SETTERWALLS

Life Sciences

REPORT

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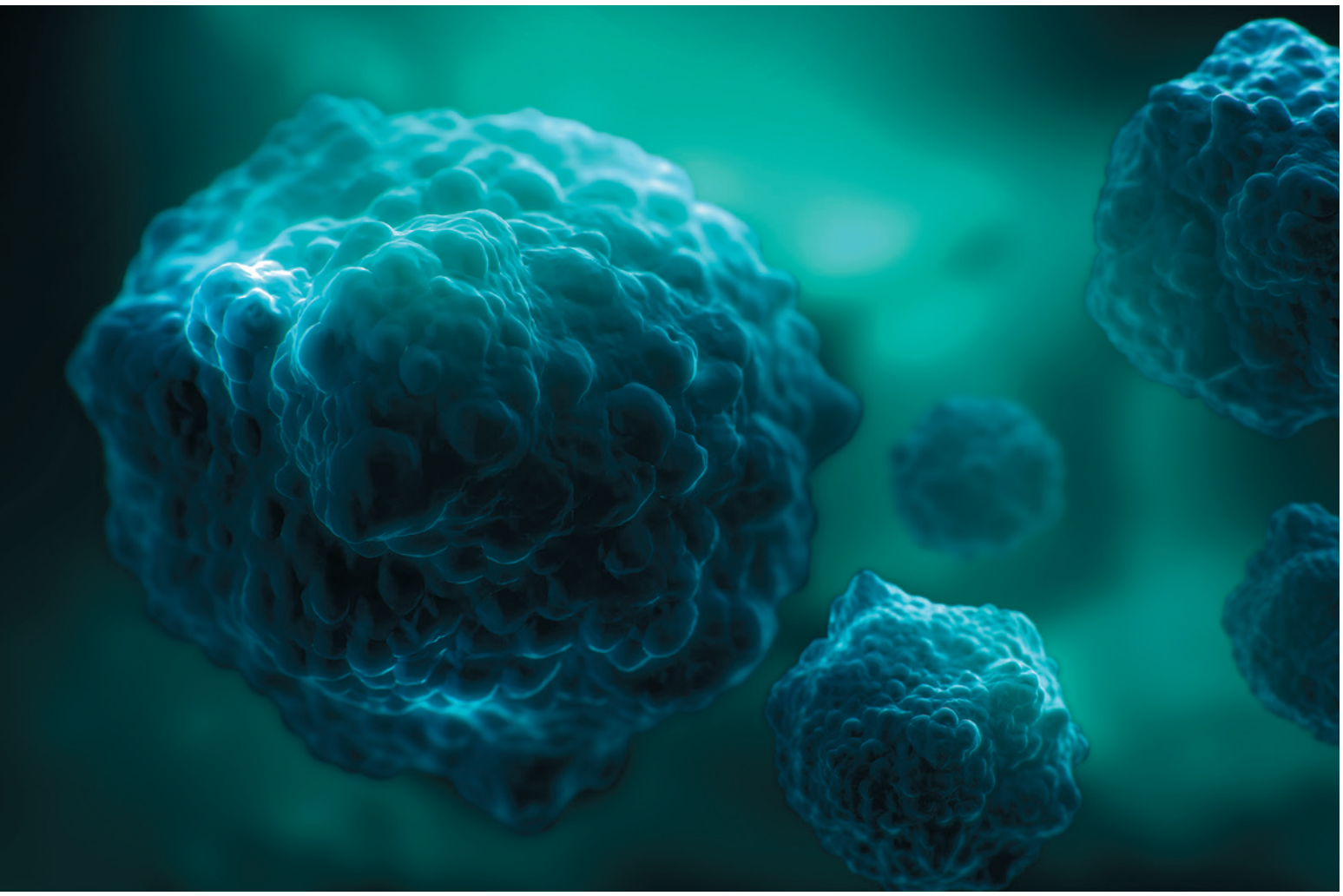

Coveted action plan for the Life Science Industry

Sweden's life science industry is currently under pressure. In their recent election pledges, the country's politicians referred to investments in this industry. However, although the new government stated in the 2015 finance bill that it wants to support life science research, it has not yet presented any concrete proposals on how it intends to do this. The industry's trade associations, however, have now put forward a coherent action plan.

There have recently been several large investments in the Swedish life science industry and these are expected to produce results in the long term. Industry representatives have identified the need for a coherent plan that enhances competitiveness through improved structures and smarter use of existing resources. It was therefore very disappointing that Sweden's new government has not addressed the issues in the finance bill.

In late October, the trade associations LIF, Swedish MedTech and Sweden BIO consequently presented a coherent action plan for the life science industry, with the aim of strengthening Sweden's competitiveness in this field.

Their proposals are divided into seven areas. The trade associations emphasise the importance of grants for research, as well as the mobility of researchers between academia, healthcare and industry. However, they also propose measures to create business growth, use innovative new treatments in healthcare and to attract industry to and retain it in Sweden, as well as coordinating and promoting Swedish life science.

With the trade associations' action plan as guidance, it is hoped that the government will soon present a coherent strategy for the industry, addressing the areas that are key to strengthening Sweden's competitiveness in this field. Setterwalls will, of course, monitor this issue closely.

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CJEU: A product must have a beneficial effect to be a medical product

In a judgment of 10 July 2014 (joined cases C-358/13 and C-181/14), the Court of Justice of the European Union (CJEU) concluded that, according to EU law, mixtures of herbs containing synthetic cannabinoids cannot be regarded as medicinal products under the definition given in Article 1 (2) b of Directive 2001/83. The term medicinal product should be interpreted as excluding substances whose effects only involve a modification of physiological functions and do not entail immediate or long-term benefits to human health.

Background to the case

The merits of the case at the CJEU were as follows. Two men in Germany marketed synthetic cannabinoids designed to induce a state of intoxication in humans. The two men subsequently became the subject of criminal proceedings so that the authorities could put a stop to their marketing activities. However, at the time it was not possible to impose criminal sanctions for marketing these new psychoactive substances as they were not yet defined as narcotics according to German law. The men were therefore charged under medical products legislation for selling unsafe medical products. However, the national court was unsure how to interpret Article 1 (2) (b) of Directive 2001/83 and referred the question to the CJEU.

Definition of a medical product

Article 1 (2) (b) of Directive 2001/83 states that a product is a medical product under the Directive if it is a substance or combination of substances that may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis. One of the questions for the court was therefore how to interpret the word "modify".

The judgment of the Court of Justice

From settled case law it is clear that not only the wording of the provisions should be considered, but also the context in which it occurs. From the context it was clear that the Directive aims to attain a high level of human health protection. The word "modify" should therefore, according to the court, be interpreted as not covering substances whose effects merely modify physiological functions and do not entail immediate or long-term benefits to human health.

It was concluded that the products in question in the case before the court were purely for recreational purposes and harmful to human health. The court stated that Article 1 (2) (b) of Directive 2001/83 should be interpreted as excluding substances which produce effects that merely modify physiological functions but do not have any beneficial effects on human health, are consumed solely to induce a state of in-toxication and are harmful to human health. The products in question were therefore not deemed to be medical products under the Directive.

The impact of the judgment

In this case, the products concerned fell outside criminal law sanctions. The actions of the German authorities are understandable, applying legislation to medicinal products in order to more effectively control and punish the marketing of these new psychoactive substances. However, a satisfactory outcome will not be achieved by applying the rules on medicinal products.

Advocate General Bot of the CJEU was clear in his opinion that the definition of a medical product is not to be used in this respect and stated that "only repressive measures based on the control of narcotic drugs will enable, through the objectives of public safety, public policy and public health pursued by such measures, a response to be given with the requisite speed to the appearance on the market of sub-stances whose effects are similar to those of narcotic drugs on account of, inter alia, their derived chemical composition and acute toxicity."

This case therefore clarifies that the rules governing medicines are not the appropriate tools to protect public health from the dangers posed to the general population by drugs such as synthetic cannabinoids. The legal system must find another approach to help control such products.

It is also clear that the term medicinal product in Article 1(2) b of Directive 2001/83 must be interpreted as not covering substances whose effects consist in a mere modification of physiological functions and which are not such as to entail immediate or long-term beneficial effects for human health.

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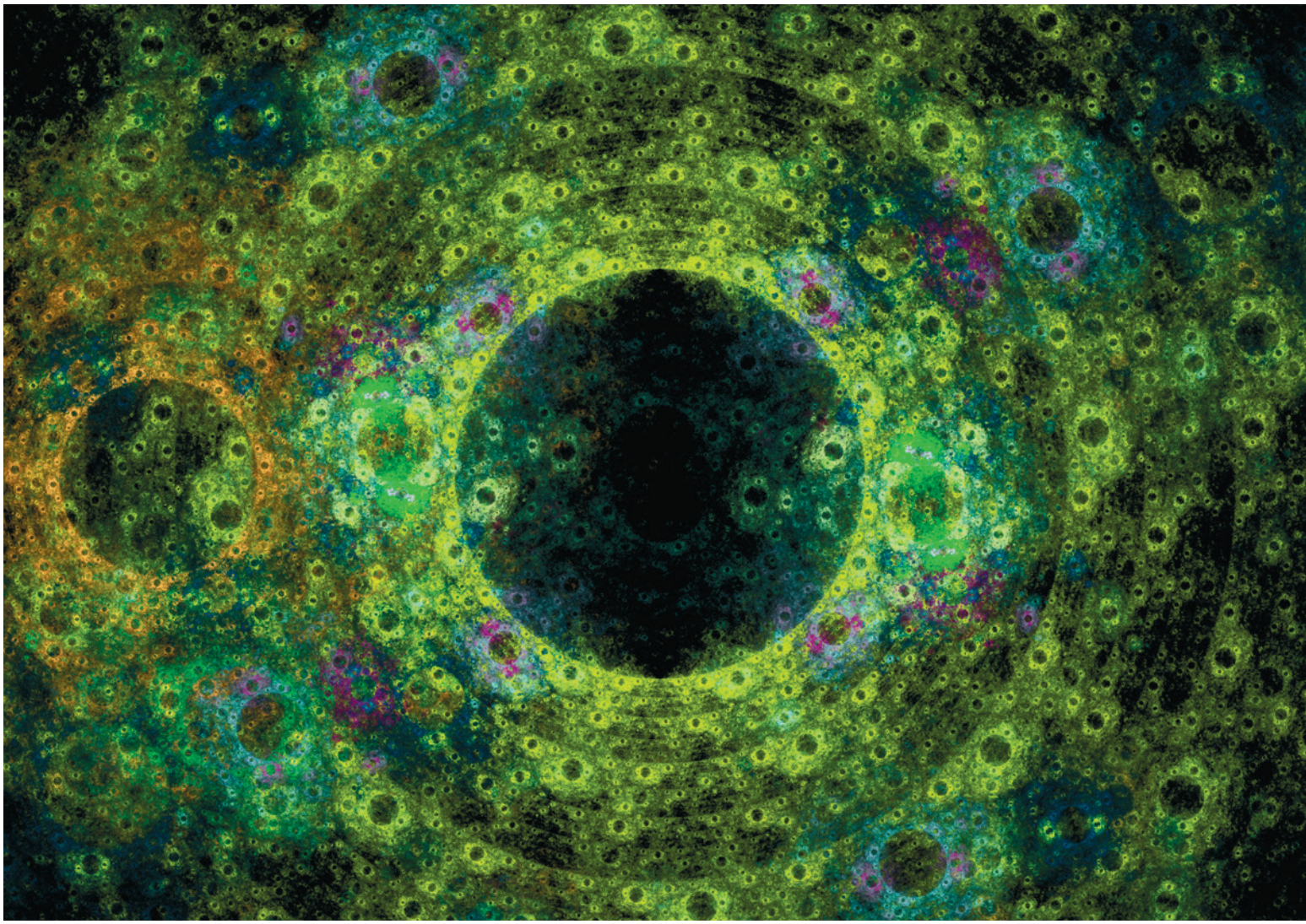
Is Sweden prepared for an outbreak of ebola?

The current outbreak of the Ebola virus has appeared to be getting more severe by the day, but we may be entering another phase now when the overall number of new cases is levelling off. However, it is the largest and most complex outbreak to date, with over 14,000 cases reported and more than 5,200 deaths. According to other sources 12,000 deaths would be a better estimate. The current outbreak represents the widest geographical spread of the disease ever reported and headlines about new outbreaks are yet to come. There is still no market-approved drug for treating Ebola and no vaccine to prevent it. As of last month, Ebola was reported in Scandinavia, raising questions about how well prepared Sweden is and; most of all whether current legislation is flexible and secure enough to combat this type of threat.



It takes on average more than 12 years to develop a new medicinal product. Once clinical trials have been completed, a pharmaceutical company may apply for marketing authorisation. Approval is granted after extensive scientific evaluation of how the new medicine works, its potential side-effects and manufacturing requirements. The quality, efficacy and safety requirements for a medicine are very high.

There is no doubt that when diseases like Ebola strike our society, and time is short, a fast track approval is required alongside the standard authorisation procedure. In Sweden, the standard authorisation procedure for medicines that have been tested on humans usually takes around 210 days, but there is a possibility of releasing untested medicines on the market even if they have not been evaluated for safety and efficacy in humans. In fact, the Swedish Medical Product Agency (MPA) may allow the prescription of a medicine to specific individuals by issuing a special license in less than seven days. Similarly, the US Food and Drug Administration has allowed the use of untested medicines to fight the deadly Ebola virus in humans. The decision was based on humanitarian reasons.

In both the US and Sweden, fast-track approval raises a lot of questions. Not only in terms of the very short timeframe within which the authority has to gather information on the medicine and review it, but also, in terms of how such information is gathered. Furthermore, there are no provisions or guidelines regulating what ethical points to consider in making such a decision. An even greater factor is, of course, the uncertainty over whether improvements in patients' conditions are actually due to the treatment and what side-effects may transpire in future. One should not forget that the fast track is used for medicines which are still at an early stage of development and only some of these medicines have shown encouraging results in the laboratory or in animals, but they have not yet been fully studied on humans.

Health authorities around the world have struggled with the ethical issue mentioned above, which was the subject of a recent report by the World Health Organisation (WHO). The WHO concludes that it is ethical to offer untrialled medicines with unknown effects and side-effects in the fight against Ebola. However, the following ethical criteria should be fulfilled: (i) transparency concerning all aspects within the health care system; (ii) the patient must be informed and have given consent; (iii) the patient should have a freedom of choice; (iv) the treatment is confidential; (v) the individual is respected; and (vi) preservation of dignity and participation in society. WHO is also of the view that a treatment includes a moral obligation to evaluate efforts in order to definitively demonstrate safety and efficacy or possibly to stop the use of the treatment. Moreover, and in order to provide information about the available experimental medicines, the European Medicines Agency (EMA) has started reviewing available information on Ebola treatments currently under development. The goal is to provide an overview of the current state of knowledge about these medicines to support health authorities in their decisions. Furthermore, the EMA Committee for Medicinal Products for Human Use will perform a formal review of the available scientific information on quality, preclinical and clinical data about various treatments under development.

The Swedish MPA has declared that Sweden is prepared for an Ebola-outbreak. But the facts remains that there are still no approved medicine either to prevent or to treat Ebola and an outbreak in Sweden would put great pressure on hospitals and other health care institutions to be prepared and to act in such a crisis.

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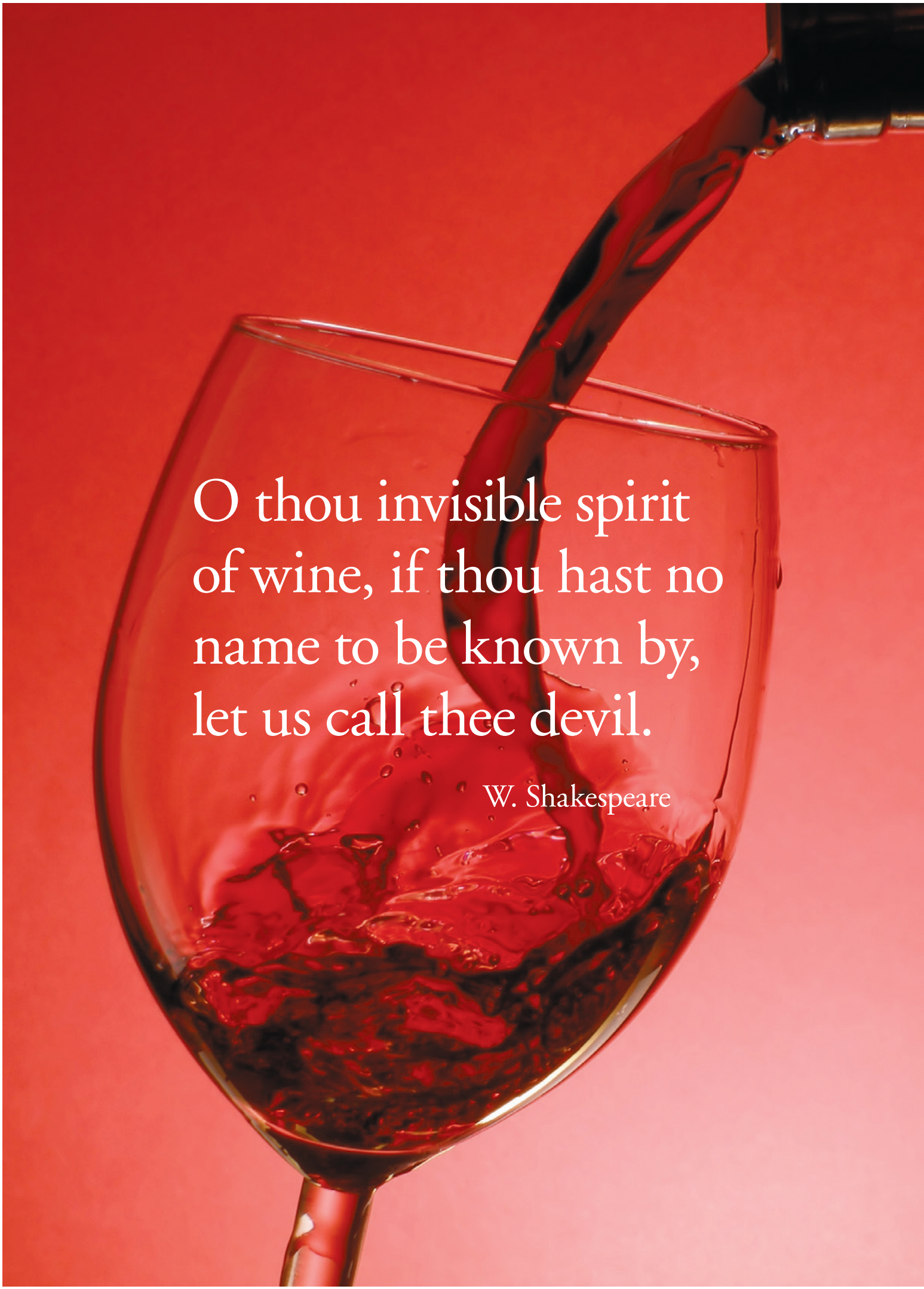
O thou invisible spirit
of wine, if thou hast no
name to be known by,
let us call thee devil.
W. Shakespeare

Distance selling of alcoholic beverages to Sweden: Who may pour the wine?

Sweden has in modern time maintained a strict approach when it comes to the sale of alcohol. A cornerstone of this approach has been the maintenance of trade monopolies. The one remaining monopoly, – the retail monopoly or "Systembolaget" as it is called – is now considered by itself, the Swedish government and its other staunch supporters – to be under siege by operators engaging in distance selling from other EU countries. The Swedish government regards this development as a threat to Swedish consumers' health, to the Swedish alcohol policy, not to mention the Systembolaget. Here's why:

In 2007, the European Court of Justice (ECJ) issued a ruling concerning the private import of alcoholic beverages to Sweden[1]. A Swedish citizen, Mr. Rosengren, and compatriots had ordered wine from a vendor in Spain and had contracted someone to arrange the transport of said wine to Mr. Rosengren et al. in Sweden. This was, at the time, in violation of the Swedish Alcohol Act. In order to import alcohol, you had to carry the goods across the Swedish border yourself. The wine was consequently impounded by Swedish Customs, and Mr. Rosengren and his fellow importers were prosecuted for violation of the Alcohol Act. The Swedish Supreme Court asked the ECJ to examine the provisions of Swedish law on alcoholic beverages to verify their compatibility with Community law, in particular the principle of the free movement of goods.

The ECJ initially stated that the Swedish provisions on the import of alcoholic beverages were separable from the operations of the retail monopoly and must be examined with reference to Article 28 EC as a quantitative restriction to trade and not Article 31 EC (now articles 34 and 37) on national commercial monopolies. The prohibition of private imports is therefore not a rule that relates to the very existence or operation of the retail monopoly.

The ECJ then pointed out that the fact that private individuals were prohibited from importing such beverages directly into Sweden, without personally transporting them, constituted a quantitative restriction on imports. The ECJ further concluded that this ban on the import of alcoholic beverages could not be justified on the grounds of protecting the health and life of humans according to Article 30 (now Article 36). Consequently, the Swedish ban on private imports was found to be non-compliant with Community law.

To add insult to injury, the Commission brought a case against Sweden for failing to fulfil its obligations under the Treaty *by prohibiting individuals from importing alcoholic beverages by independent intermediary or professional transport*[2].

The ECJ decisions led to a change in Swedish applicable legislation. Since these decisions and the changes to the Swedish Alcohol Act, distance selling and consequently private imports of alcohol has increased. In particular, there are a growing number of distance sellers and services that promote distance sales and sellers. Some of them are Swedish companies co-operating with companies based in other EU member states that are the actual sellers. The products are sold and packaged in the other member state and transported to the consumer in Sweden. Consumers may have the goods transported to their home or can pick up the goods at a transport hub of some sort. Some claim that this setup is compliant with current legislation, while others claim it is a misinterpretation due to lack of clarity in the legislation. Attempts have been made to get Swedish prosecutors to try the companies involved in this practice for violation of the Alcohol Act, so far without success. To date, prosecutors have not found the practice to be in violation of the Alcohol Act.

This may change, however. In 2013, a Swedish grocery chain began collaborating with a Danish distance seller of wine, offering customers the opportunity to purchase wine from the Danish company in conjunction with purchasing groceries online, and the groceries and wine are then delivered together to the customers' home addresses or made available for pickup at the nearest grocery store. The orders for the wine

[1] C-170/04

[2] Translation from C-186/05. The decision is only available in Swedish and French.

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and the groceries are made by the consumer in one go, on-line, but are then separated so that the grocery chain receives the order for the groceries and the wine company receives the order for the wine. The same applies with regard to payment. Thus the grocery chain does not receive or handle any orders or payments for the wine – this goes directly to the wine company. The consumer's order is coordinated when the wine has reached Sweden and the groceries and the wine are then delivered to the consumer at the same time.

The idea of buying food and wine together in Sweden (other than in a restaurant) is highly controversial. For this reason, it is not possible to buy wine at a grocery store in Sweden. You have to go to the Systembolaget's store, which, by the way, is often located next door to major grocery retail stores. If you don't have a Systembolaget store nearby, you can order the alcoholic beverages from the Systembolaget online and pick them up in the nearest grocery store, which acts as an agent for the Systembolaget. Alternatively you can collect the items from a post office, which these days are often located in a grocery store… But importing goods from a distance seller and not from the Systembolaget is a different story. It should be said that Swedish alcohol tax also applies to private imports, as do age restrictions and the prohibition against giving alcoholic beverages to intoxicated individuals.

Until now, private imports has not been on the top of the government's legislative agenda. It's been considered too insignificant. Last year, private imports accounted for 2% of total alcohol sales in Sweden, so now the government feels that something has to be done.

This spring, the Swedish government established an inquiry, which presented its conclusions in the summer, including a proposal on how to restrict distance selling and the purchase of alcohol. This inquiry proposes an exception for private import, which specifies that a private individual can import these products for personal use, either by themselves or through a vendor, if the products come from a country within the European Economic Area, provided the transport of the goods is organised by a professional or private carrier that must be independent of the vendor. No intermediation service other than the actual transportation service is permitted.

Moreover, commercial promotion of private imports of alcoholic beverages will be prohibited. This ban is supposedly to highlight the fact that it is against the law to commercially facilitate the sale of alcoholic beverages from abroad or other-wise contribute to such sales. Businesses that initiate various types of business relationships and co-operations with other companies which role is to act as intermediary between buyer and vendor to promote private import of spirits, fall under this prohibition.

An interesting point made by the inquiry, much to the Systembolaget's dismay, is that foreign sellers may, notwithstanding the prohibition on promotion, conduct marketing activities. These activities include advertising in "normal" advertising media, whatever that is these days.

So, everything's crystal clear? Hardly!

There is a further requirement proposed: the goods have to be transported to the consumer's home address. It is not permissible to arrange to pick up the goods elsewhere, such as parking lots, grocery stores or any other venues deemed suspicious. One reason for this is that the inquiry sees a danger that deliveries to places other than consumers' homes may induce complimentary offers of more alcohol and so on. The inquiry claims that the above measures are necessary if Sweden is to uphold its restrictive policy concerning alcohol and maintain the retail monopoly, i.e. Systembolaget. The inquiry claims that there is support in EU legislation and the Court of Justice's case law for both its concerns in this regard, as well as for its proposals for further restrictions. It holds the measures to be both necessary and proportionate to safeguard the purpose of the Swedish alcohol policy, i.e. to protect consumers, public health and order. In this context, it should be noted that Sweden has so far been successful in the Court of Justice in defending a prohibition against the promotion of foreign gambling services[3] [4].

On the other hand, Systembolaget's sales are increasing year after year and it generates a rate of return well above that stipulated by its owner, the Swedish state. It continuously takes steps to make itself more available to consumers, improving its services as well as developing new ones, and one of its latest innovations is home delivery. Annual Swedish alcohol consumption measured in terms of pure ethanol per capita is 9.9 litres compared to 11.1 in Denmark, which has no retail monopoly. Distance selling cannot compete with retail stores when it comes to availability. While the former

[3] C-447/08 and C-448/08

[4] However, it should also be noted that the EU-Commission has recently decided to bring Sweden before the ECJ for non-compliance with the Treaty with regard to the Swedish gaming monopoly including the promotion of foreign gambling services. Many of the Commissions arguments concerning the Swedish gaming laws are ap-plicable on the alcohol legislation and the monopoly held by the Systembolaget. So, who will have the last word is still anybody's guess.

requires planning, the latter does not, provided you have a Systembolaget store nearby. The tax applied to privately imported products means distance selling prices are equal to those of Systembolaget. Checks on identity, level of inebriation and age can be handled as efficiently by the transport companies involved in distance sales as by Systembolaget.

One might question what effect promotional schemes or partnerships between Swedish and foreign companies on the distance selling of alcoholic beverages really have on total alcohol sales. Or indeed why Swedish consumers should be restricted to sellers that do not have in-house distribution resources. How does the requirement to use an independent transporter really benefit Swedish health? Does the banning of cooperation between operators – one established in Sweden to provide a technical platform for e-commerce and marketing, and the other contractually being the seller, corrupt the pure Swedish people? Is it really a threat to Sweden's public health to be able to combine delivery of food and wine ordered online from two different sources? And even if you put all the measures together, what benefits do they really have on the Swedish consumer's health? If availability is an issue, on-line orders which have to be planned, and which deliveries you have to wait several days for, will always take "a back seat" to the availability provided by physical stores open Monday through Saturday. In addition to controlling the retail monopoly stores the Swedish state also have other significant protective measures to apply in the interest of preserving public health – none of which are affected by the occurrence of distance selling and private imports.

So, one might wonder if these proposals aren't merely covert protective measures not of health, but of the Swedish retail monopoly's own import, online sales and home delivery services? Services through which you can order alcoholic beverages of all kinds for which the limit is eight parcels, equivalent to ninety-six (96) 70 cl bottles per delivery? The positive public health effects of the proposals, if any, are not at all clear, and neither is it apparent how they will save the vulnerable Swedish people from the detrimental effects of alcohol in general. It is clear, however, that the Swedish government is still adamantly defending its policies on alcohol in general and Systembolaget in particular (and the annual return it yields).

Adult citizens in Sweden may be of legal age in most social respects, but with regard to alcohol, we appear to remain wards of the state. In other words, apart from in restaurants and bars, Swedes have to plan their consumption of alcohol carefully if someone other than the Swedish government is to pour the wine.

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New ceiling price model in Sweden's pharmaceutical benefits system

On 1 July 2014, new rules came into force allowing the Swedish Dental and Pharmaceutical Benefits Agency ('TLV') to issue regulations on price changes for certain drugs that are more than 15 years old.

The regulations come on the back of amendments to the Pharmaceutical Benefits Act (2002: 160) and the agreement reached between the government and the research-based pharmaceutical industry in Sweden (LIF) in autumn 2013.

The agreement between the government and LIF

This agreement involved a 7.5 percent reduction in the price of drugs that were introduced in 1998 or earlier. The price reductions were launched at the beginning of 2014, and will also mean successive price reductions for the next three years on those drugs that have then been on the market for 15 years or more. In 2015-2017, additional average savings of SEK 130 million (AIP) a year will be achieved, which equates to an additional reduction of approximately SEK 400 million between 2015 and 2017. The agreement means that the pricing model known as International Reference Pricing could be avoided.

In a report of 17 March 2014, TLV announced that the savings for 2014 are equivalent to about SEK 400 million (AIP). This means that the first part of the agreement has been fulfilled.

New regulations

In light of this, on 19 June 2014, TLV submitted a proposal for new regulations and general advice about the pricing of some older drugs. These come into force on 1 November 2014. The first price reductions under the new rules will apply from 1 January 2015 and a preliminary list of the products concerned has been published. Approximately 100 companies with a total of about 500 different products are affected.

According to the regulations section 4, a new, lower price will apply from the decision made in the month, or immediately following the month, marking 15 years since the drug was first approved for sale. The calculation of a drug's age is based on the earliest date of product authorisation of the drug's substance-form group.

General recommendations stipulate that drugs with the same substance and form are part of a particular substance-form group. The calculation of a drug's age is based on the earliest approval in each such group. Combinations of active substances are defined as new substances, apart from certain minerals, vitamins and solutions. Form is defined by the form of administration and does not distinguish between administration device or storage form.

With regard to the new lower price, the regulations in section 5 show that the unit price of a drug represents 92.5 percent of the original price unless TLV decides otherwise. The price of a pack, however, will never correspond to less than a purchase price of SEK 15.

In general, the original price is the price per unit, based on the purchase price that the drug had under the pharmaceutical benefits system at 31 October 2012.

With regard to the handling of the cases, TLV will publish a list of the products that the authority preliminarily believes meet the criteria for a new lower price and what the new lower price will be.

The companies will then be allowed a period within which they can submit comments on the list. It is also possible to request exemptions. It is still not clear how this will be implemented. TLV will then publish an updated list of the future price changes. The companies are allowed to submit an application for a price reduction in accordance with the list. At the beginning of the decisions month, TLV will contact the companies that have not applied for a price reduction and will inform them that TLV intends to decide on price reductions for their products on its own initiative.

The future

Price reductions will be implemented twice a year, in a process that will continue for four months. Not all pharmaceutical companies will be affected by this work to the same extent. The number of products affected by the reduction at any one time will vary, as will the number of companies concerned. One estimate is that about 30 companies and 30 products will be affected on each occasion of a price reduction. A product is only expected to be affected once by the 15-year rule.

It is anticipated that the regulations will affect different companies in different ways. The impact will be especially great for companies that have several older drugs in their portfolio. In addition to the future price reductions, the new regulations will mean that companies incur increased administration costs. This will include assessing whether TLV is correct in its preliminary list, and assessing whether an exemption application may be appropriate. If the price reduction is warranted, it is up to the companies to apply for new, lower prices for the products in question.

Furthermore, there is uncertainty over the size of the future price reductions. As mentioned above, TLV may decide that the price reductions at a certain time should not be 7.5 percent, but that a different figure should be applied to achieve the savings requirement for the period.

TLV will follow up the impact of the regulations to ensure that the agreed savings are achieved for the entire period. The authority states that a review will be needed at the beginning of 2015 to examine whether the percentage reduction, or other variables such as the management of any exemptions or the intervals, need to be changed. We are following developments closely.

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Medicinal products in Sweden: even more substitution?

Substitution of prescribed medicinal products is a key feature of the Swedish reimbursement system and has contributed to substantial savings for Swedish taxpayers since its introduction in 2002. However, an increasing number of products are being excluded from the substitution regime.

Where a substitute product with reimbursement status is available, Swedish pharmacies must, as a rule, give a patient the cheapest available substitute to the prescribed medicinal product. The Medicinal Products Agency (MPA) used to decide which products are substitutes only after reimbursement status had been awarded by the Reimbursement Agency. Since 2007, however, the MPA decides on substitutability upon granting marketing authorisation to a medicinal product and thus prior to the potential award of reimbursement status.

Prescribed products without reimbursement status may not be substituted, regardless of whether a cheaper substitute with reimbursement status is available. This has not been a major issue up to now, as most companies traditionally have applied for reimbursement status and most products therefore have been part of the reimbursement system. However, recently we have seen a trend of many products being forced out of or voluntarily withdrawn from the reimbursement system.

One reason is the Reimbursement Agency's increasingly strict approach when it comes to requiring price cuts to maintain reimbursement status. Companies may decide to withdraw from the reimbursement system rather than lowering their prices, e.g. in order to protect their prices in more important foreign markets where international reference pricing systems are applied by the authorities. It has also been suggested that certain originators may withdraw from the reimbursement system in connection with patent expiries, in order to avoid

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price competition and to make it more difficult for generic products to gain effective market access.

If an originator product withdraws from the reimbursement system, this may make it more difficult for a generic product to be awarded reimbursement status. If the generic product is nevertheless awarded reimbursement status, the withdrawal of the originator product from the reimbursement system will still mean that no substitution can take place at pharmacies. Traditionally, doctors prescribe the originator products that they have become familiar with during the patent term. If prescription patterns do not change, generics would have to make significant investments in marketing to gain effective market access. Hence, withdrawal from the reimbursement system may assist originators in maintaining significant market share even after patent expiry without having to engage in price competition with generics. Of course, the viability of this strategy will depend on pricing, patient preferences, indications, length of treatment and other factors related to the individual medicinal product.

The Swedish government has realised that the increasing number of medicinal products outside the reimbursement system may present a challenge to the system and the financing of medicinal products in Sweden. In April 2014, the government instructed the Reimbursement Agency to analyse the consequences of certain medicinal products not being included in the reimbursement system and to present proposals on how to deal with the situation.

The Reimbursement Agency published its first report on 1 October 2014. The report states that the costs for medicinal products without reimbursement status has increased from SEK 0.5 billion to SEK 2 billion in the last 10 years. The increased costs are borne both by the county councils, who pay for certain categories of medicinal products regardless of reimbursement status, and by patients. According to the report, the main categories of products without reimbursement status are anti-infectives and birth control products. The report discusses several issues related to medicinal products without reimbursement status, including free pricing, equal treatment between county councils, ineffective competition and lack of price information. The Reimbursement Agency confirms that the current legislation does not permit substitution if the prescribed product does not have reimbursement status. According to the agency, this means that the scope for price competition is reduced and that patients will have to pay a higher price for their products unless they are aware that cheaper substitutes exist and are able to convince their doctors to prescribe these substitutes.

The Reimbursement Agency does not propose any legislative or other measures in this report. The final report, due for presentation to the Swedish government no later than 1 March 2015, will contain such legislative and other proposals. However, the existing report states that the Reimbursement Agency has considered the option of extending the substitution regime to also cover medicinal products outside the reimbursement system. According to the report, the agency has discussed this option with the MPA, which has undertaken to prepare a legislative proposal on how to implement such an extended substitution regime.

Given the analysis presented in the report and the fact that the MPA already decides which products are substitutable from a medicinal perspective irrespective of reimbursement status, we consider that it is likely that the substitution regime will be extended in the next few years to also cover medicinal products outside the reimbursement system. However, prior to adopting such an extended substitution regime, the legislator must consider a number of difficult questions. Should substitution only be allowed if the substitute has reimbursement status or should substitution also be allowed between two products without reimbursement status? If the doctor prescribes a product without reimbursement status and the pharmacy gives the patient a substitute with reimbursement status, should this mean that the county council should reimburse the patient's costs? Is it acceptable that the choice of product and whether the patient's costs are reimbursed may differ between pharmacies depending on the price of the originator product at the individual pharmacy? Does the supervision of the extended substitution regime require a system for supervising the prices of non-reimbursed products?

We expect the proposal to be presented by the Reimbursement Agency and the MPA to answer these questions and others. We also expect the proposal to stir up a fair amount of criticism, at least from the innovative parts of the pharma industry.

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Facts and figures

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

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

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

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

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

Practise areas

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Energy & Commodities
Environment
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Infrastructure & Construction
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