Bird & Bird & Public procurement of medicinal products

White Paper

Common legislation but diverging implementation approaches throughout the EU

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1. INTRODUCTION

The purpose of this white paper is to provide an overview of the applicability of public procurement legislation in the healthcare sector, and more specifically the challenges it sets to the pharmaceutical industry. As will be shown in this white paper, despite a deep harmonization of the rules on public contracts throughout the European Union, the practical implementation of those rules varies, and while in some member states most supply contracts in the healthcare sector are awarded through tender procedures, the situation is completely different in other member states.

This white paper is intended to identify some of the issues the healthcare sector is currently facing with respect to public procurement rules, and to comment on some of the current discrepancies among member states, as well as to provide an overview of the different regimes applicable throughout (the major national markets of) Europe. A cross-border survey shows that the differences in the approaches amongst member states result in very different legal solutions and situations in practice.

This white paper also shows that the application of public procurement legislation is partly reshaping the healthcare sector part of the medicinal products market.

2. APPLICABILITY OF PP DIRECTIVE : SCOPE *RATIONE MATERIAE* AND *RATIONE PERSONAE*

2.1 Scope *ratione materiae* of the public procurement directives

Medicinal products and other medical supplies such as medical devices can be the subject-matter of public contracts ruled by national legislations on public procurement, which implement the European directives on procurement procedures (Directive 2004/17/EC of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors[1] ("Utilities" sectors) or Directive 2004/18/EC of 31 March 2004 on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts[2]).

Below the thresholds for European publicity[3], specific national requirements may be imposed and exemptions may apply, but the general principles of public procurement (equal treatment, transparency, free competition, etc.) remain applicable. In the light of public procurement rules, these products are treated like any other goods.

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[1] Directive 2004/17/EC of 31 March 2004 coordinating the procurement procedures of entities operating in the water, energy, transport and postal services sectors, O.J., L 134, 30 April 2004, as lastly modified by Commission Regulation (EU) No 1251/2011 of 30 November 2011, *O.J.*, L 319, 2 December 2011.

[2] Directive 2004/18/EC of 31 March 2004 on the coordination of procedures for the award of public works contracts, public supply contracts and public service contracts, *O.J.*, L 134, 30 April 2004, as lastly modified by Commission Regulation (EU) No 1251/2011 of 30 November 2011, *O.J.*, L 319, 2 December 2011.

[3] Currently set at 207 000 EUR (excl. VAT) for supply and/or services contracts for most contracting authorities, and 134 000 EUR (excl. VAT) for Central Government authorities.

Medicinal products and medical devices are notably listed in the CPV classification[4] (classes 33000000-0 to 33698300-2), and can indeed be the subject-matter of "a contract for pecuniary interest concluded in writing between one or more economic operators and one or more contracting authorities and having as their the supply of products and/or the provision of services"[5].

The above-mentioned directives will remain in force until 18 April 2016, the date on which a new set of Directives that replaces them shall have been implemented into the national law of the Member States[6]. While the new set of European Directives on public procurement includes some significant changes with regard to procedural features[7], the new directives entail no substantial change as to the material scope of the public procurement rules.

Medicinal products will thus remain into the scope of application of those rules, despite the negative impacts they might have on the industry. However, some questions remain open, with respect of the more complex products for instance, like biosimilars. The substitutability of such products is not yet considered as acceptable, so that such products might in most cases qualify for "simplified" procedures, on grounds of the existence of exclusive rights.

2.2 Scope *ratione personae* of the public procurement directives

The healthcare sector is a sector of activity that is characterized by a rather wide diversity across Europe. Depending on the level of intervention of the states, the public health policies in place from one country to another, in particular with respect to reimbursement policies, or the administrative structures in place, the entities that are supposed to acquire medicinal products under the public procurement rules can vary.

In some countries, the public authorities buy the products directly and supply them to the health institutions and pharmacies, based on the "kiwi" model as enforced in New Zealand for instance. In other countries, the hospitals buy their medical supplies, including medicinal products, directly from the industry. Some of these hospitals can be public entities, while other are privately operated.

In apublic procurement reasoning, this diversity leads to the question of the qualification of these public and private entities as "contracting authorities" in the meaning of the public procurement directives.

The European Court of Justice established that "*financing of a statutory sickness insurance scheme [...] which is brought into being by a measure of the State, is, in practice, guaranteed by the public authorities and is secured by methods of collection*

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[4] Regulation (EC) No 2195/2002 of the European Parliament and of the Council of 5 November 2002 on the Common Procurement Vocabulary (CPV), *O.J.*, L 340, 16 December 2002, as lastly modified by Regulation (EC) No 596/2009 of the European Parliament and of the Council of 18 June 2009, *O.J.*, L 188, 18 July 2009.

[5] See Article 1, (2), (a) of Directive 2004/18/EC, and the similar wording of article 1, (2), (a) of Directive 2004/17/EC.

[6] This set of new directives is composed of (i) Directive 2014/24/EU of the European Parliament and of the Council of 26 February 2014 on public procurement and repealing Directive 2004/18/EC (O.J., 28 March 2014), which will replace directive 2004/18/EC and (ii) Directive 2014/25/EU of the European Parliament and of the Council of 26 February 2014 on procurement by entities operating in the water, energy, transport and postal services sectors and repealing Directive 2004/17/EC (O.J., 28 March 2014), which will replace directive 2004/17/EC. In the meantime, these new directives will have to be implemented into national law by all European Member States.

[7] *Inter alia*, the possibilities of recourse to the negotiated procedure are extended.

which fall under the provisions of public law"[8] and considered that this satisfies the condition of being financed, for the most part, by the State for the purposes of the application of the Community rules on the awarding of public contracts.

The consequence in the case at stake is that AOK Rheinland had to be considered as a contracting authority (a fact which was denied by AOK Rheinland in the main proceedings that gave rise to the request for preliminary ruling).

The essential consequence of this case is that in most countries where a public insurance scheme is in place that funds, directly or indirectly, healthcare entities (be it sickness insurance funds or hospitals), those entities have to recourse to public procurement procedures for their works, supply and services contracts.

3. SOME OPEN ISSUES WITH RESPECT TO THE IMPLEMENTATION OF PUBLIC PROCUREMENT RULES ON MEDICINAL PRODUCTS

The practical implementation of public procurement rules for the supply of medicinal products can lead to difficulties in practice, which notably result from the specificities of medicinal products. In comparison, the procurement of medical devices and other types of material does not raise such issues.

The nature and extent of the issues encountered in the practice of public procurement of medicinal products notably depends on the identity of the contracting authorities (see Table 1 below for national specificities in that respect, and Table 2 for a comment on the issues actually encountered in the different jurisdictions examined herein).

3.1 Issues linked to the choice of the contract award procedure

3.1.1 Exclusivity rights and negotiated procedure

One of the specificities of medicinal products that comes into consideration is the fact that those products may be under patent or other IP rights protection at the time of the launch of the tender procedure. Public tendering entails that competing medicinal products are proposed to contracting authorities, and are then compared in the light of award criteria. Innovative, patented products, can qualify as being protected by exclusive rights, which in certain circumstances allows contracting authorities to have recourse to the (less burdensome) negotiated procedures under the public contracts legislation.

However, in a landmark case[9], the European Court of Justice has ruled that such justification was not sufficient to have a systematic recourse to a negotiated procedure. In that case, while Spain claimed that the medicinal products market is highly regulated by Community law itself and that the Spanish legislation ultimately complied with the restrictions resulting therefrom, the Court responded that none of the exceptions authorized by the directive is defined by reference to the type of product in question or the legal rules applicable to it, so that medicinal products are covered by the public procurement directives, like any other product and without any restriction .

The Court moreover held that "*it is not sufficient for the pharmaceutical products and specialities in question to be protected by exclusive rights; they must also be capable*

[8] Judgment of the Court of 11 June 2009, Case C-300/07, *Hans & Christophorus Oymanns GbR, Orthopädie Schuhtechnik v AOK Rheinland/Hamburg*.
[9] Judgment of the Court of 3 May 1994, Case C-328/92, *Commission of the European Communities v Kingdom of Spain*, paragraph 18.

of being manufactured or delivered only by a particular supplier", that requirement being satisfied "*only with respect to those products and specialities for which there is no competition in the market*." In other words, as soon as a product is distributed by more than one operator, the product has to be procured through a public tendering procedure.

3.1.2 Tendency for grouping of orders

The launch and further follow-up of public tenders is a formal and rather burdensome process. In order to mitigate the burden on their procurement services, contracting authorities may have recourse to grouping of orders mechanisms, or to other mechanisms provided for in the public procurement legislation such as electronic auctions or a dynamic purchasing system. The last two purchasing systems are rather new, and not yet put into practice at a wide scale.

It can be observed that grouped orders, and more specifically "central purchasing bodies", as defined under article 1, 10 of Directive 2004/18/EC, are being put in place in several member states (it is the case in France, for example), and that in some regions, a relatively important proportion of the public contracts relating to the supply of medicinal products is managed and contracted by such central purchasing bodies.

3.2 Definition of award criteria and unique specificities of proposed products

When a contracting authority launches a procurement procedure with a view to awarding the contract to the most economically advantageous tender (M.E.A.T.), it has to define award criteria, in light of which the submitted regular tenders will be assessed.

Applying award criteria supposes that the products proposed by the candidate suppliers are sufficiently comparable, not to say substitutable. The award criteria themselves must ensure that the principle of equal treatment of the tenderers is complied with.

3.3 Outcome of tendering procedure vs. therapeutic freedom

In most of the European countries, therapeutic freedom, and its corollary, prescription freedom, are recognized to doctors (with variations in the extent of the freedom from one member state to another).

The usual outcome of a tendering procedure is the award of the contract to a particular supplier, for the supply of a specific medicinal product (a molecule/active substance, under a particular brand). In countries where a prescriber is entitled to prescribe any type or make of medicinal products, it may happen that the prescribed product is not the product that was retained at the end of the procurement process. In cases where the concerned product is not substitutable by another product (most countries forbid the substitution of a prescribed product by another while others allow pharmacists to proceed to "generic" substitution under certain conditions), this can lead to situations where the prescribed product, which the doctor specifically intended for the treatment of the patient, is not readily available in the hospital pharmacy. In this kind of circumstances, the hospital may have recourse to a negotiated procedure.

The European Court of Justice admitted in a case dating back from 1994 that an urgent need for a particular pharmaceutical speciality may well arise in a hospital pharmacy, but considered that the freedom to prescribe pharmaceutical products cannot justify "a

priori *systematic recourse to a negotiated procedure for all supplies of pharmaceutical products and specialities to hospitals*[10]".

This white paper examines the implementation and enforcement of public procurement legislation in 14 European jurisdictions. The first table below identifies the entities in the healthcare sector that acquire medicinal products and investigates how and in how far public procurement procedures are implemented by these authorities. The second table sets out national specific specificities and discusses current trends and issues encountered in the jurisdictions under review.

The purpose of this exercise is to provide an overview of the similarities and divergences across jurisdictions in the EU.

[10] Judgment of the Court of 3 May 1994, Case C-328/92, *Commission of the European Communities v Kingdom of Spain*, paragraph 18.

TABLE 1

Identification of the national contracting authorities that organize the public procurement of medicinal products in practice

Country	Type of entities in the healthcare sector that acquire medicinal products	Do these entities qualify as "contracting authorities" in the meaning of public procurement legislation?
Belgium	- Belgian State (Ministry of Health, Ministry of Defence, a.o.), Regions, a.o. public entities - Hospitals (public and private) - Elderly homes (public and private)	All entities listed in the left column qualify as "contracting authorities", except for some privately operated elderly homes (insofar their public funding (direct or indirect) does not exceed 50 percent) (in line with AOK Rheinland case law). Recently, the case law of the Council of State showed some hesitations concerning the applicability of the public procurement legislation in the cases where elderly homes ordered medicinal products for their residents. According to the Council of State, he public procurement legislation does not apply in such a situation, insofar the mandate given by the resident for the purchase of medicinal products can be proven by the elderly home (see Council of State, nr. 216.686, 5 December 2011, *s.c.r.l. Atelier de Tromcourt-Architectes Associés* and nr. 220.945, 10 October 2012, *s.a. Pharmacie du Centre*).
Czech Republic	- Ministry of Health and all entities financed from public resources, hospitals directly managed by the state (University hospitals and some not privately owned hospitals, Medical Rescue Service and Emergency Services), - public elderly homes, - spa therapeutic centres, - Health insurance companies.	All entities listed in the left column qualify as "contracting authorities".

Denmark	In Denmark, the healthcare system is organized in 5 regions. The regions manage and operate the Danish hospitals. The regions have centralized their procurement of pharmaceuticals. A central purchasing body named Amgros ensures that the public hospitals in Denmark always have the necessary pharmaceuticals available and that these always are purchased at the lowest possible price. Amgros accounts for approx. 98% of all of the purchases of medicine made from the regional Danish hospitals.	The regional authoritiess and Amgros are contracting authorities and are subject to the rules of the Public Procurement Directive. As an underlying basis private hospitals and private elderly homes are not qualified as a contracting authority and are therefore exempted from the scope of application of the Directive. However, if a hospital or an elderly home are financed or supported, for the most part, by the State, regional or local authorities, the hospital or elderly home might be considered as a contracting authority subject to the Public Procurement Directives. The regional authorities and Amgros use the Public Procurement Directive. Amgros subjects all purchases exceeding a total value of 500,000 DKK (€ 67,000) to a EU procurement process.
Finland	Public procurement procedures relating to the supply of medicinal products are typically organized and managed regionally by a group of (often four) hospital districts. Hospital districts are formed by municipalities (i.e. cities and towns). There are currently 20 hospital districts in Finland.	Hospital districts as well as the municipalities are public entities and qualify as "contracting authorities".
France	In the French healthcare sector, three types of entities that acquire medicinal products and equipment: - Public health institutions (public hospitals); - Private health institutions of collective interest (associations or foundations);	Public health institutions are “contracting authorities” in the meaning of public procurement legislation. Only the public hospitals are required by law to acquire medicinal and medical products through public procurement procedures. On the contrary, private practices are corporations

	- Private practices.	submitted to private law, and private health institutions of collective interest are only encouraged to apply those procedures but are not obliged to do so.
Germany	Public procurement procedures relating to the supply of medicinal products are mainly organized and managed by statutory sickness insurance funds and to a lesser degree by hospitals operated by public bodies, by statutory accident insurances, statutory pension insurances and the federal armed service (BAAINBw).	Based on the AOK-Rheinland case law and on additional national legislation, all the entities listed in the left column qualify as contracting authorities. In recent time, there seems to be a trend in case law to qualify private hospitals as contracting authorities as well even when they are entirely operated by private enterprises. Despite their private form of organisation these hospitals would fulfil public medical services and would not have the goal to earn profits.
Hungary	(i) the National Health Insurance Fund (Országos Egészségbiztosítási Pénztár, "OEP"); (ii) the National Institute for Quality- and Organizational Development in Healthcare and Medicines (Gyógyszerészeti és Egészségügyi Minőség- és Szervezetfejlesztési Intézet, "GYEMSZI"); (iii) in special cases, by health institutions. OEP and GYEMSZI supply the products to the health institutions. OEP procures medicinal products relating to specific active substance of medicinal products and group of diseases, active substance as well as single-use devices and implants; GYEMSZI procures medicinal products, medical devices and disinfectants for the benefit of institutions, which are financed by the Health Care Insurance Fund and provide	All the entities listed in the left column qualify as "contracting authorities", except for privately operated institutions. However, if the procurement launched by a privately operated institution is funded directly by one or more entities falling within the category of "contracting authorities" to an extent exceeding 50% in case of procurements equaling or exceeding the EU threshold, and to an extent exceeding 75% in case of procurements reaching the national threshold but not reaching the EU threshold, the concerned privately operated institution qualifies as "contracting authorities".

	clinical care to inpatients.	
Italy	National NHS institutions, NMA, local healthcare agencies, scientific care and research institutions, hospital institutions, hospital institutions. Private clinics and care institutions accredited with the NHS	All public entities listed in the column on the left are considered public administrations and qualify as contracting authorities in the meaning of the directives. The same applies to consortia or central purchasing bodies acting on their behalf. Private clinics and care institutions accredited with the NHS are not per se subject to public procurement legislation, but they have strict budgetary constraints.
Poland	Public healthcare entities ("ZOZ") Ministry of Health as the major awarding entity. Controlling authorities (Chief Pharmaceutical Inspectorate, Office for Registration of Medicinal Products etc.) – these authorities as such do not acquire any medicinal products but they supervise and control whether all formalities are observed when medicinal products are being purchased by the healthcare sector. Thus, I think they should be deleted here as irrelevant for the question. Non-public healthcare entities ("NZOZ") to the extent they use public funding.	In general, every entity using public funding, in particular financed by central government / territorial government / EU funds is obliged to apply public procurement procedures. The ZOZ and the Ministry of Health qualify as "contracting authorities". The NZOZ would also qualify as "contracting authorities", if they spend public / EU funds or if (i) they are financed in more than 50% by public sector institutions (public companies etc.), (ii) have more than half of shares or stocks owned by public sector or (iii) are supervised by public sector.
Slovakia	1. Public hospitals (e.g. hospitals that are controlled or entirely/predominantly financed by the Slovak Republic, municipalities, higher territorial units ("vyšší územný celok" etc.); 2. Private hospitals, 3. Public Health Insurance Company (Všeobecná zdravotná poisťovňa, a.s.), i.e. the sole public health	Yes, all entities listed in the left column can qualify as "public contracting authorities". However, private hospitals qualify as "public contracting authorities" only if the Slovak Republic, higher territorial unit or municipality provide the private hospital with more than 50 % of the financial resources that are necessary for the delivery of the medicinal products that are being procured. This is the case e.g. when the private hospital

	insurance company in the Slovak Republic; 4. Rescue Services	obtained more than 50% of the financial resources from EU funds in order to buy e.g. medical equipment (e.g. via Operational Program Health). Public Health Insurance Company qualifies as a "public contracting authority" due to the fact that 100% of the shares are owned by the Slovak Republic. Rescue Services qualify as "public contracting authorities on condition they are controlled or entirely/ predominantly financed by the Slovak Republic, municipalities, higher territorial units.
Spain	Healthcare services are provided by the regional authorities (Comunidades Autónomas). The main contracting authorities purchasing medicinal products are: - Regional health departments ("Consejerías de Salud" or "Servicios de Salud") - Public hospitals depending on the abovementioned departments. In some case of centralised purchasing proceedings, the Spanish Ministry of Health awards certain framework agreements	The entities mentioned in the left column qualify as "contracting authorities".
Sweden	County Councils are responsible for healthcare and the supply of medicinal products for inpatient care and to some extent outpatient care.	The entities mentioned in the left column qualify as "contracting authorities".

The Netherlands	Academic hospitals. Non-academic hospitals Elderly homes and home health care	All academic hospitals qualify as 'contracting authority' in the meaning of public procurement legislation. Non-academic hospitals do not qualify as 'contracting authority' according to Dutch case-law, except in the case that a contracting authority has (financial) control over, or supervision on such non-academic hospital. As from 2015, municipalities will operate elderly homes and home health care, which are public bodies and are as from that moment thus regarded as 'contracting' authorities.
UK	Central government Various sub-bodies of the National Health Service (NHS) e.g. NHS trusts/regional collaborative procurement hubs. Department of Health (Commercial Medicines Unit - CMU) or, by NHS bodies in Scotland and Wales.	All central government and NHS purchasers are contracting authorities for the purposes of Directive 2004/18. There are a limited number of private hospitals and care homes (run by companies such as BUPA) which are not contracting authorities.

TABLE 2

National specificities and current trends and issues encountered across jurisdictions

Country	Topic	Comment
Belgium	National specificities with respect to the application of public procurement legislation	The situation in Belgium has evolved significantly with the entry into force, on 1 July 2013, of a whole new legislation on public procurement. Until that date, the legislation that was in force exempted public and private hospitals from the scope of application of the public procurement legislation below the European publicity thresholds[11]. Even above those thresholds, the public procurement legislation was not applied by the hospitals. Since the AOK Rheinland preliminary ruling, the legislation should have been adapted, but it has not been, so that in practice, most hospitals, public and private, have not gone through public tenders for the procurement of medical supplies. That situation has changed since 1 July 2013, as all exemptions have been waived under the new public procurement legislation.
	Therapeutic freedom and substitutability	In Belgium, the principle of therapeutic freedom is still vivid and enforced. The application of public procurement rules may not lead to a diminution of that freedom, but it is still unclear whether hospitals might provide for sufficient supply of medicinal products in order to face specific prescriptions of products that would not have been chosen in the course of a public procurement procedures. From a legal perspective, a negotiated procedure without notice can be used for such orders, insofar the volume of orders does not exceed the threshold of 8.500 euros on a yearly basis that has been set by Royal Decree (in which case the order can be validly placed on the basis of a simple invoice) and/or the recourse to the procedure is duly justified by the urgency of the situation.
	Definition of the subject-matter of the contract	Contracting authorities will generally define the subject-matter of public contracts relating to the supply of medicinal products on the basis of the INN. While different approaches are possible, such as a reference to therapeutic indications in the subject-matter of the contract, or placing orders for whole hospital departments, these approaches make it more difficult to

[11] More precisely, because it was considered at the time that private hospitals were exempted from public procurement rules (in contradiction with the AOK Rheinland case law), the legislator had deemed it necessary, in order to avoid distortions of competition between private and public hospitals, to provide for a provision that would exempt the public hospitals from the application of public procurement rules (Article 115 of the Act of 14 January 2002).

		compare the different offers.
	Discounts and rebates	The Belgian public procurement legislation does not provide for a sophisticated system of discounts and rebates. However, when a public contract is separated in lots, a tenderer may propose discounts linked to the award of several lots. This means that the percentage of discount may be made dependent on the number of lots that would be awarded to the tenderer. This system of discounts and rebates may allow companies proposing a wider range of medicinal products to propose such high discounts in case they would be awarded all lots of a given public contract, and this could have a negative effect on smaller companies of which the portfolio would not be that wide. Therefore, it has been suggested to the healthcare sector that such "conditional rebates" should be limited to a certain amount of lots, which should be identified in advance in the tender documents.
	Award criteria	"Lowest bid" tenders will probably be used in some cases, although the pharmaceutical sector currently seeks the inclusion of other criteria, notably relating to additional services they could provide to the contracting authorities in addition to the mere supply of pharmaceutical products (e.g., training, emergency delivery service, etc.)
Czech Republic	Therapeutic freedom and substitutability	Therapeutic freedom is limited at two levels. First, when prescribing medicinal products for human use, doctors have to proceed in a way that avoids inappropriate or uneconomical handling of medicinal products, taking into account the nature of the disease and the duration of treatment. Second, the Czech reimbursement system contains more than 150 reference groups of therapeutically interchangeable products with similar clinical efficacy and safety. In principle, the basic reimbursement is calculated for every group of therapeutically interchangeable products on the basis of the cheapest ex-factory prices of the products. Since only one or two products in every group would be reimbursed completely, there is some kind of pressure on doctors to prescribe the cheapest products. New rules will enter into force on 1 January 2015. When prescribing medicinal products for human use, doctors will have to proceed in a manner that will avoid discrimination in favour of a pharmaceutical service provider or intervening in the patient's right to choose a pharmaceutical service provider.
	Definition of the	Generally, the definition of the subject-matter of the contract will depend merely on the needs of contracting

	subject-matter of the contract	authorities. Under Czech Public Procurement Act, the subject-matter of the contract should not be defined too broadly, but also not too narrowly. The Contracting entity is entitled to subdivide a public contract into several separate lots only if it is admitted by the nature of the subject-matter of such a contract. In addition, the subject-matter of the contract must include (if possible) the description of the health effect of the product and its diagnostic and therapeutic indication.
	Award criteria	Generally, the price combined with additional technical parameters would be the most common criteria in tenders. Approximately, 25 per cent of tenders are structured as "lowest bid". Moreover, since 2013, public bodies directly subordinated to the Ministry of Health are obliged to use "lowest bid" tenders where possible and even when it is impossible and additional criteria are used, the weight of price criteria must be at least 70 per cent.
	Other	In the Czech Republic, Contracting authorities are generally obliged to cancel the tender if only one tenderer participates (unless very strict conditions are met). This is a big issue for the contracting authorities in healthcare sector, because since there is very often only one unique supplier of the product or service, many tenders must be cancelled repeatedly. Discussion about this problem resulted in the amendment of the public procurement legislation. Since 1 January 2014, it is possible for only one bidder to win the public tender in the situation when the same tender was cancelled once before (if certain other conditions are met).
Denmark	Therapeutic freedom and substitutability	Although the principle of therapeutic freedom exists in Denmark, economic conditions and regulatory requirements apply in connection with the choice of pharmaceuticals. All the regional hospitals' needs for pharmaceuticals are covered through call for tenders organized by Amgros. In practice, hospitals communicate their pharmaceutical needs to Amgros, which organizes global purchases on behalf of all the regional hospitals in Denmark. This centralization has the consequence that pharmaceuticals typically is procured through tenders above the EU threshold. The purchase of pharmaceuticals is influenced by the instructions from RADS. RADS is a national committee that is responsible for ensuring that patients are offered a high level of treatment across the regional hospitals. This is achieved by the issuance of instructions for the medical treatment. Which have to be followed by the hospitals.

		The RADS instructions are based on a medical assessment and they are intended to ensure the best treatment. However, the instructions are also made to ensure that the regional hospitals make the most efficient use of the resources. This is relevant in connection with the choice between similar, e.g. when there is a choice between an expensive and cheap product with the same characteristics.
	Definition of the subject matter of the contract	Amgros primarily uses the Anatomical Therapeutic Chemical (ATC) classification system from WHO. The medicinal products to be procured are thus classified according to the main therapeutic use of the main active ingredient.
	Award criteria	In connection with pharmaceuticals, Amgros awards the contracts to the "lowest bid". There is no knowledge of Amgros planning to use the “most economically advantageous tender” award scheme.
	Electronic tenders system	Suppliers must submit their bid through Amgros' electronic tenders system, which automates the majority of the routine tasks related to the tendering process. This means that the suppliers only have to send the relevant information to Amgros through a secure internet connection. It is a very quick process, because the award criteria is the “lowest price”, and lots are specified by using the ATC classification system. To insure flexibility Amgros uses framework agreements.
Finland	Definition of the subject-matter of the contract	The subject-matter of public contracts relating to the supply of medicinal products is generally defined on the basis of the INN or with a reference to the therapeutic indication(s) of the product(s).
	Discounts and rebates	Discounts are widely used. In practice, tese discounts can be up to 60%, but in most cases they are in the range of around 30%).
	Award criteria	The "economically most advantageous tender" approach is preferred, with award criteria including price, usability, patient and work safety, and expenses incurred from switching from the medicinal product previously used. The "lowest bid" approach is also used, mainly for less sophisticated products.
	Other	The role of the public healthcare system has traditionally been very strong in Finland and the arrangement of social and healthcare-related (public) services is currently widely discussed and debated in the media and

		among political parties. It is possible (or even likely) that a major change/reform in terms of the fundamentals of the system will take place in a near future in Finland.
France	Therapeutic freedom and substitutability	The therapeutic freedom and more precisely the freedom of prescription are recognized under French law. Even in public health institutions, where public procurement rules apply, the doctor's professional independence and freedom of prescription are guaranteed. In addition, hospital practitioners are represented within the Medical Establishment Commission (MEC), that is competent for listing the medicinal products of which the use is recommended. The representation of hospital practitioners within this commission allows them to retain their therapeutic freedom although the purchase of medicinal products is operated by the institution and not directly by them.
	Definition of the subject-matter of the contract	All contracting authorities have to define beforehand the nature and extent of their needs. In the medicinal products field, the need may first be defined qualitatively, that is to say, based on parameters specific to them, according to the International Nonproprietary Name (INN), for example based on their therapeutic category, pharmacologic category or particular anatomical category. The needs can also be defined based on expected outcomes or performance. In addition, the need must, as often as possible, be defined quantitatively including for pharmaceutical products regularly prescribed and used. However, it is rare to have an exact quantitative knowledge of pharmaceutical products in a given period. Public health institutions can use purchase orders contracts to overcome this difficulty.
	Discounts and rebates	Offering price discounts in the framework of a public contract is not common practice. In most cases, it is impossible for a tenderer to propose discount in the event that he would be awarded several lots. However, companies can legitimately, and in the respect of the competition rules, offer a lower price than their competitors, for example because of a different cost structure, a particular innovation or dynamic commercial policy.
	Award criteria	The award criteria of tenders will most often be based on the technical and clinical value of the products, their overall running costs, the associated delivery costs, delivery times, the security of supply or their cost

		throughout their life cycle. The criteria related to delivery time, the ease or security of supply can be decisive criteria to purchase products such as pharmaceuticals ones that have special requirements as to their destination: emergency care, quick assistance…
Germany	National specificities with respect to the application of public procurement legislation	Above the European publicity thresholds, statutory sickness insurance funds apply the legislation on public procurement. The legislation is not applied as thoroughly for medicinal aids. Reason for this lies in part in the possibility to procure these aids via a kind of open book contracting model, to which interested suppliers can become a contracting party even after the initial contract was signed. The other listed contracting authorities (with the exception of the BAAINBw) only seldom apply the legislation on public procurement.
	Generic pharmaceuticals	Since the statutory introduction of allowance contracts in relation to generic pharmaceutical products in 2006, litigation regarding the procurement of these contracts has covered most of the controversial topics in national and European procurement law. Some of these are e.g. the need to sub-divide contracts into lots, award criteria, currency clauses, questions regarding the conclusion of contracts with more than one pharmaceutical company (division of market share between the companies), the question regarding what kind of information is needed by the tenderer to calculate his price, the possibilities to tender as a group of suppliers and/or to subcontract.
	Biosimilar, cytostatic and/ or patented pharmaceuticals	Since all of the statutory sickness insurance funds are under constant pressure to keep costs under control and because of the success with allowance contracts both in patient compliance as well as economically, there has been some effort to tender allowance contracts for biosimilar / bioidentical / cytostatic and / or patented pharmaceuticals. A recent case law in December 2013 ruled that the statutory sickness insurance funds must apply the legislation on public procurement and perform proper procurement procedures for patented pharmaceuticals as well.
	Medical Aids	Since there is only limited opportunity for competition between the different statutory sickness insurance funds, most of these insurances have been very reluctant in applying the public procurement legislation to the full range of medicinal aids, fearing that a one-sided supply strategy of medical aids might lead to difficulties regarding the security of supply, negative patient compliance and therefore to a loss in members and a shrinking market share. There is also the question of sub-dividing the contracts to ensure close to home supply

		and support services. There have been some flagship projects and it stands to reason that there will be an increase in public procurement of medical aids in the near future.
	Primary care physician centred care and integrated care concepts	It is by now generally accepted that contracts for integrated care concepts and (in special cases) contracts for primary care physician (PHP) centred care have to be tendered. The statutory sickness insurance funds are very reluctant to contract PHP centred care contracts, fearing an increase in costs. Integrated care concepts are on the rise, though most of these contracts are – with the exception of some flagship projects – not tendered.
Hungary	Therapeutic freedom and substitutability	In Hungary, the principle of therapeutic freedom applies, and can be relied upon in the following hypotheses : • in case of extreme urgency, justified by the need for therapeutic treatment, a negotiated procedure without notice may be used. • The need for immediate provision of clinical care must be proven. Immediate provision of clinical care is necessary, if the patient would be in a direct life-threatening situation, incur serious or irreversible damage to health and the life expectancy and the quality of life would be affected adversely. • The approval of the head of the competent healthcare body or medicinal public body is necessary to the justification of extreme urgency. • The circumstances invoked to justify extreme urgency must not in any event be attributable to the negligence of the contracting authority.
	Definition of the subject-matter of the contract	The subject-matter of the public procurement may be defined on the basis of (i) the specific indication of the medicament concerned; or (ii) all indications of the medicament which is authorized to being put into circulation. Regarding the technical specification, the subject matter may be determined by referring to (i) the provisions of the related laws; (ii) in case of medicaments, the ATC and OENO codes; (iii) in case of medical devices, ISO, GMDN, EAN or OENO codes. In case of medicinal products, the subject matter of the public procurement is determined by considering the active substance or group of active substance listed in the nationwide basic medicament list applicable to hospitals.
	Discounts and rebates	A contracting authority may prescribe the obligation to provide rebate on goods and determine the amount of the rebate. Aside from this provision, the Hungarian public procurement legislation does not provide for a sophisticated system of discounts and rebates.

Italy	National specificities with respect to the application of public procurement legislation	Public procurement procedures relating to the supply of medicinal products are increasingly organized and managed by central purchasing bodies. The main central purchasing bodies act at the regional level, but attempts to introduce national centralized purchases are under way.
	Therapeutic freedom and substitutability	In Italy, the principle of therapeutic freedom is not always respected. The economic downturn, together with the crisis of public finances and the fact that healthcare spending is the main component of national public expenditure, spurred exceptional measures to further drive down prices from 2011 onwards and to limit public healthcare expenditure. A system of national expenditure thresholds and per company budgets, that if exceeded makes it mandatory for the manufacturers of medicinal products to pay back to Regions part of their revenues, has been further tightened. Furthermore, many Regions adopted rules which make it mandatory for local healthcare institutions to purchase only the cheapest available products on the market. Such measures are increasingly limiting the freedom to prescribe of doctors and consequently the therapeutic freedom of the contracting authorities. It is therefore unclear whether hospitals and other local healthcare institutions might provide for sufficient supply of medicinal products in order to face specific prescriptions of products that would not have been chosen in the course of a public procurement procedure. From a legal perspective, a negotiated procedure without notice can be used for such orders, insofar the volume of orders does not exceed the threshold of 40.000 euros per contract.
	Definition of the subject-matter of the contract	Contracting authorities define the subject-matter of public contracts relating to the supply of medicinal products on the basis of the INNs. However debate still exists in Italy in case of supply of certain medicinal products (e.g. biological medicinal products and relating biosimilar) where it is unclear whether it should be used as a basis the specific product. While different approaches are possible, such as a reference to therapeutic indications in the subject-matter of the contract, or placing orders for whole hospital departments, these approaches make it more difficult to

		compare the different offers.
	Discounts and rebates	The Italian public procurement legislation does not provide for a sophisticated system of discounts and rebates. In the event a tender is divided into several lots, each lot is treated separately from the rest and conditional offers or conditional discounts are not permitted. Furthermore, the base price for the tender is freely set by the contracting authority. Due to the rigidity of the system, is not uncommon to come across borderline practices such as "free" supply of items or services, free loans of equipment, training etc.
	Award criteria	The type of award criteria may vary according to the nature of the product (medical devices, medical or medicinal products, and amongst medicinal products which type of medicinal products – e.g radiopharmaceuticals). The most common type of award scheme used for common medicinal products is the "lowest bid" scheme. M.E.A.T. is commonly used for medical devices and certain medicinal products where additional services can be provided to the contracting authorities in addition to the mere supply of a product.
	Other	In the general trend towards drastic cuts in the healthcare spending, the national public procurement authority (AVCP) has been tasked in 2012 with conducting a general survey of prices of medicinal products and medical devices purchased by local institutions nationwide, in order to set a list of national average "reference prices" for each product. Such "reference price" has two effects: it gives all SSN bodies the legal right to renegotiate prices that are at least 20% higher than the reference price under threat of contract termination, and it makes the "reference price" as starting price for further tender procedures. The system has come under heavy criticism but seems to be bound to survive judicial scrutiny.
Poland	National specificities with respect to the application of public procurement legislation	The Polish Public Procurement Act has to be applied by the "contracting authorities", unless the contract value does not exceed 14.000 EUR. NZOZ usually organize ordinary tenders under Polish Civil Code rules (unless bound by the Polish Public Procurement Act when they need to apply specific public procurement procedures).
	Therapeutic freedom and	In most cases, hospitals do not consider prescriptions requirements specified by doctors while ordering medicinal products in the course of public procurement procedures. Choosing different products or substitutes in practice is possible only within the resources available at the hospital. The principle of therapeutic freedom

	substitutability	is almost impossible to enforce in case of reimbursed medicinal products, as the hospitals are very often forced to order a specific product to be consistent with the Reimbursement Act, which are the products with the lowest price. However, in many cases there is only one product included in the reimbursement list in the given product category and no substitutes. Nevertheless, doctors may have an indirect impact on the list of ordered products, as the hospitals start to implement medicines management programs and are more and more often trying to avoid grouping of orders.
	Definition of the subject-matter of the contract	Contracting authorities will generally define the subject-matter of public contracts relating to the supply of medicinal products on the basis of the INN. However, usually they also indicate the trade names of the specific products as examples. From the legal perspective, the indication of specific trade names is not binding for the supplier. Moreover, as under the Polish Public Procurement Act the hospital has to provide equal opportunities and fair competition for all tenderer, indication of specific trade names instead of the INNs could be considered as violation of this rule, unless justified by the fact that the product in question is the only product available in a given category.
	Discounts and rebates	Under Polish law, hospitals are obliged to buy reimbursed medicinal products at a price which is not higher that the official sale price plus the official wholesale margin, if applicable. This results in fixed prices for reimbursed medicinal products. Moreover, the law explicitly forbids any subjects involved in the manufacturing and wholesale of medicinal products to offer hospitals any discounts or rebates. These prohibitions are currently strongly discussed. In a recent communication the Polish Ministry of Health stressed that the official price of the reimbursed medicinal products should be regarded as a maximum price. Hence, the wholesalers are allowed to offer lower prices to hospitals.
	Award criteria	Polish law requires that the price constitutes an award crierion with at least 50% of the weighted value of all award criteria. The"lowest bid" award scheme is used in approx. 85 % of the cases. However, hospitals also use other awarding criteria such as delivery term, additional services (workshops or trainings).
Slovakia	National specificities with respect to the application of public procurement	Until 9 March 2012 there existed an exemption from the application of the rules of public procurement which applied to procurement of vaccines by the health insurance company. From 2006 until 2008, Slovak legislation on public procurement explicitly did not apply, among others, to the procurement of drugs and medical instruments by the health insurance company.

	legislation	
	Therapeutic freedom and substitutability	Therapeutic freedom is partially curtailed due to the fact that certain drugs are subject to the so-called "generic prescription", i.e. prescription of drugs via the active pharmaceutical ingredient as opposed to the prescription of the specific drug. However, generic prescription concerns only a limited number of drugs.
	Award criteria	"Lowest bid" is used in almost all published tenders in the healthcare sector.
	Other	According to a survey on public procurement practices conducted from 2009 to 2012 by the Slovak hospitals, in more than 50 % of the tenders, only one bid was submitted. In only 6 % of the cases, at least five bids were submitted.
Spain	National specificities with respect to the application of public procurement legislation	As a general principle, where medicinal products can be provided by two or more suppliers, the open procedure is the most commonly applied. Framework agreements are also common.
	Therapeutic freedom and substitutability	Although therapeutic freedom is expressly recognized by law, it encounters some restrictions in the scope of the National Healthcare Service. Within the National Healthcare Service (NHS), medicines have to be included in the NHS's official list in order to be prescribed and, when prescribing medicines, doctors should apply criteria that encourage prescription by active pharmaceutical substance. Both in cases of acute isolated processes or when initiating treatment for chronic processes, the prescription should be made by reference to active pharmaceutical substance. However, when prescription is related to the continuity of treatment for chronic diseases, medicines under its trade names might be prescribed. There are also some exceptions to the "prescription by pharmaceutical substance" rule, provided the principle of efficiency of the NHS is respected, or also in cases of non-substitutable medicines. The criteria used for the definition of lots in a public contract for the supply of medicines recently caused controversy. A ruling of the Central Administrative Court of Contractual Appeals) has supported the grouping criterion used by the contracting authority, which was based on the active pharmaceutical substance.

	Discounts and rebates	Spanish law expressly prohibits offering rebates or incentives to healthcare professionals, as individuals, in particular to doctors, pharmacists or managers responsible for prescribing, dispensing or managing medicinal products, in order to ensure their independence. However, this prohibition does not apply to the rebates that could be offered not to individuals with specific independence obligations (doctors, pharmacists, public servants…) but to healthcare providers, i.e. as public bodies or organizations, when acquiring medicinal products by means of contractual proceedings. In other words, suppliers are allowed to offer discounts in the framework of public tenders, i.e. early payment discounts or discounts depending on purchase volume.
	Award criteria	Price can be the only award criteria. However, in practice, price is usually combined with other award criteria related to technical requirements or other services that could be provided to the contracting authorities.
Sweden	National specificities with respect to the application of public procurement legislation	It is common that the procurements are coordinated regionally and sometimes nationally (for example procurement of vaccine for national vaccination programs). In 2011, the Swedish Association of Local Authorities and Regions, together with the councils and regions, initiated a national project called ELIS (Streamlining Pharmaceutical Procurement in Cooperation). The project aims at developing proposals on how pharmaceutical procurement can be streamlined and organized on short and long term with regard to the opportunities for innovation, synergies, trade-offs in relation to patient safety, cost-effectiveness etc. The first coordinated procurement was carried out in 2013. It concerned a procurement of drugs for Gaucher Mb, and it has further planned/initiated procurements of vaccines in the national childhood vaccination, procurement of cephalosporins and electrolytes in non confusingly similar packaging and procurement of X-ray contrast agents and chemotherapy.
	Therapeutic freedom and substitutability	There is a freedom of prescription. Should the drug in question not be included in the list of drugs already publically procured by the council, it is assumed that a negotiated procedure without notice, or - if below the threshold value - a so called "direct procurement" (value below 28 % of the threshold value, situations that would allow negotiated procedure without notice or extraordinary situations) could be used depending on the situation. However, there are strong recommendations from the councils to prescribe/use already publically procured pharmaceuticals and the councils strive to avoid this situation by carefully planning their procurements.
	Discounts and	There is no national system for discounts/rebates. However, in their procurements, the county councils can achieve rates that are lower than the prices established by the TLV (The Dental and Pharmaceutical Benefits

	rebates	Agency, the government agency that i.a. decides how much a medicine or a medical device in the high-cost threshold should cost and determines what margin pharmacies should use when selling products, meaning the difference between the wholesale and retail prices). A study published by the OECD in 2007 estimated the county councils discounts of 8-10 percent. The county councils' own forecasts and reports of drug costs show that the rebates in 2009 lowered the total cost of inpatient drug with between 11 and 14 percent.
The Netherlands	Therapeutic freedom and substitutability	In the Netherlands, a "Preference Policy" (Preferentiebeleid) is in place. Most of the health insurance companies apply this Policy. This means that from a group of medicinal products having the same active ingredient, (individual) health insurance companies designate a specific medicinal product which will be reimbursed by them. Designation will usually occur based on the best price, but other conditions may be of value as well. We have not come across public procurement procedures of medicinal products by health insurance companies. The Preference Policy may be elaborated in a transparent way, or by way of a closed envelope (onder 'couvert'). As regards therapeutic freedom, Dutch law provides that in case it would be medically irresponsible to treat a specific patient with a designated medicinal product, it would be possible to replace and reimburse the designated medicinal product. Thus, only in case it is medically necessary, the designated medicinal product may be replaced by another product. As regards (generic) substitutability, the pharmacist may only substitute the prescribed medicinal products in case the prescriber and the patient agree. According to a recent manual published by the Dutch Pharmacists Association (KNMP), a biological should not be substituted with a biosimilar if the patient has already been dispensed the biological. Prior to such substitution, compatibility/substitutability of the biological with the biosimilar should be confirmed in such studies. However, if a biological is dispensed for the first time, there are no objections against the substitution by a biosimilar. In any event, the medical practitioner is supposed to use the generic term for its prescriptions and hence, the pharmacist should be free to make its choice for the supplier of the medicines. That is different if the practitioner uses a trademark.
	Award criteria	"Lowest bid" tenders will also in the Netherland probably be used in some cases, although most tenders regarding medical devices will award the tender on the basis of the "most economically advantageous tender" (MEAT), notably relating to additional services they could provide to the contracting authorities in addition to the mere supply of the medical devices (i.e. training, plan of collaboration emergency delivery service, etc.)

		and some price-related criteria (i.e deviation from the average price).
UK	National specificities with respect to the application of public procurement legislation	Use of collective purchasing and framework agreements is common so that individual bodies do not have to undertake lengthy procurement processes every time they purchase medicinal products or medical equipment. Current rules are contained in the 2006 Public Contracts Regulations (new rules are due to be implemented in 2015, with choice of procedure getting broader). Procurement can be either at local level (e.g. directly with hospital), a regional framework agreement (e.g. through collective procurement hubs) or a national framework agreement (e.g through NHS supply chain). Historically, tendering for pharmaceuticals was focussed on hospital medicines often at the end of patent life but it is now used much more widely to procure medicines earlier in their patent protected period. Many of the hubs use the CMU to run their tenders for pharmaceuticals. There are no central procurement agreements for "specials". For contracts below the European thresholds, the general principles of transparency and equal treatment still apply. The majority of pharmaceuticals tenders use a restricted procedure (separate qualification stage) but framework agreements are also commonly used, and there are other options (e.g. open procedure, or competitive dialogue for medical devices) Most medical equipment is procured by NHS Foundation Trusts, although General Practitioners also now have powers to purchase on their own behalf through GP Commissioning bodies. NHS Supply chain carries out centralised procurement of medical devices (amongst other things, but not medicinal products) and trusts can place orders under framework agreements established and managed by NHS Supply Chain, or under framework agreements established and managed by "hubs" or General Procurement Organisations (alternatively they can place orders under pan-government contracts or run their own tenders). There is an increasing tendency to encourage pre-tender engagement; pre-procurement market research is allowed (and encouraged).
	Therapeutic freedom and substitutability	The decision to purchase a branded drug for a particular condition is ordinarily informed by relevant guidelines drawn up by the National Institute for Health and Care Excellence (NICE). Some types of treatment are not covered by NICE guidelines and then there is more therapeutic freedom when it comes to purchasing and prescribing drugs. (Scotland has a separate system). In terms of medical devices, the current NHS procurement improvement initiative aims to better identify

		opportunities for product substitution through NHS supply chain.
	Definition of the subject-matter of the contract	The Department of Health Commercial Medicines Unit tenders for framework agreements for branded, generic and specialised medicines, on a rolling work plan basis. Generics contracts are typically national in scope meaning that any acute trust within the NHS can purchase under them. For solid dose generics, 100% of the English market is offered at the same time and it is generally possible to award all the business to one supplier as there is a range of buyers; for injectable generics 33% of the English market is tendered at a time (since secondary care is the only market, so to help avoid a monopoly and manage supply) and ideally awards are made to more than one supplier. Historically, branded contracts tended to be regional in scope (i.e. CMU tendering on behalf of regional groups), but national contracts for branded medicines are known. For pharmaceuticals just coming off patent, 100% of the English market is usually tendered but the duration is shorter than for normal frameworks.
	Discounts and rebates	Competitive proposals linking price to volume can be made. One of the aims of the current initiative to improve NHS procurement is to better maximise the purchasing leverage of the NHS. Section 6.45 of the 2009 PPRS Agreement (the UK -wide Pharmaceutical Price Regulation Scheme for branded prescription medicines supplied to the NHS) states that: "Pharmaceutical companies may continue to offer schemes or discounts to the local NHS outside NICE appraisals so long as these do not contravene any aspect of the PPRS, but decisions on whether to participate in such schemes and the terms on which they are offered are matters for the relevant pharmaceutical companies and the local NHS."
	Award criteria	Most tenders are evaluated on the basis of the "most economically advantageous" criterion, although there has recently been an increasing tendency to weight cost more heavily than quality, with other criteria such as product training / range and customer support depending on the nature of the contract subject matter. There has been some recent (controversial) trialling of "therapeutic tendering" for some specialist commissioning, where the goal of the tender is a specific therapeutic outcome. Under recently announced changes to NHS procurement, simply considering price, rather than quality as the only award criterion will be discouraged - the NHS is aiming for more consistent tendering throughout the organisation with more outcome-focussed award criteria i.e. more emphasis on clinical outcome data / long term value alongside commercial considerations. New procurement standards aim to ensure that SMEs, charities and other "encouraged businesses" are given opportunities to supply.
	Other	NHS procurement is complex and constantly evolving; there are many different procurement routes with different peculiarities, and very little consistency across the NHS at present. Going forward, a "Procurement

		Development Programme for the NHS" will attempt to address this. An e-procurement strategy is currently being launched. Combined purchasing (for example, through purchasing consortiums) and the use of framework agreements is very common in the UK with the intention of aggregating spend to reduce costs and reduce procurement spend. There have been some complaints about the way in which these framework agreements have been utilised in practice although we are not aware that legal proceedings have been brought. Currently, NHS Trusts tend to use procurement partners as a source of framework agreements, picking the ones that suit their needs. Recent initiatives by the Department of Health's Procurement, Investment and Commercial division are aimed at streamlining and improving the NHS procurement process.

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