

## **EUCOMED - position paper regarding national tenders for medical technology products**

### **Summary:**

**Certain Member States have proposed to introduce or are considering tendering systems whereby centralised purchasing entities award contracts on an almost country-wide basis<sup>1</sup>. Such an approach can distort competition and have a negative impact on the innovative efforts of the manufacturers. The present paper discusses the concept of national tenders as well as its impact; and it contains a few proposals aimed at preventing the above mentioned potentially negative effects.**

### **1. Background**

With the principal aim of ensuring the economical and efficient management of the procedures for supplying the public sector, some countries have developed centralised systems for purchases by public administrative entities (also known as “centrales d’achat”). Under such systems, a master contract is signed between the “centrale d’achat” (representing all the relevant public administrative entities) and the company that is awarded a supply contract upon completion of a public tender procedure.

Upon conclusion of the aforesaid contract, any public administrative entity which plans to be supplied with goods and services under the contract shall issue a supply order addressed to the contractor. By executing the agreement, the said contractor shall undertake to guarantee the requested supply under the conditions and at the prices specified in the relevant agreement, for the quantity set forth therein. Upon award of the contract, there will be no separate tendering procedures by any of the entities belonging to the “centrale d’achat”.

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<sup>1</sup> This is e.g. the case for the initial Italian draft Consip legislation, which proposed to introduce a system that *de facto* would oblige public bodies to bundle their requirements to purchase healthcare products and to buy only from one contractor.

## **2. The potential anti-competitive effects of centralized purchases for public demand**

### **2.1 Buying power**

Under centralised purchasing systems, the buyer (“centrale d’achat”) plays the role of sole purchaser (“monopsonist”), or, more specifically, of sole representative for the “public demand”.

Such a system implies that in those markets where the public demand (obliged to adhere to centralised national contracts) accounts for nearly the entire market <sup>2</sup>, almost the entire demand for goods and/or services at a national level will be affected. Therefore, on such markets, the laws and regulations at issue lead to a situation whereby the national entity in charge of national tenders is granted substantial buying power by giving the entity a virtual exclusive right of demand.

Such buyer power does not necessarily facilitate competition and it may even seriously affect and impede competition. The exercise of such buying power may cause inefficiencies, i.e. reduction in the quality of the products (cf. 2.2 *infra*), reduction in the efforts for innovation (cf. 2.2 *infra*), and may lead to discrimination between companies (cf. par. 2.3 (b) *infra*).

Furthermore, in the long term, the exercise of excessive buying power on the part of the buyer (monopsonist) may cause: (i) the exclusion of certain operators from the market; and (ii) suppliers to impose increased prices on other buyers that have no buying power<sup>3</sup>.

### **2.2 The Elimination of competition “in the market”: impact on the quality of the products and on R&D**

The centralised purchasing system not only implies the existence of a sole party negotiating the purchasing conditions, but also tends to lead to artificial monopolisation of the offer (i.e. the existence of one single supplier at a national level).

Indeed, the laws and regulations governing centralised purchasing systems provide that the identification of the suppliers shall be made through public tender procedures. Consequently, the provisions at stake grant the possibility of assigning to certain

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<sup>2</sup> An example could be the Italian market of sanitary incontinence diapers: In Italy the “public” demand (hospitals, public nursing homes, ASL – i.e. local health entities -, and pharmacies), to be construed as demand for reimbursable products, accounts for 95% of the entire market (Source: Assobiomedica).

<sup>3</sup> In the case of diapers the other buyers would represent 5% of the market.

companies (i.e. the contractors) a kind of “monopoly” or exclusivity in relation to supplies for public administrative entities. One might argue that competition is in any case guaranteed by the fact that the designation of the sole supplier is made through public tender procedures (competition “for the market”). However, such a system of competition “for the market” by a centralised purchasing entity entails a limitation on the number of operators on the market and risks impeding the future development of competition, neither of which can be justified through bringing safety benefits to the consumer. In particular:

- the *de facto* exclusion of competitors from the market may considerably affect the future development of the market, discouraging technological innovation, research and development activities;
- the adoption of the lowest price as the only criterion to award a contract during national calls for tender with a single supplier ignores the fact that the cheapest products are not always the most efficient and effective products;
- the system of the national tender contracts tends to favour unfairly the companies which have already been awarded previous contracts in respect of the companies that are excluded from the calls for tender (the former will be in an advantageous position from a productive and economic viewpoint, and will, therefore, be able to offer lower prices);
- the reduction in the number of suppliers in the various markets is likely to lead to a reduction in the competitive pressure, which in turn can lead to an increase in the prices of products/services.

### **2.3 The discriminatory effects deriving from the criteria for identifying the contractor**

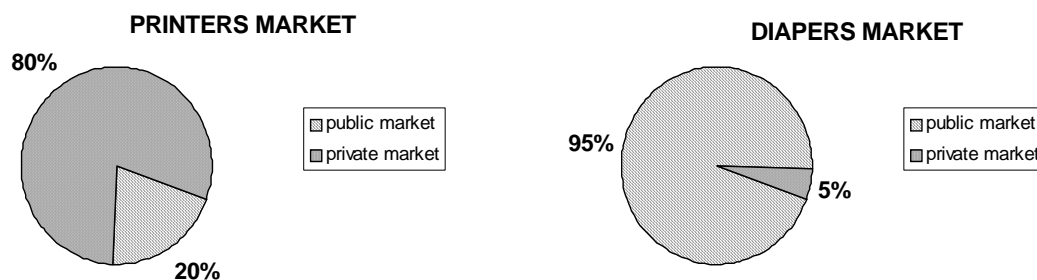
#### **(a) Discrimination of companies manufacturing high quality products**

The EU directives concerning public tenders for supplies and services set forth two criteria according to which a contract can be awarded, without establishing an order of preference between the same: the “lowest price” and the “offer which is economically most advantageous”. In the latter case, in addition to the price, other parameters shall be taken into account, which may even be more important in awarding the contract.

If national public tenders only consider the cheapest products, the added value of companies that invest into research is not recognised, and therefore such companies

are excluded from the market, since they are unable to offer prices similar to those (lower prices) offered by the companies offering products of lower quality.

This is even worse in sanitary markets where most probably almost 95% of the total market will be affected by national tenders (see above, footnote no.2), than in many other markets, such as pencils, printers, fuel and so, where the public market represents a much smaller percentage of the total market



Notes:

- The 'printers market' percentages are estimates
- The Diapers market data are [Assobiomedica](#)'s estimates about Italy

#### **(b) *Discrimination of small and medium-sized companies***

The practice of calling tenders on wide territorial areas implies that the tendering companies will be limited to large-scale companies. Indeed, it is difficult, if not impossible, for small and medium-sized companies to submit tenders on these types of calls. The system concerning national tenders contracts therefore risks causing the over-sizing of the offering structures in respect of the optimal structures which are necessary to manufacture the goods or services which are the subject of the agreement, with a consequent unnecessary incentive to concentration.

#### **2.4 International references**

The anti-competitive effects deriving from the centralisation of purchases in the healthcare sector have been the subject of examination in other countries. In particular, it seems appropriate to provide a brief outline of the results of the examinations conducted in the United States, France, and the United Kingdom, which seem to support the above considerations:

- (i) in the United States no system of centralisation of the purchases made by the administrative health entities has been adopted at national level.

However, according to common practice, hospitals and other health operators usually set up smaller purchasing units in order to purchase the goods or services necessary to satisfy their needs. In this respect, in 1993 the Department of Justice (“DoJ”) and the Federal Trade Commission (“FTC”) adopted a number of Statements relating to the application of the antitrust principles in the health sector. One of the aforesaid Statements (No. 7) identifies the anti-competitive risks deriving from centralised purchase agreements entered into between hospitals and other health operators, and establishes a so-called “safety zone” for the antitrust evaluation of these types of agreements. According to the aforesaid Statement No. 7, the DoJ and the FTC will not challenge any joint purchasing arrangement among health care providers where two conditions are present: (1) the purchases account for less than 35 percent of the total sales of the purchased product or service in the relevant market; and (2) for joint purchasing arrangements including direct competitors, the cost of the purchased items must account for less than 35 percent of the total market for the purchased items, and the cost of the purchased items must account for less than 20 percent of the total revenues of each purchaser<sup>4</sup>.

- (ii) In France, a specific entity has been set up known as “Union des groupements d’achats publics” (“UGAP”) with the function, among other things, of purchasing and selling products and services intended to be used by public entities and private entities that provide public services. However in France, the public administrative entities or the entities which perform public services are not obligated, but rather have the option, to adhere to the agreements managed by the UGAP.
- (iii) As far as the United Kingdom is concerned, its administrative health entities have adopted measures to centralise purchases in the health sector. In particular, in 1991 NHS Supplies was set up and this led to the creation of the NHS Purchasing and Supply Agency (“PASA”) in 1999 specifically for the purpose of optimising purchases for the National Health Service. Although, to our knowledge, the public administrative entities have no obligation to adhere to the agreements executed by the PASA, there is widespread awareness of the negative aspects of such a system. In particular, in a study conducted upon the request of the UK health

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<sup>4</sup> See EC Commission Guidelines on the Applicability of Article 81 of the EC Treaty to horizontal cooperation agreements. Para. 130 refers to threshold of 15% combined market share on purchasing

department, the *Oxford Economic Research Associates* (OXERA) have thoroughly illustrated the anticompetitive effects of the system implemented by the PASA (*Fundamental Review of the Generic Drugs Market*, July 2001).

### **3. The Central Buying systems are not appropriate for medical technology products**

The main concerns about National Public Tenders in general are linked to their anticompetitive effects: the high volumes of supply involved may exclude de facto the small and medium sized companies, even when they come together in a consortium, and can facilitate the creation of a cartel among the big competitors.

When centralised purchasing systems are applied to healthcare products, other effects should be evaluated.

Some of the negatives of National Public Tenders applied to health technology products are as follows:

- They maximize the standardization of the products purchased. This results in less effective and lower quality products, with a possible final cost increase to the Public Administration; for example, by not taking into account the compatibility of the products bought with the technical environment of the buyer in which the products operate;
- They can easily lead to buying technologically obsolete products because the duration of the tender is too long to keep pace with the development of new medical technology. Cheaper, lower quality products may result in increased costs to healthcare systems;
- Centralized systems are often associated with electronic tendering systems<sup>5</sup>. Electronic tender systems enhance efficiency when buying homogenous and relatively simple products where the lower price is the selection criterion or where the quality component is easy to calculate in a standardized way. They are not practical for products where quality and price are both important and the selection criterion is the economically most efficient offer, which is difficult to translate into a formula that applies automatically.

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market below which the joint purchasing is unlikely to have a negative impact on competition

<sup>5</sup> Such as to our knowledge in Italy and the Netherlands

Overall, the patients' needs are unique and it is often impossible to satisfy them by using a single product.

#### **4. Conclusions**

The above illustrated regulatory situation can cause serious distortions with reference to the supply of goods and services to public healthcare entities that are in blatant conflict with the principles concerning competition, equal treatment, and non-discrimination, with no benefit to the patients.

There could be various negative effects in the healthcare markets, in terms of both less competition and reduced consumer welfare. National centralised public tendering procedures in the healthcare sector risk to eliminate competitors and competition and thus to stifle innovation: this is bad for the patient, who should be the central point of focus in this context.

As a monopolistic position is granted to the winner of the tender, other companies may have difficulties in introducing new products in the market and will lose interest in investing in Research and Development. Moreover, the business may be perceived as involving high risk, because, if a company loses the entirety of the business some time later, all the investment in production line and employees may need to be divested with high costs. This will lead to higher prices to compensate the portfolio risk. Moreover, the economies of scale and the rationalisation of the expenditure of the public administrative entities, which are the objectives pursued by the laws and regulations at stake, seem insufficient to justify and, above all, to balance the effects on competition deriving from the very same laws and regulations. In any case, any potentially positive effect deriving from centralised purchasing systems would only be of a limited duration because of the negative effect in terms of reduction of competition in the market.

Regarding effects on consumers, the centralised buyer's decision is too remote from the patients' needs, as it is focused more on financial aspects than on suitable therapy solutions. In a centralised purchasing system, end-users suffer from lack of freedom in choosing the products meeting their needs. Moreover, in the medium- to long-term, the centralised public tendering system will lead to inferior product quality and less innovation in many instances.

In such a situation, EUCOMED respectfully requests the EU Commission to adopt recommendations on the necessary changes to the laws and regulations to guarantee the existence of greater and actual competition in the markets concerned, and, where

appropriate, to undertake the necessary actions against the Member States so as to guarantee that the free competition (which is one of the key objectives pursued by the EC Treaty) is not undermined and jeopardised by any centralised public tendering rule.

Eucomed recommends that the following guidelines should be considered:

- A maximum threshold should be fixed with respect to the purchases that can be bundled in each market concerned.
- The autonomy of the public administrative entities in making purchases should be acknowledged.
- In healthcare related sectors, the size and duration of tender contracts should be such as to avoid anticompetitive distortion and to encourage investment in the Research and Development of new products.
- Instead of focusing on price, the tenders in healthcare related sectors should evaluate the quality and value of care and take into account the end users' right to have a good standard of life.
- The opportunity for end-users to be able to choose from the widest possible range of products should be guaranteed.

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