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Regional Discount Agreements in Sweden: A Legal Minefield

REGIONAL GOVERNMENTS IN SWEDEN ARE INCREASINGLY LOOKING TO LEVERAGE THEIR PURCHASING POWER IN ORDER TO SECURE DISCOUNTS AND REBATES ON THE LIST PRICES OF BRANDED DRUGS. HOWEVER, AS NOTED BY ELISABETH EKLUND, PARTNER AT LEADING COMMERCIAL LAW FIRM DELPHI, SUCH AGREEMENTS RISK RUNNING FOUL OF BOTH SWEDISH AND EUROPEAN UNION (EU) LAW. *FOLLOWING HER PRESENTATION AT THE RECENT NORDIC MARKET & PATIENT ACCESS FORUM, STAGED BY NEXT LEVEL PHARMA IN STOCKHOLM, EOIN JENNINGS SPOKE WITH HER FOR PPR.*

MARKET ACCESS CHALLENGES IN SWEDEN

Eklund began by briefly outlining the challenges facing manufacturers seeking access to reimbursement in Sweden. "Manufacturers seeking to obtain reimbursement must apply to the Dental and Pharmaceutical Benefits Agency (TLV – see Box 1). The TLV makes decisions on both the drug's price, and on whether the product should be reimbursed," she noted.

"Getting the 'right' price, therefore, is key," she advised, "but this can be very difficult to achieve, since it is not just a question for the national market in Sweden. Indeed, prices in Sweden are referenced by a number of other European countries, and manufacturers also have to be aware of the challenges posed by parallel trade.

"If reimbursement is not approved, there remains the possibility of negotiating discount agreements with the New Drug Therapies Group (see Box 1). This has particularly been the case for new cancer drugs, which tend to be very expensive, and where the TLV has tended to be quite restrictive in terms of the value attached to these products.

"In addition, the TLV has been given a mandate by the government to review the existing subsidies for pharmaceuticals (see *PPR* February 2014, pp48-50)," she continued. "As a result, there has in recent years been a large number of pharmaceuticals that have been forced to either lower their prices to stay within the reimbursement system, or where the TLV has found that cost-effectiveness hasn't been proved, and has removed the drug from reimbursement.

"There is free pricing for drugs that are outside the reimbursement system: such cases typically occur, for example, in certain therapy areas where the majority of pharmaceuticals have been removed from reimbursement. Doctors are theoretically free to prescribe these medicines if they wish, but they are very strongly discouraged from doing so. Finally, it is worth noting that Sweden recently introduced mandatory price cuts for certain older drugs (see *PPR* February 2014, pp48-50)," she said.

Eklund noted that while the pricing and reimbursement process is conducted at the national level by the TLV, it is the county councils that are responsible for funding the reimbursement of both in-patient and out-patient prescription medicines. And while Sweden has weathered the economic storms of the last few years better than many of its European neighbours, regional governments remain under pressure to deliver savings. As a result, the question of whether Swedish and EU law permits regional discount/rebate agreements for reimbursed drugs has come to the fore in recent years, she remarked.

PUBLIC PROCUREMENT

A key area of contention in relation to drug pricing in recent years has centred on the issue of public procurement, Eklund observed. "Knowledge of public procurement rules for in-patient pharmaceuticals is essential," she advised. "It is really important for drug companies to monitor and to participate in public procurement".

"In Sweden, there is public procurement for virtually all pharmaceuticals used in hospitals. Indeed, the minimum contract value that is subject to public procurement is even lower in Swedish law than that required by EU legislation, so there are a very high number of tenders out there at any given time.

Box 1: Pricing and Reimbursement in Sweden

Manufacturers must submit a proposed price to the Dental and Pharmaceutical Benefits Agency (*Tandvårds- och läkemedelsförmånsverket*, TLV) as part of the combined pricing and reimbursement application. The potential price of a new drug is linked to both its cost-effectiveness and the marginal benefit it offers versus existing therapies. The higher the demonstrated marginal benefit of the drug, the higher the potential price.

A drug must meet the following criteria in order to be eligible for reimbursement:

- Cost-effectiveness: the price of the medicine must be judged to be "reasonable" from a medical, humanitarian, and socio-economic point of view
- Marginal benefit: the TLV must be satisfied that there are no alternative treatments available that can be considered to be "significantly" more efficient.
- Patient need: if the need for the drug is judged to be low (based on quality of life and/or life expectancy considerations), it is unlikely to be reimbursed, irrespective of its cost-effectiveness or marginal benefit.

It is noteworthy that since 2009 the New Drug Therapies Group (*NLT-gruppen*) issues recommendations on "problematic drugs" – including hospital drugs and drugs not granted reimbursed status by the TLV. Recommendations made by the *NLT-gruppen* (which consists of representatives from the county councils) are not binding upon councils, however.

Source: IMS Pharmaceutical Pricing and Reimbursement Concise Guide: Sweden

"And it is important to remember too that the TLV now has a role to play in the in-patient sector, via the *klinikläkemedelsprojektet* [clinical drugs project], which requires the agency to conduct health economic evaluations of existing in-patient pharmaceuticals (see *PPR* January 2014, p23 *et al*).

"What has become a bigger issue in recent years, however," she said, "is whether public procurement rules may also apply in certain cases to drugs used in out-patient care."

Procurement Rules

"The 21 county councils, which are responsible for funding healthcare, are considered state bodies which are required to follow the public procurement rules," Eklund stated. "Procurement rules are based on EU Directives, which have been transposed into Swedish law as the Act on Public Procurement (*Lagen om offentlig upphandling*, LOU).

"Procurement can be in the form of a contract, or a framework agreement. Framework agreements are very common, since county councils are often reluctant to specify the exact volumes of pharmaceuticals that they will need.

"When procuring medicines, county councils may choose to act alone, or together with other councils. There have also been some national procurements (*eg* for vaccines), but these remain quite rare. Procurement covers public hospitals, but private hospitals may choose to participate in the procurement if they wish to do so, although there is no obligation.

"The rules are designed to ensure that a number of key principles are adhered to when procuring prescription drugs. These include the principles of non-discrimination, equal treatment, transparency, proportionality, and mutual recognition. Essentially, it's all about ensuring that taxpayers' money is used in the best way," she emphasised. "It's also a way of opening up borders to encourage trade between EU member states."

However, while the rules seem clear, Eklund observed that recent years have seen a growing debate about the applicability of the public procurement rules to the out-patient sector. "The general rule is that procurement only applies to in-patient care," she said. "But the lines have become somewhat blurred. There is a growing debate about whether county councils should follow public procurement rules if they negotiate discount agreements with pharmaceutical companies for reimbursed out-patient drugs."

In this regard, Eklund highlighted two recent cases that have brought this issue to greater prominence.

Skåne

"For years, manufacturers in the Swedish system could be assured that once a product had secured out-patient reimbursement, its price would be more or less guaranteed," Eklund noted. "However, in recent years, the county councils have struggled with budget cuts, and have sought to cut their drugs bill as much as possible. In the in-patient sector, this has led to greater pressure for discounts on the list prices of drugs."

In 2012, the government of the Skåne region invited a number of drug manufacturers to negotiate an agreement to provide discounts on TNF-alpha inhibitors for use in the out-patient setting. Under the agreement, the county council undertook "as far as possible" to encourage the first-line use of the TNF-alpha inhibitor that offered the greatest economic benefit to the regional government. "In other words," Eklund explained, "a large discount". The 'contract' was won by UCB Pharma, which agreed to provide a rebate to the county council on all sales of its TNF-alpha inhibitor Cimzia (certolizumab pegol) (see *PPR* January 2014, p14 *et al*).

As Eklund noted, "the agreement soon prompted the question of whether the public procurement rules laid down by the LOU should apply. In the event, the agreement was challenged by Abbott, manufacturer of a competitor to the drug in question, on the basis that the deal violated public procurement rules."

Following an initial hearing in a lower court, the case was heard by the Administrative Court of Appeal in Gothenburg, which found that the county council was not in breach of the LOU. "The court ruled that the regional government had undertaken to provide a service – in the form of a recommendation to use a certain drug – for which the county council was paid in the form of a rebate. In short," Eklund said, "the court ruled that the agreement was not a public procurement, and that the provisions of the LOU did not apply."

Stockholm

A similar discount agreement concluded between Merck, Sharpe & Dohme and Stockholm county council, also covering TNF-alpha inhibitors, resulted in a further legal tussle between Abbott and the authorities in 2013. On this occasion, however, Eklund noted, the Stockholm Administrative Court sided with Abbott and found that the rebate mechanism employed under the agreement contravened the LOU. The court ruled that the public procurement rules applied, since Stockholm county council had agreed to purchase the product in question.

Notably, however, this judgment was subsequently overturned by the Stockholm Administrative Court of Appeal. As a result, Eklund noted, "since we now have two Administrative Court of Appeal judgments saying the same thing – *ie* that no public procurement is needed in these situations – I would say that that is how the law now stands."

"It seems clear," she continued, "that the public procurement rules do not prevent county councils from negotiating discounts on out-patient prescription drugs. However, just at the point where most observers believed that this was a settled legal issue, the TLV got involved in the debate.

"Its view is that such deals between manufacturers and regional governments may contravene the terms of the Pharmaceutical Benefits Act, and are therefore illegal. And this question is now before the Stockholm Administrative Court of Appeal."

PHARMACEUTICAL BENEFITS ACT

"The Pharmaceutical Benefits Act," Eklund explained, "regulates many aspects of the pharmaceutical sector. The legislation gives to the TLV the authority to decide whether a drug should be reimbursed, and to determine the purchase and selling price of reimbursed medicines. Elsewhere, the Act governs substitution rules: it states that substitution (either with generics or parallel imports) can be prohibited by prescribers on medical grounds."

The TLV's opposition to regional discount agreements rests on its interpretation of these provisions of the Act. Eklund explained that the TLV has specifically sought to oppose the 2012 discount agreement negotiated between the Skåne region and UCB Pharma, covering Cimzia (see above

and *PPR* January 2014, p14). Notably, that agreement also included a commitment by the government of Skåne to encourage prescribers to forbid substitution of Cimzia with cheaper parallel-imported versions when writing a prescription.

"In January 2013," Eklund noted, "the TLV prohibited the Skåne region from concluding or renewing any pricing agreements with pharmaceutical manufacturers, for drugs covered by the pharmaceutical benefits system. The Agency also forbade the regional government from urging prescribers to prohibit substitution for any reason other than medical reasons.

"The TLV argued the discount agreement essentially meant that Skåne had negotiated a separate price for a product that was included in the pharmaceutical benefits system. And since the TLV holds that it alone has the power to negotiate prices for reimbursed drugs, based on the Pharmaceutical Benefits Act, it argued that the agreement ran contrary to the Act.

"Similarly, the TLV felt that the county council's agreement to encourage doctors to prohibit substitution of Cimzia also contravened the Act, since the legislation only permits substitution to be prohibited on medical, rather than economic, grounds (see *PPR* April 2013, p120).

"The case ended up before the Stockholm Administrative Court in October 2013," Eklund continued. "The Court sided with the TLV on the issue of price negotiations, and found that the Agency's prohibition on the conclusion of discount agreements was in line with the provisions of the Pharmaceutical Benefits Act. Moreover, it also based its judgment on the terms of the EU Transparency Directive, which requires drug price negotiations to be concluded within 90 days of the manufacturer's original application (see *PPR* April 2013, p116).

"However, the Court declared null and void the TLV's prohibition on the ability of Skåne to urge prescribers to forbid substitution on non-medical grounds. It found that the wording of the Pharmaceutical Benefits Act did not support the TLV's interpretation.

"As a result, both the TLV and the government of Skåne have appealed the ruling, with leave to appeal having been granted in January 2014. It's likely, I think, that we'll get a judgment sometime in the autumn of 2014. And that's going to be very interesting to hear," she said.

"I think that the legal situation here is fascinating," Eklund added, "because the TLV's action relates only to the specific agreement between Skåne and UCB Pharma, so does not necessarily prohibit any other such agreements. And as far as I'm aware, the TLV has not taken action against any other such agreements to date."

NON-REIMBURSED DRUGS

Finally, Eklund moved to address the question of whether discount agreements are permissible for out-patient drugs that have not been approved for reimbursement.

"It is theoretically possible to negotiate these kinds of agreements, since the TLV's sole power to negotiate prices under the Pharmaceutical Benefits Act does not extend to non-reimbursed medicines," she observed.

"Manufacturers can negotiate discounts with the *NLT-gruppen* (see Box 1). However, I think that one disadvantage of this mechanism is that the *NLT-gruppen* is not a legal body. It is rather a group of representatives of the various county councils, so even when it issues recommendations, it doesn't have the power to enter into agreements with manufacturers," she cautioned.

"So, as a manufacturer, although you may have concluded discussions with the *NLT-gruppen*, you are then expected to enter negotiations with each of the individual county councils. And as the county councils are self-governing bodies, they don't have to listen to the *NLT-gruppen*, or to each other. As a result, different councils may reach different decisions, which can make life very complicated for drug manufacturers.

"In theory, if everything works smoothly, the idea is that the *NLT-gruppen* is able to discuss a solution with manufacturers, which individual county councils would then be happy to sign up to. But that hasn't really been the case so far – although I hope that perhaps this is a process that will improve over time," Eklund concluded PPR