

ÖBIG Forschungs- und Planungsgesellschaft mbH



# **Tendering of Pharmaceuticals in EU Member States and EEA countries**

## **Results from the country survey**

**Final version**

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# ÖBIG Forschungs- und Planungsgesellschaft mbH



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# 1 Project Outline

## 1.1 Background

In the course of the Pharmaceutical Forum, which was established by Vice President Verheugen and Commissioner Kyprianou in June 2005 to examine the competitiveness of the European-based pharmaceutical industry and related public health issues, some of the most crucial issues outstanding from the G10 Medicines process, in particular Information to Patients, Relative Effectiveness and Pricing/Reimbursement are being dealt with. The three technical Working Groups, supported by a Steering Committee, are aiming at sharing experiences and exploring possible concrete and practical ways forward.

The Working Group on Pricing and Reimbursement was established in February 2006 and focused its work mainly on four work streams:

- Control of expenditure, including use of price control and the variety and impact of national cost-containment strategies in line with Member State responsibilities for pricing and reimbursement decisions and ensuring the sustainability of their health systems.
- Access to pharmaceuticals, for all patients within Europe, including availability and affordability issues.
- Market and trade, including organisation of distribution and cross-border trade of pharmaceuticals.
- Transparency of pricing and reimbursement data, exchanged between Member States

In 2006 the Directorate General Enterprise and Industry commissioned the Andalusian School of Public Health (EASP) to conduct a report on “Analysing the differences and communalities in pricing and reimbursement systems in Europe”<sup>1</sup>, which was published in 2007. The purpose of this study was, on the one side to obtain an updated, overall picture of the application of pharmaceutical policies and practices in European countries and on the other side to build an in-depth understanding of six selected policy practices (direct product price regulations, cost-sharing, reference pricing, payback, providing incentives for more efficient prescribing, generics’ policy) as implemented in different countries. A further outcome of this report was the “toolbox” exercise performed on behalf of the Pharmaceutical Forum.

The Progress Reports 2006 and 2007 of the Pharmaceutical Forum provided the mandate for further work for the three Working Groups. Based on the Progress Reports the Commission has developed a work programme 2007-2008 that was discussed at the meeting of the Working Group on Pricing and Reimbursement on 1 October 2007.

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<sup>1</sup> Espin, J., Rovira, J., Analysing the differences and communalities in pricing and reimbursement systems in Europe. DG Enterprise and Industry, June 2007

In the planned work programme it is foreseen to further develop and pilot the guiding principles for good practices, focusing on specific examples (conditional pricing, risk sharing agreement, national pricing/recommendation, availability in small Member States, availability of orphan medicines).

Following the discussions of 1 October 2007 in the Working Group on Pricing and Reimbursement, several stakeholders as well as Member States showed interest to extend this list to include the topic “Tendering”. In the Working Group on Pricing held on 12 December 2007, based on a proposal by ESIP (European Social Insurance Platform), the group decided to explore the practice / use of tendering for pharmaceuticals in the EU Member States and EEA countries. On behalf of ESIP, the Main Association of Austrian Social Health Insurance Institutions commissioned the Austrian based research institute, ÖBIG Forschungs- und Planungsgesellschaft mbH (further: ÖBIG FP) to conduct a study on “Tendering of pharmaceuticals in Europe”.

## 1.2 Objectives

The Working Group on Pricing and Reimbursement has observed a need for increased knowledge on the application of tendering procedures in the European Union as well as the potential benefits and risks.

This report therefore aims at

- presenting an overview (“**landscape**”) of existing tendering practices and their characteristics as well as
- analysing the methodology and the procedures of the current tendering systems in Europe.

The core deliverable is – literally – to draw a map of the current tendering situation to illustrate which countries are currently using tendering for which types of markets, patients or products and how they have designed the respective public tendering system(s).

## 1.3 Methodology

### Survey

As with other Guiding Principles the chosen method to explore the experiences of Member States (MS) with public tendering of pharmaceuticals was a survey using an electronic questionnaire.

The first version of the questionnaire was drafted by ÖBIG FP to cover the retail as well as the hospital market.

After approval of ESIP, it was sent out to the country representatives in the Working Group on Pricing and Reimbursement on 24 January 2008.

In the subsequent meeting of the Working Group on 13 February 2008 the questionnaire was enlarged by questions regarding the criteria applied for awarding a tender and regarding the results of the tendering procedure to be published or not (cf. final questionnaire in the annex). It was then sent out by the Secretariat of the Working Group on Pricing with the request for completion by 21 February 2008.

## Response rate

In total 20 countries out of the 30 countries participating in the Pharmaceutical Forum Working Group on Pricing, as reflected in the country overview beneath, completed the circulated questionnaire which equals a response rate of 66.6 %, as shown in Figure 1. For four of the 20 responding countries, the results are based on the 1<sup>st</sup> version of the questionnaire.

In the following part an analysis based on the responses received from the questionnaires as well as additional clarifications from telephone conversations has been conducted. In the tables the following country abbreviations have been used:

AT	Austria	LT	Lithuania
BE	Belgium	LU	Luxembourg
BG	Bulgaria	LV	Latvia
CY	Cyprus	MT	Malta
CZ	Czech Republic	NL	Netherlands
DE	Germany	PL	Poland
DK	Denmark	PT	Portugal
EE	Estonia	RO	Romania
EL	Greece	SE	Sweden
ES	Spain	SI	Slovenia
FI	Finland	SK	Slovakia
FR	France	UK	United Kingdom
HU	Hungary	CH	Switzerland
IE	Ireland	IS	Iceland
IT	Italy	NO	Norway

## Definition

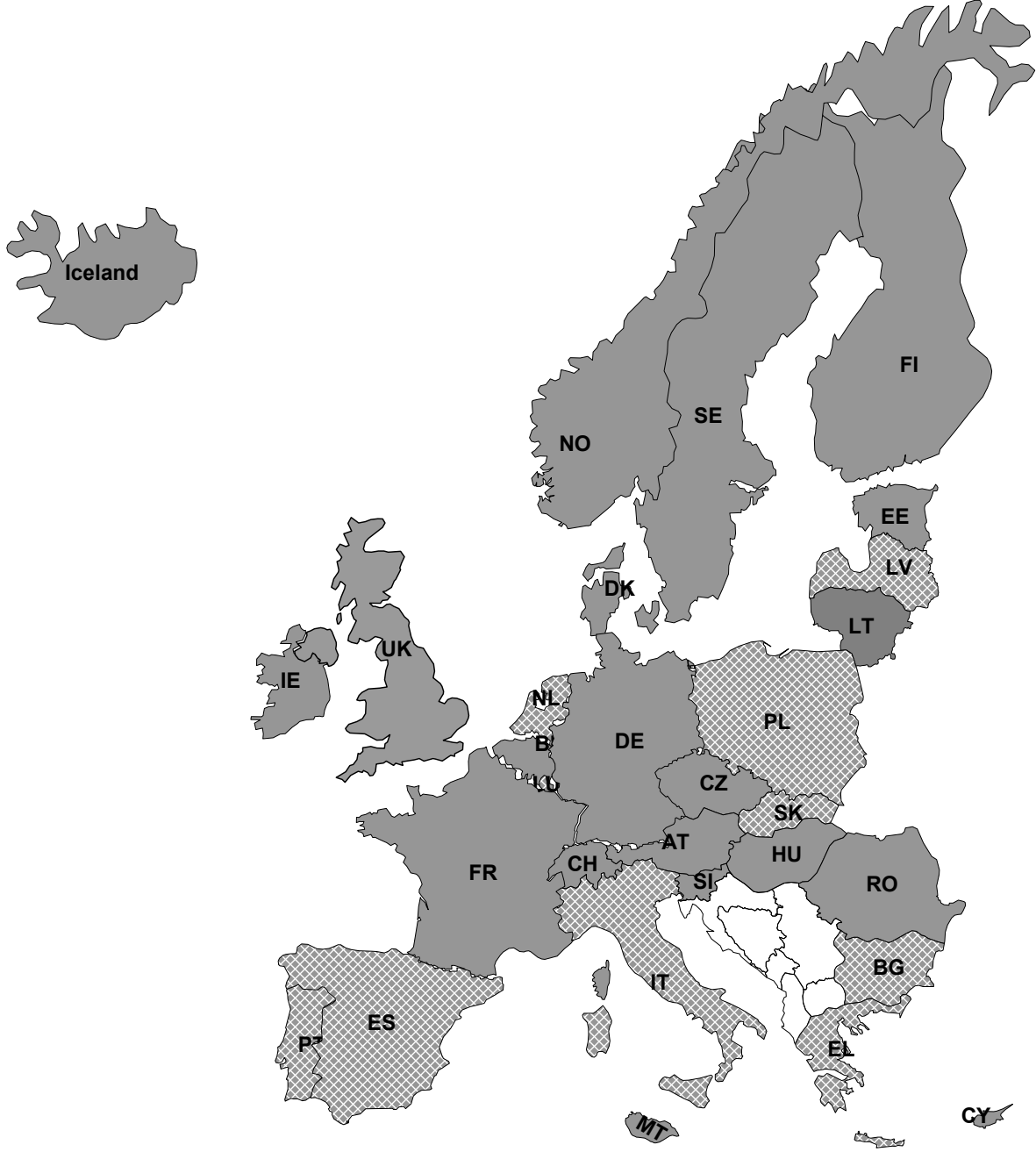
Tendering is defined as:

*“Buying pharmaceuticals by purchasers like public hospital associations on the basis of a – often strictly defined – tendering procedure with granting the contract to the pharmaceutical company / importer who offered the best bid.”*

This definition has been developed by ÖBIG FP together with ESIP as well as in accordance with the Working Group on Pricing and Reimbursement.

However, following the survey this working definition could be further developed.

Figure 1: Overview on replies



■ = filled out questionnaire

▨ = questionnaire not filled out

Source: Tendering Survey by ÖBIG FP, February 2008

## 2 Results

### 2.1 Tendering Systems in the EU Member States and EEA countries

Public tendering of pharmaceuticals is widely used around Europe. In 18 out of the 19 countries participating in the survey tendering systems are in place. Buying pharmaceuticals through a tendering system can either be applied in a hospital settings or in primary care.

As Table 1 shows, all countries use tendering for pharmaceuticals used in hospital settings, some countries additionally used tendering for public functions, such as rather specific product groups (like pharmaceuticals as defined in pandemic plans) respectively for a defined patient groups (for instance soldiers). Only a few countries (BE, CY, EE, HU, IE, LT, MT, RO, SI; IS) use tendering for ambulatory care, cf. Table 1 for an overview.

Table 1: *Tendering Systems in the EU Member States and EEA countries, 2008*

Country	Tendering System in place	Year of introduction	For hospital care	For public functions <sup>1</sup>	For ambulatory care
AT	yes	-	√	√	-
BE	yes	-	√	√	√
CY	yes <sup>1</sup>	Before 1970	√ <sup>2</sup>	√ <sup>2</sup>	√ <sup>2</sup>
CZ	yes	-	√	√	√
DE	no <sup>3</sup>	-	-	-	-
DK	yes	1990	√	√	-
EE	yes	-	√	√	√
FI	yes	-	√	-	-
FR	yes	-	√	-	-
HU	yes	1994	√	√	√
IE	yes	-	√	√	√
LT	yes	1998	√	√	√
MT	yes <sup>2</sup>	-	√ <sup>2</sup>	√ <sup>2</sup>	√ <sup>2</sup>
RO	yes	March 2002	√ <sup>2</sup>	√ <sup>2</sup>	√ <sup>2</sup>
SE	yes	-	√	-	-
SI	yes	January 1998	√ <sup>2</sup>	√ <sup>2</sup>	√ <sup>2</sup>
UK	yes	-	√	√	-

Country	Tendering System in place	Year of introduction	For hospital care	For public functions <sup>1</sup>	For ambulatory care
CH	yes	-	√	√	-
IS	yes	January 2004	√	√	√
NO	yes	-	√	√	-

Ph. = pharmaceuticals

<sup>1</sup> E.g. for military service or pandemic plans

<sup>2</sup> Only valid for public sector (hospital and ambulatory sector)

<sup>3</sup> Sickness funds in Germany can negotiate discounts for pharmaceuticals. It is currently discussed – under involvement of jurisdiction – whether these contractual discounts negotiated by sickness funds are to be considered as tendering or not. The Federal Ministry of Health does not consider this as tendering.

Source: Tendering Survey by ÖBIG FP, February 2008

Only in a few countries (Sweden only for hospital products, and United Kingdom for all pharmaceuticals used in secondary care) all pharmaceuticals are purchased through a tendering procedure.

Besides the hospital sector, tendering is also used for public functions. As Table 2 shows, many countries procure pharmaceuticals for special purpose(s); this could be vaccines, pharmaceuticals as defined in pandemic plans or pharmaceuticals against communicable diseases.

In seven countries (AT, BE, HU, LT, MT, UK; CH) pharmaceuticals for specific customers such as the military, pensioners or prisoners are being procured.

Table 2: *Types of procured pharmaceuticals, 2008*

Country	All ph.	Reimbr. Ph.	Ph. used for public functions	
			Ph. for special purpose	Ph. for specific customers
AT	-	-	Vaccines, ph. as defined in pandemic plans	Military, Pensioners
BE	-	-	Vaccines, ph. as defined in pandemic plans and specific therapeutic groups of pharmaceuticals (molecules indicated by the Minister of Social Affairs)	Military, Prisoners
CY	-	√ <sup>1</sup>	-	-
CZ	-	-	Vaccines, ph. as defined in pandemic plans, ph. relevant for public hygiene in competence of MoH	-
DE	-	-	-	-
DK	-	-	Vaccines, ph. against communicable disease, pandemic	-
EE	-	-	Vaccines, ph. against communicable disease and drug addiction disorders	-



Country	All ph.	Reimbr. Ph.	Ph. used for public functions	
			Ph. for special purpose	Ph. for specific customers
FI	√	-	-	-
FR	-	√	-	-
HU	-	-	Vaccines, ph. against communicable disease, pandemic	Ph. for specific customers
IE	-	-	Vaccines, ph. against communicable disease, pandemic	-
LT	-	√	Vaccines, ph. against communicable disease, pandemic and against oncology	Military and hospitals
MT	-	√	-	Ph. used in government hospitals
RO	-	-	Vaccines, ph. as defined in pandemic plans	-
SE	√ <sup>2</sup>	-	-	-
SI	-	√	-	-
UK	√ <sup>3</sup>	-	Vaccines, ph. against communicable disease, pandemic	Prisoners
CH	-	-	Vaccines, ph. as defined in pandemic plans	Military and hospitals
IS	√	-	-	-
NO	√	-	Ph. as defined in pandemic plans	-

Ph. = pharmaceuticals

<sup>1</sup> only in the public sector

<sup>2</sup> only for pharmaceuticals used in hospital settings

<sup>3</sup> all pharmaceuticals in secondary care

Source: Tendering Survey by ÖBIG FP, February 2008

## 2.2 Institutions in charge of tendering

Pharmaceutical tendering is a complex process which involves several steps/routes as well as stakeholders (agencies, ministries and manufacturers). Depending on the purpose of the pharmaceuticals (e.g. army supply) the institution in charge may differ. Table 3 gives an overview on the different institutions dealing with tendering.

Taking Belgium as an example, hospitals purchase their pharmaceuticals through tendering on an individual basis whereas for the military service the central military hospital is in charge of procuring all pharmaceuticals. The Ministry of Public Health has the responsibility to procure pharmaceuticals defined in federal pandemic plans and the Ministry of Social Affairs defines the centrally purchased pharmaceuticals for the Social Health Insurance. Additionally, the districts such as Flanders, Wallonia and Brussels can initiate tendering procedures. The Ministry of Justice is in charge of purchasing pharmaceuticals through tendering for prisoners.

Table 3: Institutions in charge of public tendering, 2008

Country	For hospitals	For public functions		For ambulatory care	Others
		Military Service	Federal Pandemic Plans	Social Health Insurance / NHS <sup>1</sup>	
AT	Cooperation of several hospitals (e.g. in a region), in rare occasions BBG	Bundesbeschaffungsgesellschaft (BBG) / Federal Procurement Agency		Regional sickness funds	-
BE	Hospitals on an individual basis	Central Military Hospital	Ministry of Public Health	Ministry of Social Affairs	Districts (Flanders, Wallonia, Brussels); Ministry of Justice (prisoners)
CY	Dep. of Ph. Service (MoH)	Dep. of Ph. Service (MoH)		Dep. of Ph. Service (MoH)	Dep. of Medical Service; Service of Public Health
CZ	-	-	Not specified	Not specified	-
DE	-	-	-	-	-
DK	AMGROS / Hospital Purchasing Association	-	State Serum Institute	-	State Serum Institute
EE	-	-	-	Ministry of Social Affairs	-
FI	Hospital districts	-	-	-	-
FR	Purchasing group of Hospitals	-	-	-	-
HU	Hospitals on an individual basis	Military Service	For Vaccines: Ministry of Health	Health Insurance for very expensive ph.	-
IE	Hospitals on an individual basis or the Health Service Executive <sup>2</sup>	Department of Defence	Health Service Executive <sup>2</sup>	Health Service Executive <sup>2</sup>	-
LT	State patient Fund under the MoH, hospitals on an individual basis	Ministry of National Defence	Ministry of Health	Ministry of Health	-
MT	Government Pharmaceutical Services with the Department of Health	-	-	Government Pharmaceutical Services with the Department of Health	-
RO	MoH; National Health Insurance	-	MoH	MoH; National Health Insurance	-
SE	21 Swedish	-	-	-	-

Country	For hospitals	For public functions		For ambulatory care	Others
		Military Service	Federal Pandemic Plans	Social Health Insurance / NHS <sup>1</sup>	
	County Councils separately				
SI	Hospitals on an individual basis	Ministry of Defence, Army	National Goods Reserve Institution	-	Publicly-owned community pharmacies
UK	NHS PASA in conjunction with NHS hospital pharmacy departments	-	NHS PASA (Department of Health)	NHS PASA in conjunction with NHS hospital pharmacy departments	-
CH	Canton Hospital Management	Federal level		-	-
IS	Hospital Purchasing Agencies	-	Directorate of Health (Chief epidemiologist)	-	-
NO	Drug Procurement Cooperation (LIS)	-	Directorate for Health and Social Affairs	-	Municipalities for municipal care services

Dep. = Department, NHS = National Health Service, MoH = Ministry of Health, PASA = Purchasing and Supply Agency, Ph. = pharmaceuticals

<sup>1</sup> Ambulatory care

<sup>2</sup> Health Executive Body is a government body under the National Health Service

Source: Tendering Survey by ÖBIG FP, February 2008

## 2.3 Legal basis for tendering systems

Tendering of goods is regulated at EU-level in the Directive 2004/18/EC. All replying countries stated to have implemented this directive into their national law. The national laws not only define the foreseen tendering procedure and the award criteria but also tendering limits / financial thresholds.

Directive 2004/18 introduces criteria for awarding public contracts (Article 53, section 3, Title II), and four detailed procedures (article 28, Chapter V, Title II) in order to make sure tender processes are conducted in a competitive manner across Europe.

In spite of the EU thresholds, the scope of Directive 2004/18/EC of 31 March 2004 is large because it applies to all public contracts except those which are mentioned in the articles of 12 to 18 of the directive (which do not exclude pharmaceutical products, quoted in Annex V with regard to public contracts in the field of defence).

In addition to national laws some countries have implemented national tendering guidelines. Besides these national guidelines international organisations such as the World Health Organisation (WHO), the World Bank and the Organisation for Economic Co-operation Development (OECD) have published different guidelines in the field of public pharmaceutical tendering.

Table 4 offers an overview of the different national laws that are the legal basis for tendering in a country and shows the national as well as EU tendering thresholds applicable in these countries.

Whereas some implementation laws (e.g. Belgian law) are short and only underline the main obligations such as information to applicants and suppliers about the decision taken by the contracting authorities, most of national laws (e.g. AT, CY, MT, UK) are very detailed and describe the scope and content of the rules governing the award for public contracts above and below the thresholds, the criteria for awarding the contracts, the four procedures and time limits set up by the EC Directive 2004/18.

Some national laws introduce more obligations than those imposed in EC Directive, such as a standstill period in Belgium and simplified procedures in Cypriot law.

*Table 4: Legal basis, national guidelines and provision of tenders, 2008*

Country	Law	National Tendering Guidelines	Provision
AT	Procurement law based on EU Procurement Directive 2004/18/EC	Federal Procurement Agency (BBA) regulations	-
BE	Law of 15 June 2006 <sup>1</sup> Decree of 17 May 2006 which introduces the new pharmaceutical procurement system ("kiwi model").	-	-
CY	Law L.12(I)/2006 on the Coordination of procedures for the award of public works contracts, public supply contracts and public service contracts	-	No thresholds for pharmaceuticals, only for services, supplies and construction works
CZ	Act No.137/2006 Coll., on tendering	-	-
DE	n.a.	-	-
DK	Procurement law based on EU Procurement Directive 2004/18/EC	-	EU threshold DKK 1.8 Mio / € 241,500
EE	Yes, but not specified	-	-
FI	Act on Public Contracts (348/2007) and Government Decree on Public Contracts (614/2007)	-	National threshold € 15,000 (estimated value without VAT) EU threshold € 206,000 (estimated value without VAT)
FR	Law No. 2005-649 of June 6 <sup>th</sup> 2005	no legal value	-

Country	Law	National Tendering Guidelines	Provision
HU	2003. CXXIX. Act on Public Procurement; 130/ 2004 (IV.29) Governmental Decree	-	National threshold (2007): HUF 8 Mio. / € 32,000
IE	Procurement law based on EU Procurement Directive 2004/18/EC Policies: HSE Procurement Policy, HSE National Financial Regulations	National Procurement Guidelines; Government Guidelines set by the Department of Finance (NPPPU)	National threshold: < € 50,000 Single quotations, € 50,000 – € 206,000 Public Tender: € 206,000
LT	Law on Public Procurement	-	-
MT	Government Procurement	-	-
RO	Emergency Ordinance 34/2006 on Public Procurement of goods, public works and services Law 337/2006, Law 128/2007, Emergency Ordinance 94/2007	-	-
SE	Law on Public Procurement	-	-
SI	Law on Public procurement Official Gazette of the Republic of Slovenia No. 128 <sup>1</sup> Law on State budget implementation (ZIPRO)	-	Financial thresholds are the same as they are defined in EU Directive 2004/18/EC for Public procurement
UK	Implementation of EU Procurement Directive 2004/18/EC by Statutory instrument 2006 No5, the public contracts Regulations 2006	-	-
CH	Law on Epidemiology; Law on specific vaccines	-	-
IS	Law on Public Purchasing and Procurement	Strategy for purchasing and procurement for the Health institutions	National threshold: IKR 5 Mio. / € 41,895 must be tendered in Iceland. EU threshold: IKR 13,1 Mio. / € 109,974
NO	Law on Public Procurement	-	-

EC = European Community, HSE = Health Service Executive, NPPPU = National Public Procurement Policy Unit

<sup>1</sup> “relative à l’attribution, à l’information aux candidates et soumissionnaires et au délai d’attente concernant les marchés publics et certains marchés de travaux, de fournitures et de services”.

Source: Tendering Survey by ÖBIG FP, February 2008

<sup>1</sup> [www.uradni-list.si/1/ulonline.jsp?urlid=2006128&dhid=86137](http://www.uradni-list.si/1/ulonline.jsp?urlid=2006128&dhid=86137)

Finally, Directive 2007/66/EC of 11 December 2007 should be mentioned. This Directive amends Directive 89/665/EC with regard to improving the effectiveness of review procedures concerning the award of public contracts (to be implemented by the member states before 20 December 2009).

The Council Directive 89/665/EC of 21 December 1989 ensures the application of Directive 2004/18/EC by making compulsory for the member states to establish effective and rapid remedies in the event of infringements of these provisions. The new directive requires public authorities to wait for several days, known as a “standstill period”, before concluding a contract. This obligation gives rejected bidders the opportunity to start an effective review procedure at the time when unfair decisions can still be corrected.

## **2.4 Methodology and criteria in tendering systems**

When analysing tendering systems, it is relevant to understand the different methodologies and criteria used, as well as the frequency of tenders and if the results are being published; a comprehensive overview being given in Table 5.

Regarding criteria for tendering, the main rule established by EC Directive 2004/18 concerning the award for public contracts (article 53, section 3 Title II), is as follows:

*“1. ...the criteria on which the contracting authorities shall base the award of public contracts shall be either:*

*(a) when the award is made to the tender most economically advantageous from the point of view of the contracting authority, various criteria linked to the subject-matter of the public contract in question, for example, quality, price, technical merit, aesthetic and functional characteristics, environmental characteristics, running costs, cost-effectiveness, after-sales service and technical assistance, delivery date and delivery period or period of completion, or*

*(b) The lowest price only”.*

In general, the methodology depends very much on the volume of the tender. In most of the countries either countrywide or EU-wide tenders are being performed. Only one country (CH) uses solely limited tenders hence invited purchaser in specific cases.

In ten countries calls for tenders occur on an annual basis. In five countries (AT, IE, RO, UK; NO) the results of the tendering procedures are being published.

Eight countries (AT, FI, HU, IE, LT, RO, UK; NO) have mentioned lowest price / best offer as one of the criteria which is of relevance when deciding on who to award the tender. Besides best price as award criteria, quality, availability, most reliable supplier and most economically advantageous tender have been mentioned as relevant criteria when choosing the best bidder.

Table 5: Methodology, frequency, criteria and publication, 2008

Country	Methodology	Frequency	Criteria	Publication
AT	Depending on tendering volume: countrywide or EU-wide tenders	Depending on the demand/need	Best price/offer	Yes, in Wiener Zeitung <sup>1</sup> and on BBA website <sup>2</sup> (restricted access)
BE	Countrywide	Annually, at the initiative of the Ministry of Social Affairs	-	-
CY	International Procedure	Bi-annually	-	-
CZ	Countrywide; Limited: only invited purchaser	Annually	-	-
DE	-	-	-	-
DK	Countrywide	Annually	-	-
EE	Depending on tendering volume: international procedure or countrywide	Annually	-	-
FI	EU-wide; Bidding procedure without amendments	1 - 3 years interval	Price, quality, supply, availability	No, but the results are public and available whenever necessary
FR	Countrywide; EU-wide; Bidding procedure with possible amendments; Bidding procedure without amendments	Annually (every two years)	-	-
HU	Limited: only invited purchaser Bidding procedure with possible amendments	Annually	Lowest price; the most reliable supplier	No
IE	EU-wide Competitive Dialogue Procedures Negotiated Procedure	Annually or multi-annually	Most economically advantageous tender	Yes, e-Tenders Website <sup>3</sup> and OJEU
LT	Countrywide; EU-wide; Limited tenders; International procedures	3-4 months before the agreement with the seller is going to end; irregular basis	Lowest price	-
MT	Countrywide EU-wide	3 years	-	-

<sup>1</sup> <http://www.wienerzeitung.at/>

<sup>2</sup> <https://bbg.portal.at/>

<sup>3</sup> [www.etenders.ie](http://www.etenders.ie)

Country	Methodology	Frequency	Criteria	Publication
RO	Countrywide	Annually	Lowest price among the bidders	Yes, Ministry of Communications and Information Technology <sup>1</sup>
SE	EU-wide	Locally decided, most commonly bi-annual	-	-
SI	Depending on tendering volume: Countrywide, Limited: only invited purchaser, EU-wide, Bidding procedure with possible amendments: framework agreement	Annually	-	-
UK	EU-wide	Determined by tendering strategy	Based on published award criteria - generally most economically advantageous tender	Yes, OJEU
CH	Limited: only invited purchaser	Only in specific cases	-	-
IS	EU-wide	Every two years	-	-
NO	EU-wide	Annually	Lowest price among bidders (for tumor necrosis factor-alpha); best economic offer (price, functionality, packing, product spectre, service)	Doffin and TED (Tender Electronic Daily)

BBA = Federal Procurement Agency, OJEU = Official Journal of the European Union

Source: Tendering Survey by ÖBIG FP, February 2008

## 2.5 Tendering volume and possible savings

In order to get an understanding of the tendering quantity (share of annual total sales) countries were asked to categorise their sales for tendering pharmaceuticals in ambulatory and hospital care (cf. Figure 2).

<sup>1</sup> <http://www.mcti.ro>

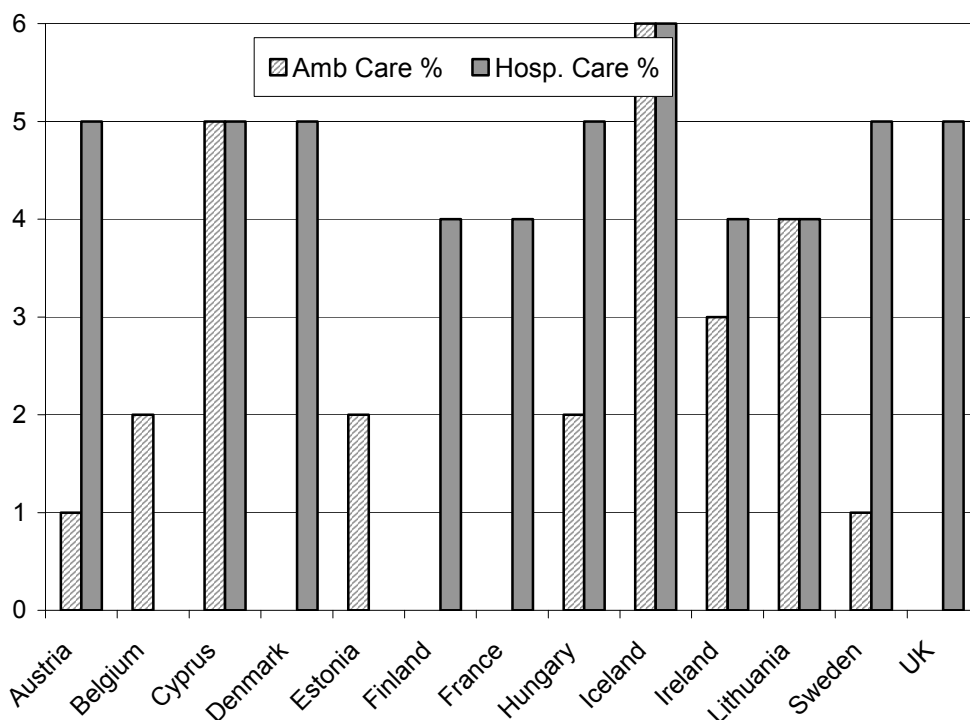


In the questionnaire, countries were asked to choose between five categories to classify their annual total sales for pharmaceuticals which demand tendering. These categories are reflected in the y-axis of Figure 2:

- smaller than 1 % of total sale,
- between 1 % and 5 % of total sales,
- between 6 % and 10 % of total sales,
- between 11 % and 25 %,
- more than 25 % and
- more than 75 % of total sales

In hospital care, eight countries (AT, CY, DK, HU, IE, SE, UK; IS) have more than 25 % annual total sales for tendering; whereas the situation for ambulatory care varies to a large extent among the countries.

Figure 2: Overview on the share of annual total sales for tendering pharmaceuticals in ambulatory and hospital care, 2008



Note: 1 = < 1 %  
 2 = 1 % - 5 %  
 3 = 6 % - 10 %  
 4 = 11 % - 25 %  
 5 = more than 25 %  
 6 = more than 75 %

Source: Tendering Survey by ÖBIG FP, February 2008

## 2.6 Case Studies

When mapping tendering in Europe, it is of added value to look at some countries' tendering system in more detail. Four countries were chosen: Belgium, Cyprus, Hungary and Ireland. Belgium was taken, since a new system has been established. Cyprus uses tendering as an important tool to purchase pharmaceuticals in the public sector. Hungary as an eastern European country and Ireland representing a country with a National Health Service (NHS).

The country examples show that tendering is mainly performed for specific groups of pharmaceuticals as it was already mentioned in section 2.1. These examples also include estimations of possible savings reached through tendering.

### *Belgium*

By the end of 2006, the legal basis for a new tendering procedure (designed for the modification of reimbursement conditions of pharmaceuticals for budgetary reasons) was established based on the principles of 'public tendering' (as e.g. performed in New Zealand). In general terms, a non-direct competitive benefit is offered to the pharmaceutical company - by means of a lower co-payment for the patients for its pharmaceutical - offering the lowest cost (perspective of health insurance and patient) of therapy. In the middle of 2007, the Minister of Social Affairs launched two of these procedures (for Simvastatin and Amlodipin). The tendering procedure launched for Simvastatin in 2007 has resulted in € 15 Mio. savings. The results of the Simvastatin procedure took effect as of 1<sup>st</sup> January 2008. For that reason it is too soon for a relevant evaluation of the results. The procedure itself has been confronted (legally) quite strongly by different companies. For Amlodipin, the procedure is still in progress.

### *Cyprus*

In Cyprus the pharmaceutical system is divided into a private sector (inpatient and outpatient) and a public sector (inpatient and outpatient). All pharmaceuticals in the public sector are bought through tenders and are given to eligible patients without any co-payments or with 50 % co-payment. Whereas in the private sector all patients have to pay the full price for pharmaceuticals out-of-pocket.

In order to analyse the saving achieved through tendering, Cyprus has made a comparison of 75 products available in both the private and the public sector. The cost of these products for their total consumption was approximately CYP 5 Mio. / € 8,543,000 for the public sector but would have cost CYP 8.5 Mio. / € 14,523,112 if they were bought at private sector wholesale prices.

### *Hungary*

In 2007, tendering has been conducted in 11 different therapeutic areas in ambulatory care. In 2008 a new regulation was introduced. The main change introduced by the new regulation

were the reduction of the number of therapeutic areas where tendering is performed (these are products for the treatment of haemophilia and HIV/Aids.)

Even though in recent years significant savings (about 2-3% of the total pharmaceutical budget) was annually realised in ambulatory care, it is believed that considering the changes of the legal environment in Hungary, there are alternative means / financing techniques available to achieve economic efficiency in terms of buying high cost pharmaceuticals.

#### *Ireland*

The Health Service Executive (HSE), a body governed by public law, has been established in recent years and is accountable for its budget to Government. The HSE has established a Tendering Directorate. The HSE is transitioning to a category management approach to its expenditure with dedicated specialist buyers managing the contracting strategies for categories of significant expenditure. The HSE has also established a Corporate Pharmacy Unit to coordinate the approach to pharmaceutical supply and achievement of value for money. A dedicated tendering team is being assigned to support the Corporate Pharmacy Unit in developing and executing strategies to achieve better value for money in the tendering and supply of pharmaceuticals. The most recent tendering initiative – National Pricing Agreement – realised a 5 % reduction in national pharmaceutical expenditure.

### 3 Summing up

Tendering is an important tool for purchasing pharmaceuticals, used in most EU Member States. It is in particular used in hospital settings, but also serves in many countries to purchase pharmaceuticals for a specific public function (e.g. vaccines or for army purposes). Only few Member States apply it for pharmaceuticals in ambulatory care distributed through the retail pharmacies. It could be observed that tendering is mainly performed for prescription-only medicines (POM).

Only Belgium, Cyprus, the Czech Republic, Estonia, Hungary, Ireland, Lithuania, Romania and Slovenia as well as Iceland use tendering for pharmaceuticals in ambulatory care. It is still unclear whether the German discount system, as applied by the sickness funds, is to be considered as a tendering system for ambulatory care. While tendering can easily be used for up to 25% of the medicines in a hospital setting, only Cyprus and Iceland use it for a significant volume of medicines in ambulatory care.

An effective tendering process ensures the availability of the needed pharmaceuticals in the needed quantities, at reasonable prices and at a recognized quality standard. Typically these elements are the main criteria used in tendering processes. The survey yielded that due to tendering an added value may be reached in terms of transparency when using public funds to purchase pharmaceuticals.

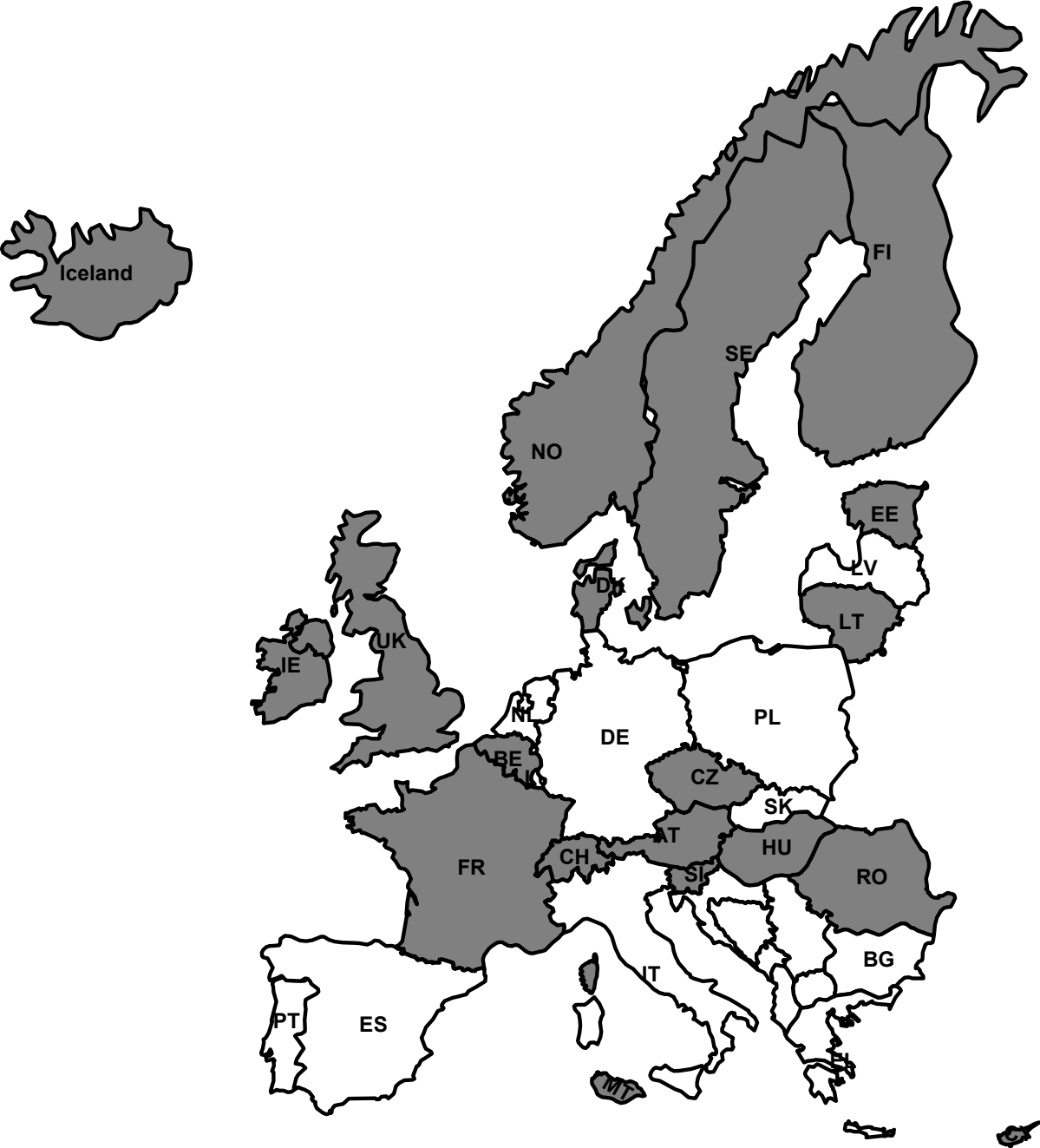
Given the impact of tendering activities on the effectiveness of health services, especially in hospital settings, and given their impact on the competitive industry landscape, it is essential that these activities are performed in a pre-defined and structured framework, meaning that there should be an underlying legal basis specifying e.g. award criteria, the frequency of tenders and the obligation of publishing the outcomes. Hence of further importance is the implementation and the surveillance of tendering processes by competent institutions. All 18 participating countries with public tendering of pharmaceuticals (though in differing volumes) claim to follow EU Procurement Directive 2004/18/EC. Many national systems add to this Directive.

In general, the countries seem to have positive experiences with tendering in hospital settings. Through tendering procedures they achieved lower prices for the purchasers and increased transparency with the use of public funds. But it is also important to mention that some difficulties were experienced in estimating the necessary quantity of the products needed. Additionally, it was mentioned that tendering procedures demand a lot of expertise and resources. In particular for ambulatory care, tendering seems to be relatively new and not much is known to date except that legal complaints significantly complicate the set-up (Belgium) and that dedicated tendering teams might be needed (e.g. Ireland).

Concluding it can be said that tendering is a well established tool to purchase pharmaceuticals in hospital settings. It enhances transparency of the use of public funds. Nevertheless, little evidence is available to date on the value of tendering in the ambulatory

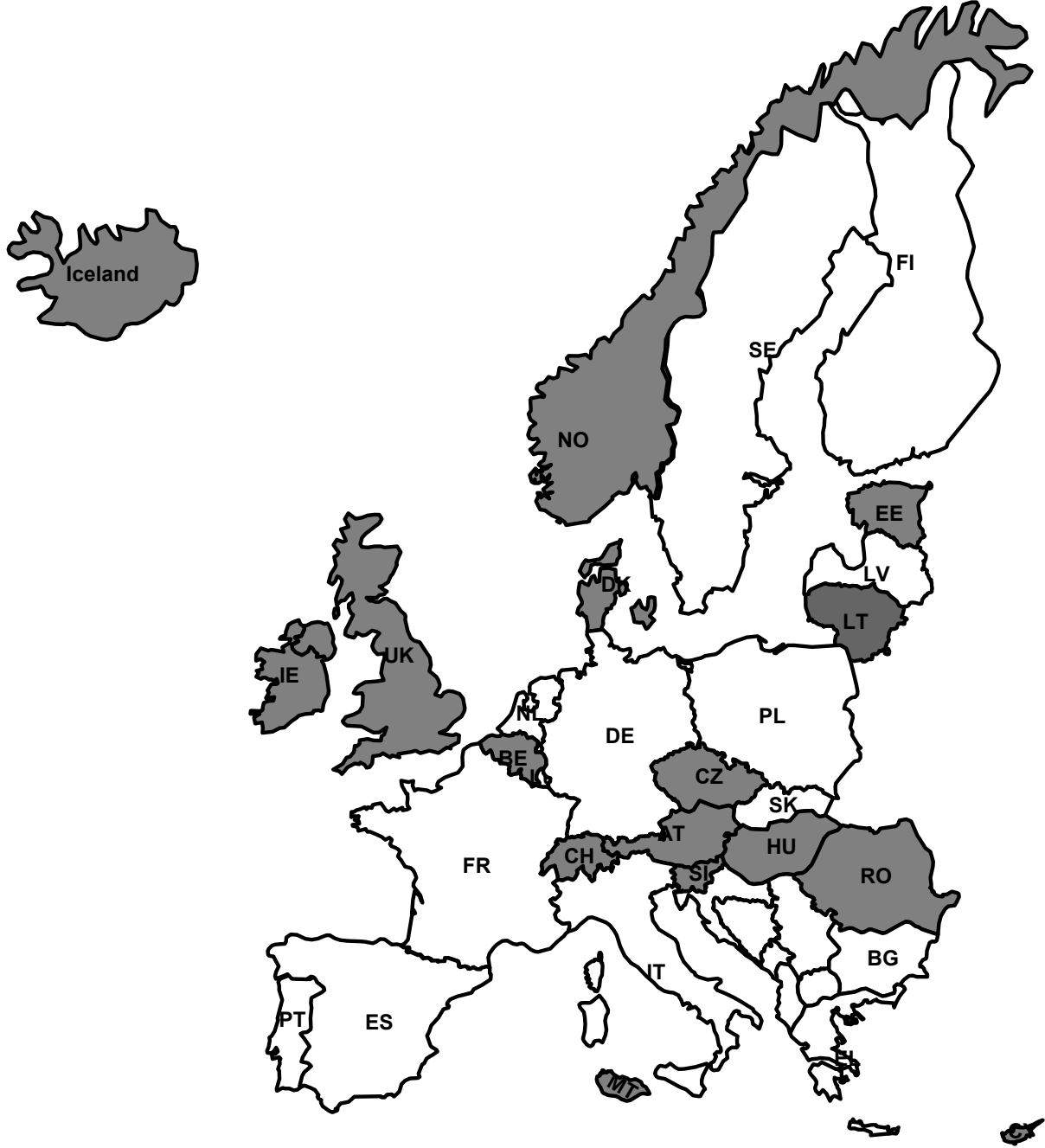
sector. It should therefore not be considered as the major tool used in a pharmaceutical policy. It needs to be seen in the context of other policy tools.

Figure 3: Map of tendering in Europe in the hospital market, 2008



■ Tendering for pharmaceuticals for hospital Care  
Source: Tendering Survey by ÖBIG FP, February 2008

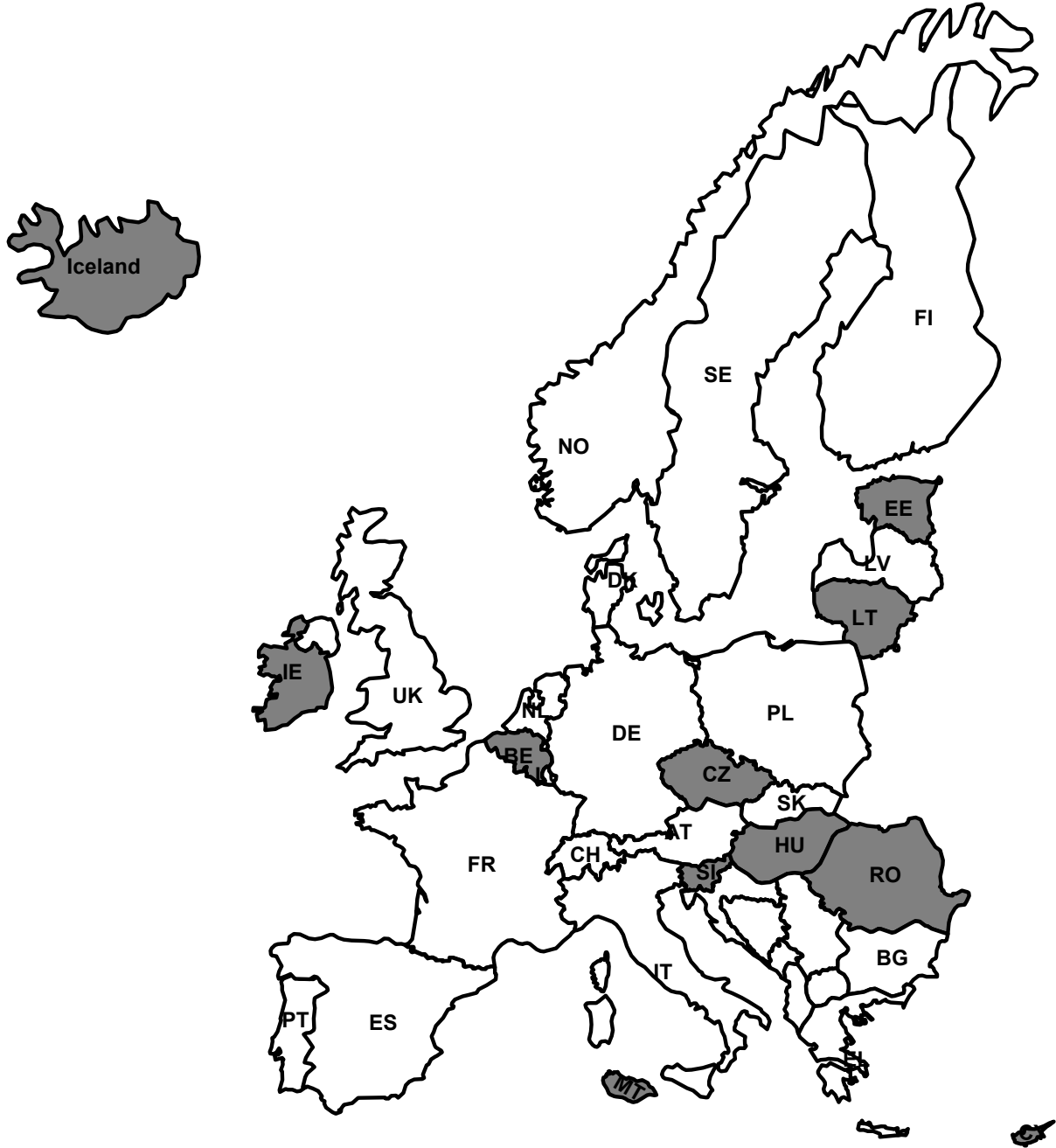
Figure 4: Map of tendering in Europe for public functions, 2008



■ Tendering for pharmaceuticals for public functions

Source: Tendering Survey by ÖBIG FP, February 2008

Figure 5: Map of tendering in Europe for ambulatory care, 2008



■ Tendering for pharmaceuticals for ambulatory care

Source: Tendering Survey by ÖBIG FP, February 2008

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# Annex

Final questionnaire

# Tendering of Pharmaceuticals in Europe

## QUESTIONNAIRE

In the last session of the WG Pricing of the Pharmaceutical Forum held on 12 December 2007 it was agreed that ESIP will explore the occurrence / use of public tendering for pharmaceuticals in the EU Member States. The objective is to further develop and pilot the “**Guiding principles for good practices**” for the “Toolbox” exercise of the Pharmaceutical Forum.

Commissioned by the Main Association of Austrian Social Insurance Institutions (MASI) the Austrian based ÖBIG Forschungs- und Planungsgesellschaft mbH has developed a questionnaire which we kindly ask you to complete and send relevant additional documents

**latest by 22 February 2008**

to

[leopold@goeg.at](mailto:leopold@goeg.at) or [habl@goeg.at](mailto:habl@goeg.at)

**We'd appreciate if you completed the questionnaire electronically,  
alternatively please fax it to +43 1 513 8472.**

In case of questions please contact: **Ms. Christine Leopold**  
**ÖBIG FP**  
**Stubenring 6,**  
**1010 Vienna, Austria**  
**Tel: +43 1 515 61 149**

**We kindly ask you to fill out your contact details:**

Completed by – please indicate your contact details:
Country:
Institution:
Unit:
Name:
E-Mail:
Direct Number

Working definition of tendering for pharmaceuticals in a broader sense:

Buying pharmaceuticals by purchasers like public hospital associations on the basis of a – often strictly defined – tendering procedure with granting the contract to the pharmaceutical company / importer who offered the best bid.

1)	Is there any tendering (cf. definition on the first page) of pharmaceuticals or other products performed in your country?			
	<input type="radio"/> YES  Since when?  _____ (Pls. give month and year)	<input type="radio"/> YES, for a limited range of products, namely <input type="radio"/> Pharmaceuticals used in primary care (extramural) <input type="radio"/> Pharmaceuticals used in hospital setting <input type="radio"/> Other _____ (please indicate)	<input type="radio"/> NO, not at the moment, but we plan to start with tendering in _____ (Pls. give month and year)	<input type="radio"/> NO (pls. continue with question No. 7c)

2)	If YES, for which type of pharmaceuticals?(multiple choices are possible)			
	<input type="radio"/> In general, for <u>all reimbursable</u> pharmaceuticals	<input type="radio"/> Pharmaceuticals for specific purposes, i.e. <input type="radio"/> Vaccines <input type="radio"/> Pharmaceuticals against Communicable Diseases (HIV, etc.) <input type="radio"/> Pharmaceuticals as defined in pandemic plans (Tamiflu, Renzenza, etc.) <input type="radio"/> Other pharmaceuticals relevant for public hygiene _____ (please indicate) <input type="radio"/> Other _____ (please indicate)	<input type="radio"/> Pharmaceuticals for specific customers, i.e. <input type="radio"/> Military Services <input type="radio"/> Pensioners, retired persons <input type="radio"/> Social Benefits organisations (Red Cross, Religious Institutions, etc.) <input type="radio"/> Prisoners <input type="radio"/> Asylum seeking persons <input type="radio"/> (War) veterans <input type="radio"/> Other _____ (please indicate)	<input type="radio"/> In general, for <u>all</u> pharmaceuticals

3)	Which institutions are procuring pharmaceuticals in your country (e.g. Hospital Purchasing Agencies, Tendering Department of National Health Service, Ministry of Finance, etc.)?		
	<input type="radio"/> For Hospitals  _____ _____ _____ (pls. indicate the institution)	<input type="radio"/> For Military Services  _____ _____ _____ (please indicate the institution)	<input type="radio"/> For Federal Pandemic Plans (Strategic issues)  _____ _____ _____ (please indicate the institution)
	<input type="radio"/> For Other  _____ _____ _____ (pls. indicate the institution)	<input type="radio"/> For Social Health Insurance  _____ _____ _____ (please indicate the institution)	<input type="radio"/> For National Health Service  _____ _____ _____ (please indicate the institution)



6)	Please indicate the frequency of the tenders:			
	Pharmaceuticals:	<input type="radio"/> Regular basis <input type="radio"/> Monthly <input type="radio"/> Bi-annually <input type="radio"/> Annually <input type="radio"/> Other: _____ (please indicate)	<input type="radio"/> Irregular basis (pls. specify)	<input type="radio"/> Never
	Other _____ (please indicate)	<input type="radio"/> Regular basis <input type="radio"/> Monthly <input type="radio"/> Bi-annually <input type="radio"/> Annually <input type="radio"/> Other: _____ (please indicate)	<input type="radio"/> Irregular basis (pls. specify)	<input type="radio"/> Never

7)	Assessment of the tendering process:	
	a) Please explain WHY you use tendering procedures / bids when buying pharmaceuticals:	
	b) Please quantify the savings you achieved by tendering (e.g. average rebate to the purchasing price):	
	in AMBULATORY / EXTRAMURAL Care	in HOSPITAL / TERTIARY Care
	c) Please explain why you DON'T use tendering when buying pharmaceuticals:	
d) Please indicate your positive and negative experiences:		

8)	a) Please estimate the share in annual total sales (value) for tendering pharmaceuticals in AMBULATORY / EXTRAMURAL Care		
	<input type="radio"/> <1%	<input type="radio"/> 5% - 10%	<input type="radio"/> more than 25%
	<input type="radio"/> 1% - 5%	<input type="radio"/> 10% - 25%	
	b) Please estimate the share in annual total sales (value) for tendering pharmaceuticals in HOSPITAL / TERTIARY Care		
	<input type="radio"/> <1%	<input type="radio"/> 5% - 10%	<input type="radio"/> more than 25%
	<input type="radio"/> 1% - 5%	<input type="radio"/> 10% - 25%	

9)	Please add any other points you consider necessary to explain / understand public tendering in your country:

10)	Kindly indicate the contact details of any institutions (e.g., hospital tendering agencies) or persons (e.g., Competition authority spokesperson, etc.) who could be addressed for further information with regarding to (public) tendering for pharmaceuticals in your country:

**THANK YOU VERY MUCH FOR YOUR CO-OPERATION!**