noted that the general principles set out in the Tort Liability Act are applicable when deciding upon the damages due to a wrongful PI. This means, among other things, that there is an obligation for the damaged party to limit its damage and that only actual damage (e.g. loss of profit, not loss of income) can be compensated.

When calculating the actual damages, the Supreme Court held that the so-called "difference principle" is applicable. This means that the court has to compare the hypothetical case in which no PI was imposed with the actual scenario in which a PI was imposed. Naturally, it is difficult for a damaged party to prove the hypothetical scenario. To mitigate this problem, the court may assess reasonable damages. However, the Supreme Court stressed that this does not relieve the damaged party of its obligation to present a calculation of the actual damages based on the facts and evidence reasonably available to the damaged party.

Calculating the reasonable damage

The Supreme Court concluded that an assessment of reasonable damages requires an overall assessment of

several aspects. In its assessment, the court considered the following aspects:

- whether Cederroth had discharged its obligation to limit its damages,

- the relevant time period for the calculation of lost profits due to the PI,

- Cederroth's contribution margin in the hypothetical scenario and how this margin would have developed over the relevant time period,

- Cederroth's sales volumes in the hypothetical scenario.

Hela Pharma argued that the Cederroth had an obligation to limit its damage by relaunching its product under a different trademark, alternatively under a generic trade name. The Supreme Court disagreed. The object of the PI is the trade mark as such, not the product that is sold under the trademark. Therefore, in the normal scenario, the damaged party has no obligation to limit its damages by relaunching the product and the potential revenues from such hypothetical sales are not to be considered in the assessment of the damages. This does not mean, however, that the damaged party can remain passive when faced with a PI. The Supreme Court stated, somewhat surprisingly, that it might be reasonable to require the damaged party to limit its damage by using the legal remedies available in order to have the PI revoked.

As regards the relevant time period for the calculation of lost profits, the Supreme Court held that Hela Pharma, as a starting point, was responsible for damages arising from the day of the PI decision until the day when the Court of Appeal lifted the PI (i.e. almost 48 months).

The Supreme Court disagreed with Cederroth that the relevant time period should be extended until the Court of Appeal's decision to lift the PI could no longer be appealed. Moreover, Cederroth argued that the relevant time period should be extended to compensate Cederroth for loss of profits during the time period from the cancellation of the PI until Cederroth had been able to relaunch its product. The Supreme Court agreed in principle, but reduced the additional time from 10 to 6 months, making the total time period approx. 54 months.

In addition to compensation for lost sales in Sweden, Cederroth also claimed compensation for lost sales in Denmark, Finland and Norway. Even though the PI was not enforceable outside Sweden, Cederroth argued that its sales strategy meant that the PI in Sweden negatively impacted its sales in the other Nordic countries. The Supreme Court disagreed and noted that lost sales outside Sweden are an unforeseeable implication of a PI, which may only be compensated in exceptional circumstances (e.g. if seeking a PI in Sweden is a conscious effort by the IPR holder to stop sales in other countries as well).

To support its claims regarding market growth during the relevant time period, Cederroth had requested the district court to order Hela Pharma to produce its sales figures. The court rejected the application and stated that it was up to Hela Pharma to consider the possible consequences of not voluntarily providing its sales figures. Despite the warning from the court, Hela Pharma refused to produce the data. Consequently, the Supreme Court made a reasonable assessment based on the estimates provided by Cederroth. Hela Pharma's refusal to cooperate thus had a direct effect on the Supreme Court's assessment of Cederroth's calculations.

It should be noted that the Supreme Court did not fully accept the calculations made by Cederroth in other respects. For example, Cederroth had not deducted costs that it would have incurred in the hypothetical scenario, such as marketing costs and costs related to selling the products.

The Supreme Court also rejected a large part of the compensation claim. Cederroth had not provided sufficient evidence regarding the effects of the de-regulation of the Swedish pharmacy market, which occurred during the relevant time period. As a result, the Supreme Court held that it was not possible to make a reasonable assessment of lost profits in this market segment and rejected this entire portion of the claim.

Concluding remarks

The Supreme Court's judgement sets a framework for the calculation of damages caused by wrongful PIs, and it will serve as a guide for future settlement discussions in all IPR fields. Parties subjected to wrongful PIs may have regard to the fact that the Supreme Court has confirmed that the IPR holder's liability is strict and that the obligation to limit one's damage does not extend to an obligation to relaunch a non-infringing product. IPR holders, on the other hand, may have regard to the fact that the Supreme Court appears to set the bar fairly high for allowing reasonable assessments of the level of the damages.

As a final remark, it is worth noting that the Danish Maritime and Commercial High Court recently awarded a generic pharmaceutical company DKK 100 million in compensation for being wrongfully kept out of the Danish market for generic quetiapine. While the reasons given for the judgment are brief and not very helpful, the parties' arguments shed light on many of the complex issues that arise in situations where the PI is based on a pharmaceutical patent and where the hypothetical scenario involves competition between the originator, a number of different generic manufacturers and parallel importers.

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New regulation on novel food – what will we be eating in ten years?

Will EU citizens eat more future food with the introduction of the new Regulation[1] on novel food? The aim is to offer us a broader choice of food and make it easier for businesses to bring new food to the EU market while maintaining a high level of food safety.

Novel food is defined as any food that was not used for human consumption to a significant degree within the EU before 15 May 1997 (when the first Regulation was adopted). Novel food can be newly developed, innovative food or food produced using new technologies and production processes as well as food traditionally eaten outside the EU. Some examples of authorised novel foods are UV-treated yeast, dairy products with added phytosterols (which help in reducing cholesterol), less sticky gum (which reduce stains on streets and blocked public drains), coriander seed oil and noni juice (an exotic fruit juice). There has been some legal uncertainty concerning insects and whether they are subject to the regulatory framework of novel food. However, insects are explicitly covered by the new Regulation.

The new Regulation replaces the 1997 Regulation and will become fully applicable from 1 January 2018. The most important changes are centralisation of the approval procedure, a simplified approval route for traditional food from third countries, a Union list of approved novel foods and the possibility of data protection for a period of five years.

The approval process for novel food is expensive, complicated and time-consuming, because the application is first made to a single EU member state and then, if accepted, circulated to all the EU member states for possible comment. These procedures impose heavy burdens on manufacturers, and the application process usually takes three years, or up to ten years in extreme cases.[2] In addition, each application is limited to a specific company and food. In contrast, granted authorisations according to the new Regulation will be valid in all EU member states. This procedure will avoid repeated applications by different companies based on the same type of novel food. Furthermore, there is an intention to reduce the current average length of the application process. Under the new Regulation, all applications will be reviewed and granted by the European Commission, hopefully enabling a simplified and faster authorisation process.

In addition, food defined as novel food in the EU, while considered traditional food in a third country, will be easier to trade from that third country. This is possible if there is a history of safe use of that food in the third country and the food has been considered as customary food by a substantial part of the population for at least 25 years.

This facilitated pathway for traditional food in third countries could cover insects, which are widely consumed around the world as a regular part of people's diet. The use of insects has been considered to bring important benefits

1. REGULATION (EU) 2015/2283 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 25 November 2015 on novel foods, amending Regulation (EU) No 1169/2011 of the European Parliament and of the Council and repealing Regulation (EC) No 258/97 of the European Parliament and of the Council and Commission Regulation (EC) No 1852/2001.
2. Szajkowska, Anna, Regulating food law – risk analysis and the precautionary principle as general principles of EU food law, Wageningen Academic Publishers, 2012, s. 73.

from an environmental, economic and food security perspective. However, uncertainties related to possible hazards have been identified, and such safety concerns could still delay the facilitated procedure for insects.

As mentioned above, granted authorisations according to the new Regulation will be generic. If subsequent applicants (other manufacturers) want to market the approved novel food, they only need to follow the same conditions that are outlined in the generic application. However, since this may negatively affect incentives for companies to continue their investments in research and development for novel food, the Regulation contains a possibility of data protection. Applications containing newly developed scientific evidence and proprietary data will be protected for at least five years after the novel food has been granted authorisation. After the end of this period, the protected data can be used for the benefit of subsequent applications.

It can be difficult for a manufacturer to assess whether the food is to be defined as novel food or not. One novelty in the regulation that may guide the manufacturer is the new Union list. This list contains all authorised novel food and is legally binding. If a product is considered as novel food and cannot be found on the list, some form of novel food authorisation is required. Another more stringent obligation under the new Regulation is that some granted authorisations may be subject to post-marketing monitoring. Time will tell if the new Regulation on novel food will change our eating habits in the EU. However, certain measures in the new Regulation will hopefully lead to a broader choice for consumers and an authorisation procedure with greater efficiency and reduced administration. Certain provisions, such as the facilitated pathway for traditional foods from third countries, will probably need further legal clarification in years to come.

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New rules regarding labelling of alcoholic beverages may be on the way

As background, a declaration of ingredients on pre-packed food products is something consumers nowadays take for granted. In addition to the declaration of ingredients, as of 13 December 2016, food producers are obliged to provide a declaration of nutritional value.

Sweden is known for its fairly rigid regulations regarding the sale of alcohol. However, the rules regarding labelling are in many ways not as strict when it comes to alcoholic beverages as they are for food products. There is nevertheless an obligation in Sweden to inform consumers of allergenic ingredients in alcoholic beverages and the percentage of alcohol by volume. However, neither a declaration of ingredients nor a declaration of nutritional value is currently required on alcoholic beverages.

For wine, beer and spirit-producing companies and wholesalers, it might be of interest that the European Parliament now has demanded new rules for the labelling of alcoholic beverages. In particular, the Parliament would like there to be regulations regarding declarations of energy value (calorie content) of alcoholic beverages. The EU is thus now tentatively adding to the rigorous Swedish alcohol-related regime.

Previously, producers of alcoholic beverages have opposed suggestions on declarations of ingredients. However, the industry is now generally more willing to inform consumers what they are really drinking. Further, many producers have started voluntarily informing consumers of the ingredients of their alcoholic beverages. This naturally follows the general trend towards consumers taking greater interest in health- and nutrition-related issues.

The European Commission has now decided to give the industry one year to present proposals for self-regulation regarding information to consumers that would be applicable to the whole alcoholic beverages sector. The Commission is for now open to the information being provided in many different ways, such as labelling on the beverage or information on the company website.

If the Commission does not find the industry's proposals for self-regulation satisfactory, it will then look at other options, typically legislation.

The Life Science Report will, of course, follow the development of labelling requirements for alcoholic beverages.

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The European Commission's nuanced approach in determining the market for pharmaceuticals in competition cases

The pharmaceutical sector is a dynamic industry experiencing rapid development and growth. Corporate transactions such as mergers, acquisitions and joint ventures are common. The European Commission (EC) and European competition authorities examine transactions that exceed certain turnover thresholds.[1] If the parties to such transactions have large market shares in a specific market, the transaction, or part of the transaction, is liable to significantly impede the existence or development of effective competition and may thus be declared not to be compatible with competition legislation.

The first step in the competitive assessment is to define the relevant geographic and product market for the products included in the transaction. The relevant geographic market for pharmaceuticals is, by default, national in scope, due to the different national regulatory frameworks as regards price and reimbursement.

In the pharmaceutical sector, the general approach to product market definition has been based on the Anatomical Therapeutic Chemical Classification System of WHO (commonly known as ATC). The ATC classification divides pharmaceuticals into different categories depending on factors such as anatomical sites of action, therapeutic use and chemical properties. The first level (ATC1) is the least detailed, and each category at this level is decided by the pharmaceutical's target organ. The fourth level (ATC4) is the most detailed and divides products into different groups based on their molecules. Traditionally, the EC ha usually maintained an "ATC3 approach" in merger filing assessments. This means that the relevant market is defin according to the product's therapeutic indications, i.e. the drug action that will deal with the disease in question. In some cases the EC also carries out analyses at other ATC levels, or mixtures thereof, if the circumstances of a case show that the ATC3 class does not lead to a correct mark definition. For example, when it comes to generic drug company mergers, ATC4 has often been used as a startin point for the EC's analysis.

Recent case law indicates that the EC is moving away fro this ATC approach in favour of a more nuanced approacl in its competitive assessment. We are not just thinking about treating prescription medicines and OTC medicine as two separate markets or dividing the market on the ba of different galenic forms (i.e. dosage, pharmaceutical for and route of administration). In some cases, such as the *Sanofi-Aventis/Genzyme* case, the EC has even stressed th the ATC3 and ATC4 categories were not relevant for mai definition of some products owing to the clear difference in indications between certain products classified in these categories.

The EC is also defining the market to an ever greater extent by reference to therapeutic use, while increasingly looking at pipeline products, i.e. products under development that are not yet on the market. In a merger between two companies with pipeline products, the EC will also consider whether the pipeline products may have an impact on competition. In the *Sanofi-Aventis/Genzyme* case the EC considered, as part of its full competitive analysis, that both parties involved had pipeline products in Phase III of clinical trials (the final stage of development before the company can apply for

1. A transaction must be notified to the Swedish Competition Authority if the parties' combined aggregate turnover in Sweden in the preceding financial year exceeds SEK 1 billion, and two parties have turnover in Sweden in the preceding financial year exceeding SEK 200 million each. If the parties' combined aggregate worldwide turnover in the preceding financial year exceeds EUR 2.5 billion, the parties must verify whether the transaction has to be notified to the EC instead.

market authorization) which it took into consideration in its competition assessment. In another pharma merger case, the *Novartis/GSK Oncology* case, the EC went further and considered information concerning Phase I and Phase II clinical projects. The EC adopted a protective position for innovation and considered that the merger would impede trials that were at an earlier stage, noting that it was likely that Novartis would abandon its broad clinical programme for certain types of cancer if the merger was completed. In the *Novartis/GlaxoSmithKline Oncology* case, the EC also raised the point that national registration and national reimbursement rules for oncology drugs, which strongly influence prescribing behaviour, may have to be taken into consideration when deciding whether a distinction should be made according to lines of treatment, and the EC considered the possibility of defining the market based on the type and stage of cancer.

The EC has also considered the biopharmaceutical market in several merger cases. In some cases, biopharmaceuticals and small molecules/chemical substances have been considered as different markets. In addition, biosimilars (a kind of generic version of a biopharmaceutical, although not an exact copy of the originator product) have been considered

a separate product market from the originator drug due, for example, to the fact that the development of a biosimilar takes six to eight years from development to marketing, and involves higher investments than generics. However, in the *Pfizer/Hospira* case, the EC noted that biological drugs are some of the most expensive therapies available. Therefore, introduction of biosimilars to the market is expected to allow wider access by patients to biological drugs. Taking into account that earlier biosimilars have led to price decreases compared to the originators' biological drugs, expectations are that biosimilars will relieve financial pressure on healthcare systems. In this case, the EC found that the originator biological product and the biosimilar be-longed to the same relevant product market.

It may be worth noting that the EC does not adhere to a *mechanical* ATC3 approach but instead uses different approaches to identify relevant product markets. The competition analysis has become more complex as the EC has attached greater importance to the specific features of the pharmaceutical industry, for example different regulatory frameworks and innovation. The EC has, in several cases, protected innovation and considered it to be of significant importance for the pharmaceutical sector. This approach is noticeable when the assessment considers potential competition from pipeline products (these products generally have a 50 percent trial success rate in Phase III and an even lower success rate in Phase I and Phase II). In view of this approach, it cannot be ruled out that a greater number of companies will have their products found to be on a different market than the market determined on the basis of ATC3. The pharmaceutical companies must thus carry out a more complex competition analysis as regards their product portfolios before taking steps towards a transaction.

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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 approx. 200 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 foods. Our clients also include companies within the innovative and speciality pharma industry.

Setterwalls' is frequently involved in IP litigation and related matters, competition law and public tenders, regulatory issues, commercial legal work and transactions, many of which matters are related to the Life Science area.

"Setterwalls is known as a highly reputed firm with excellent capabilities in contenious matters, particularly relating to IP and patent disputes. Also handles transactional and regulatory issues on a national and cross-border level. Client base includes major international players in the pharmaceutical and biotech sector. Recent activity includes assisting with a number of cases involving new technology and data protection" Chambers Europe 2016

With statements from clients "The team was professional and structured in its approach, and always tried to understand what would do the trick for the business and the issue at hand." Setterwalls' Life Sciences group is top ranked by Chambers Europe 2016.

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 bringing together the experience and expertise from all offices and has in-depth knowledge of the sector.

Practise areas

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

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