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## **COMPETITION IN PUBLIC BIDDING EXERCISES FOR PHARMACEUTICAL PRODUCTS**

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# COMPETITION IN PUBLIC BIDDING EXERCISES FOR PHARMACEUTICAL PRODUCTS

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Chiara Sammarco♦

## **Abstract:**

The present paper stems from the need, shared by several European states, to identify compatible and adequate tools capable of containing the cost of medicines, fostering research and development (R&D) of new pharmaceuticals and allowing all patients access to appropriate drugs. Certain Member States have achieved significant savings to the benefit of consumers when health insurers carried out tenders or similar processes for some products. This contribution intends to evaluate both whether the purchase of medicines through a tendering system can bring efficiencies into the pharmaceutical market and also how this can be achieved. Particularly the following analysis has focused on the comparative study of the features of the tendering system and of the peculiarities of the pharmaceutical market in order to identify 1) the general mechanisms of the tender that are compatible with the features of pharmaceuticals and 2) the specific needs of the drugs that require further adaptations of the tendering procedures. According to my conclusions, the purchase of medicines through tendering enhances efficiencies in the pharmaceutical sector provided that public procurement rules are adapted to suit the particular features of the pharmaceutical products and market. This study will therefore focus on three main areas analysing: I) the diffusion of tendering of drugs in European countries, II) the competition potentials of tenders in general and the application of the same to the Italian system, III) the principles which should be enforced to ensure that tenders for the purchase of drugs are an efficient tool, in terms of cost savings and incentive to encourage R&D. Although the analysis is limited to the Italian market where public tenders of pharmaceuticals take place mainly in the hospital sector, the conclusions drawn can well be applied, *mutatis mutandis*, to other experiences.

*Key words:* Pharmaceutical tenders; Italian tendering system; generic drugs; monopsony; co-marketing.

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## 1 – Development of the tendering system in European countries

In order to find solutions to the most common problems in the public health field, in 2005 the European Commission established a Pharmaceutical Forum in which a “High Level Group On Innovation and Provision of Medicines” identified a number of mutual issues around which it invited international stakeholders to debate. Three groups were created with different purposes i.e.: I) working group on information to patients, II) working group on pricing and reimbursement, III) working group on relative effectiveness. In October 2008 the Forum produced its report<sup>1</sup> containing partial conclusions emerging from the debate. However the primary role of the Forum was to give strategic direction and a political push for further initiatives. Consequently following the impulse given by the European debate, several international organizations became interested in scrutinizing problems connected to pricing and reimbursement policies and protection of intellectual property rights. For example the recent competition inquiry of the European Commission<sup>2</sup> into the pharmaceutical sector dealt with evaluating why generic medicines entered the European Market late. According to the European inquiry “Member States that want to fully benefit from the potential budget savings brought about by generic products also need to reflect about policies that facilitate speedy generic uptake in volume terms and effective price competition among generic producers”<sup>3</sup>. In this light, the Commission invited Member States to consider the use of tenders as a tool that can help ensure that price reductions offered by generic companies do not stay in the distribution system, but are passed on to consumers and reduce costs for public health budgets<sup>4</sup>. Besides, also according to the opinion of the OECD<sup>5</sup>, tendering procedures can be used to achieve significant savings in the pharmaceutical market, particularly in cases where purchasing power is high and there are multiples potential sources for the product. A comparative study was conducted by Austrian institute of research ÖBIG-FP<sup>6</sup>. It investigated the issue of the functioning of public procurement of pharmaceuticals in European states (within European Union and European Economic Area) in order to verify whether such a procedure could be a general bargaining tool capable of ensuring greater savings for public funds, while increasing healthcare. The final ÖBIG-FP’s Report stressed that tendering is an important tool in the purchase of pharmaceuticals. Indeed, it is used in a significant number of EU and EEA Member States. In particular, while some circumscribe the use of tendering for pharmaceuticals to the hospital setting, others expand their application to other public uses, involving

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<sup>1</sup> High Level Pharmaceutical Forum 2005-2008, *Final Conclusions and Recommendations of the High Level Pharmaceutical Forum*, October 2008, available at <http://ec.europa.eu/pharmaforum>.

<sup>2</sup> European Commission, *Pharmaceutical Sector Inquiry. Final Report*, 8 July 2009, available at <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html>.

<sup>3</sup> European Commission, *Pharmaceutical Sector Inquiry. Final Report*, 8 July 2009, supra note 2, § 13.

<sup>4</sup> European Commission, *Pharmaceutical Sector Inquiry. Final Report*, 8 July 2009, supra note 2, § 1605.

<sup>5</sup> See OECD Health Policy Studies, *Pharmaceutical Pricing in a Global Market*, September 2008, p. 150.

<sup>6</sup> Cf. ÖBIG-FP, *Tendering of pharmaceuticals in Europe and EEA countries*, June 2008, available at [http://ppri.oebig.at/Downloads/Publications/Final\\_Report\\_Tendering\\_June\\_08.pdf](http://ppri.oebig.at/Downloads/Publications/Final_Report_Tendering_June_08.pdf). This study was conducted by the Austrian institute of research ÖBIG-FP (ÖBIG Forschungs- und Planungsgesellschaft mbH) and it was commissioned by ESIP (European Social Insurance Platform) which was a member of the working group on pricing and reimbursement created by the European Commission in 2005. Please note that the study results are based on questionnaires filled out by Countries such as Iceland, Ireland, UK, France, Belgium, Germany, Switzerland, Denmark, Norway, Sweden, Finland, Czech Republic, Austria, Slovenia, Hungary, Romania, Lithuania, Estonia, Malta, Cyprus.

specific product groups (such as pharmaceuticals involved in pandemic plans) or defined patient groups (e.g. military). Only a few countries apply tendering for pharmaceuticals in ambulatory care distributed through retail pharmacies<sup>7</sup>.

Surprisingly ÖBIG-FP's Report mentioned but did not describe in depth the German trading system and nor did it deal with the Dutch system, which nonetheless deserves a brief mention here. This note is of added value considering the position occupied by these states in the pharmaceutical market. In fact the German trading system is capable of influencing the process of price bargaining in other nations and this is the case because this country is a role model regarding the price of medicines. Besides in Germany the public price of drugs is fixed by the companies and, as in the case of the Netherlands, a reference pricing system applies at molecular level, which has also been extended to molecules that are considered to be therapeutically equivalent (known as "jumbo reference groups"). As regards the German tendering system, it is one of the few examples in Europe of tendering in the ambulatory care setting. According to national regulations, there are several *Krankenkassen* (German public health insurance companies), which cover the health and pharmaceutical expenses of citizens: each one is responsible for a part of the territory. In order to obtain the maximum discount, the *Krankenkassen* negotiate the price of drugs with manufacturers through the so-called rebate or discount agreements which might somehow evoke tendering procedures, although they are partially different<sup>8</sup>. In fact the procedures for procuring the rebate contracts vary from contracts negotiated directly with specific manufacturers to competitive procedures that allow manufacturers to compete with each other<sup>9</sup>. Discount agreements work as follows: firstly, sickness benefit funds define a number of drugs considered equivalent. Secondly, they enter into discount agreements with every single company and negotiate the price at which each company intends to sell its drug, in the retail market. Only the company which offers the lowest price and a full range of that product's portfolio (i.e. the number of product presentations based on dosage) will be awarded the framework contract and obtain the reimbursement for the sale of that drug in the territory where *Krankenkasse* works. The duration of the contracts vary in time but normally they have been for one to two years: this means that medicines which do not obtain the contracts are effectively excluded from the reimbursement in that particular

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<sup>7</sup> For a specific reference to countries affected by the results and for an in-depth view of the individual national system see ÖBIG, *Tendering of pharmaceuticals in Europe and EEA countries*, supra note 6, p. 5 et seq.

<sup>8</sup> For further discussion about the adjustment of the drug purchase in Germany see P. Kanavos, L. Seeley and S. Vadoros LSE Health London School of Economics, *Tender systems for outpatient pharmaceuticals in the European Union: Evidence from the Netherlands, Germany and Belgium*, October 2009, available at [http://ec.europa.eu/enterprise/sectors/pharmaceuticals/files/docs/study\\_pricing\\_2007/tendering\\_systems\\_en.pdf](http://ec.europa.eu/enterprise/sectors/pharmaceuticals/files/docs/study_pricing_2007/tendering_systems_en.pdf).

<sup>9</sup> P. Kanavos, L. Seeley and S. Vadoros LSE Health London School of Economics, *Tender systems for outpatient pharmaceuticals in the European Union: Evidence from the Netherlands, Germany and Belgium*, October 2009, supra note 8, p. 23 et seq.

area. As a consequence, manufacturers lose a share of the market and their product has to be purchased by patients exclusively out-of-pocket<sup>10</sup>.

On the other hand the peculiarity of the Dutch tendering system is that it is mainly performed for specific group of pharmaceuticals bound to be supplied in the retail market. Particularly in the Netherlands in order to achieve lower prices of medicines, health insurers have implemented a new purchase method called “Preference Policy”<sup>11</sup>. Under this scheme, national drug procurement is tendered for off-patent (branded or unbranded) medicines containing the same active ingredient, that are eligible for reimbursement. Only manufacturers proposing the lowest price, or prices within 5% of the lowest price can be designated as the preferred suppliers. Products outside that range are not eligible for reimbursement. Consequently, except in the case of medical need, insured patients have to pay for non-preferred products out-of-pocket. Moreover the status of preferred product remains valid for a period of six months, after which procurement begins again in order to stimulate competition between companies and give other manufacturers the chance to supply the market.

Putting aside the specific legislations described and returning to the EU’s perspective, it can be concluded from the comparison of the experiences in European states that the purchasing of pharmaceuticals by tendering enhances efficiency within the healthcare system. In fact, the ÖBIG-FP’s Report shows that an effective tendering process ensures the availability of the required drugs, in appropriate quantities, at reasonable prices and of an acceptable standard of quality. Besides according to this survey an added value may be obtained in terms of transparency when using public funds to purchase pharmaceuticals through tendering<sup>12</sup>. However, the conclusions of the Report also point out that in order for the tendering procedures to have a competitive impact in the pharmaceutical sector, “*it is essential that these activities [be] 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*”<sup>13</sup>. Therefore, establishing the specific conditions under which tenders should develop is what this paper is trying to address.

## 2 – Tendering procedures as a guarantee of competition, Italian experience

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<sup>10</sup> For further information on the German system of drug price bargaining see ECJ of 16 March 2004, in Case C-264/01 – AOK-Bundesverband e.a., GU C 94, 17.04.2004, p. 2; cf. ECJ of 11 June 2009, in Case C-330/07 – Hans & Christophorus Oymanns, [GU C 19 dal 24.01.2009, p. 6](#); see M. Bedau and B. Tugendreich, *Are German health insurers obliged to purchase drugs by public tender?*, August 2007, available at [http://www.pharmacist.or.kr/webapps/attach/data/pds03/Aug07\\_Euralex\\_MBedau\\_BTugendreich.pdf](http://www.pharmacist.or.kr/webapps/attach/data/pds03/Aug07_Euralex_MBedau_BTugendreich.pdf).

<sup>11</sup> See P. Kanavos, L. Seeley and S. Vantoros LSE Health London School of Economics, *Tender systems for outpatient pharmaceuticals in the European Union: Evidence from the Netherlands, Germany and Belgium*, October 2009, supra note 8, p. 7 et seq.

<sup>12</sup> On this matter see C. Dawson (European Social Insurance Platform member), *Cost Containment in the pharmaceutical sector*, July 2008, available at <http://www.peer-review-social-inclusion.eu/peer-reviews/2008/cost-containment-in-the-pharmaceutical-sector-innovative-approaches-to-contracting-while-ensuring-fair-access-to-drugs/stakeholder-esip/download>.

<sup>13</sup> Cf. ÖBIG, *Tendering of pharmaceuticals in Europe and EAA countries*, supra note 6, p. 20

Tendering procedure is widely used in any purchase made by the public administration. Through public tenders, procurement entities can choose the best bid and, at the same time, guarantee both the transparency in the management of public funds as well as the incentive of the competition among the participating companies<sup>14</sup>.

In Italy, unlike other European countries, public procurement is employed for the purchase of reimbursable medicines and not for fixing the price of the reimbursable products; in fact, this price is decided in a previous phase. More specifically, the price of in-patent drugs is established through negotiation between AIFA (Italian Drug Agency) and pharmaceutical companies, while the reimbursable pricing of off-patented medicines is decided with the system of “reference pricing”. According to “reference pricing”, several clusters of equivalent off-patented (branded and un-branded) drugs are identified and the National Health Service (NHS) then identifies within each cluster which drug has the lowest price: this will be the reimbursed price. In actual fact, the Italian government has recently tried to introduce a selection procedure – which in some respects looks like Dutch “preference policy” – to limit the entry of drugs into those reference clusters. In fact, Article 9, paragraph 9 of the draft conversion law of emergency decree n. 78 of 2010 proposed that the reference price for reimbursable medicine should be decided on the basis of a cluster constituted by not more than four drugs. It also suggested that the medicines with lower prices which were eligible to compose clusters should be selected through a tendering procedure organized by AIFA. Furthermore, according to this law, two kinds of pharmaceuticals should be excluded from participating in tendering procedures: the pharmaceuticals that are losing their patent (branded off-patent drugs) and those that benefited from such a patent before it was lost (branded off-patent drugs produced in co-marketing regime)<sup>15</sup>. The suggested amendment was never passed, and consequently the application of the tender system continues to be important only in the distribution phase. In particular, currently in Italy pharmaceuticals are purchased through public tender in order to achieve two aims: firstly to meet the needs of hospitals and, secondly to deliver the drugs direct to the patients in home care or discharged from hospital<sup>16</sup>. In both cases, the purpose of the rules governing purchases is to ensure the maximum

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<sup>14</sup> Cf. G. Fidone, S. Gambuto, G. Mele, *Meccanismi elusivi e limitazione della concorrenza nella prassi amministrativa degli appalti pubblici*. Biennial reports of the CSC, Centro Studi Confindustria, edited by I. Cipolletta, S. Micossi, G. Nardozzi, S. Trento, March 17 of 2006 Biennial Conference, Rome. Document available at [http://www.confindustria.it/AreeAtt/DocUfPub.nsf/3087977852662c0ac1256f65003aa57c/5bf88442620420eac1257132005edcc1/\\$FILE/PAPER\\_7d.pdf](http://www.confindustria.it/AreeAtt/DocUfPub.nsf/3087977852662c0ac1256f65003aa57c/5bf88442620420eac1257132005edcc1/$FILE/PAPER_7d.pdf).

<sup>15</sup> For a comment on Article 9, paragraph 9 of the draft conversion law of the emergency decree No 78 of 2010 see Polo M., *Un ministro comprensivo*, 25.06.2010, WWW.LAVOCE.INFO Sanità/ Concorrenza e Mercati, available at [http://www.lavoce.info/binary/la\\_voce/articoli/cache\\_pdf/UN-MINISTRO-COMPRESIVO-1001799.pdf](http://www.lavoce.info/binary/la_voce/articoli/cache_pdf/UN-MINISTRO-COMPRESIVO-1001799.pdf). Pammolli F., Salerno N. C., *Il prezzo di riferimento e le gare sui farmaci off-patent: quanta confusione anche tra esperti*, CERM, SHORT NOTE N. 2/2010.

<sup>16</sup> With regard to the first function, Article 9 of Law No. 386 of 1979 requires pharmaceutical companies to grant Primary Care Trusts a discount of at least 50% on the retail price of pharmaceuticals. An exception to this rule is the case in which drugs are approved by mutual recognition or by centralized procedures (the reference is to those medicines which represent a truly therapeutic or scientific innovation) for which, according to the CIPE's deliberation of 1 February 2001, the

availability of pharmaceuticals at the lowest price, to correlate protection and cost savings for public funds.

According to some authors<sup>17</sup>, if tendering procedures were applied to a market such as that of health care – characterized by high specialization, contracts and detailed but necessarily incomplete specifications and few potential competitors – they could be considered inefficient tools because in this way the dialogue between procurement officials and contractors might be eliminated. However another scholar, Mario Libertini<sup>18</sup>, defines public tenders in general as a tool that does not always ensure the efficient functioning of the markets but is certainly an acceptable compromise to avoid any irregularities by public administration. This is by virtue of its weakness, in that it represents both individual and collective interest, or conversely as a result of its power, due to the monopsony position that it enjoys in the bargaining process, which could produce distortion of competition in the relevant markets. Furthermore, as noted by the same scholar<sup>19</sup>, tendering develops in a monopsony regime in which only one body represents demand while some competitors meet, repeatedly but intermittently, to decide who is to be the supplier for that demand<sup>20</sup>. In such a market, the protection of competition should not be understood only in the static sense as a guarantee of legislative measures aimed at restoring the balance, but also in the dynamic sense as an introduction of mechanisms that are intended to create conditions for the free development of competition<sup>21</sup>. Therefore, starting from Libertini's point of view, the author of the present article will analyze the specific use of public procurement in the pharmaceutical market and attempt to demonstrate that purchasing drugs through tendering procurement can help to achieve significant savings to the benefit of consumers.

### 3 – Criteria to incentivize fair competition in public procurement

In order to achieve an efficient result, it is necessary to pay attention to how the procurement entities behave in the application of both general criteria enforceable on all tenders and also those criteria

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bargaining price (ex-factory price i.e. the retail price without VAT and distribution margins) may be subjected only to the discounts arising from tendering procedures and not also that of 50%.

Instead with regard to the second function, in accordance with Article 8 subsection a) of L. No. 405 of 2001, the Region can enter into agreement with the trade union association of the pharmacies operating within the National Health Service, that can be public or private, to allow patients to be provided with medicines where they require frequent control.

<sup>17</sup> Cf. G. Fidone, S. Gambuto, G. Mele, *Meccanismi elusivi e limitazione della concorrenza nella prassi amministrativa degli appalti pubblici*, supra note 14.

<sup>18</sup> Cf. M. Libertini, *La tutela della concorrenza e i giudici amministrativi nella recente giurisprudenza*, in *Giornale di Diritto Amministrativo* No. 6/2007 pp. 632-642.

<sup>19</sup> Cf. M. Libertini, *La tutela della concorrenza e i giudici amministrativi nella recente giurisprudenza*, supra note 18.

<sup>20</sup> With this statement the author intends to embrace the opinion that for the tendering procedures the relevant market could be limited to the market in which tendering develops. *Ex plurimis* cf. State Council, sent. No. 1796, sect. VI, March 25 of 2009; cf. State Council, sent. No. 548, sect. VI, February 10 of 2006; cf. State Council, sent. No. 926, sect. VI, March 2 of 2004.

<sup>21</sup> Cf. Constitutional Court, sent. No. 14 of January 2004, in *Giur. It.*, 2004, p. 853. In this decision, the judges of the Supreme Court assert the importance of safeguarding competition that must be understood in a dynamic sense. The sentence was passed on state aid but it represents a leading case which has inspired subsequent judgements also in the tendering area. For further details on this matter cf. C. Lacava, *I contratti pubblici tra Stato e Regioni e la tutela della concorrenza*, in *Giorn. di Dir. Amm.* No. 6/2008, pp. 624-632.



effectively<sup>26</sup>. According to some authors<sup>27</sup>, the flow of information exchanged between candidates and public purchasers in order to find a common solution – as is the case in particularly complicated tendering procedures – would prepare the ground for the spreading of significant distortions in technical planning and signalling of price. The setting of a “reserve price”, in the sense of identifying a maximum price that the station contractor is willing to pay for given goods or services, is also debatable. According to some<sup>28</sup>, setting a “reserve price” would limit the opportunity for participants to collude because they cannot negotiate a higher price than the one stated. In the opinion of another scholar<sup>29</sup>, the “reserve price” could be an incentive for creating a syndicate which would have as a reference point the maintenance of the price stated in head office. The same author<sup>30</sup> also affirms that, when a central price is not indicated, collusion might be possible between the parties if they inquire about the prices that are paid by public purchasers in the previous tenders.

Therefore in the arrangement of the call for bids there exists a trade-off between: i) the guarantee of non-discriminatory procedures which is controlled by applying a transparent process and ii) the need to exclude collusion by the interested parties where the conditions offered by them are clear and known.

One of the aims achieved by the public procurement Directive 2004/18/EC, which is enforced also in pharmaceutical tendering, is to avoid restrictions on competition related to the exchange of information between candidates and the public purchaser. However, the limit of the law is that cooperation is a natural feature of the tender process and consequently it is impossible to prevent collusive effects by imposing a rule<sup>31</sup>. According to a study conducted by the OECD<sup>32</sup>, the risk of collusion between competitors exists both in the “ordinary” market and also in public tenders: however, unlike the private purchaser, the public buyer does not possess the flexibility to choose its purchasing strategy and this is due to limitations imposed by legislation and detailed administrative regulations and procedures on procurements. From this observation it is possible to make a series of comments about how procurement entities could behave in order to bring greater flexibility to the purchase procedure. First of all the auction design should not be “one size fits all” but should be adapted to suit the specific market where it intends to proceed. Consequently i) in the procurement market where there are enough firms to sustain reasonable competition, efficient procurement outcomes can usually be achieved

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<sup>26</sup> Cf. OECD, *Public Procurement: The Role Of Competition Authorities In Promoting Competition*, 2007, available at <http://www.oecd.org/dataoecd/25/48/39891049.pdf>.

<sup>27</sup> Cf. A. Sánchez Graells, *Distortions of Competition Generated by the Public (Power) Buyer: A Perceived Gap in EC Competition Law and Proposals to Bridge It*, August 2009, available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1458949](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1458949).

<sup>28</sup> Cf. AGCM, AS333, *Previsioni sul modello di gara da adottare per l'evoluzione della rete unitaria per la pubblica amministrazione (rupa) nell'ambito del sistema pubblico di connettività*, in bulletin No. 8/2006; Cf. L. Fiorentino, *Lo stato compratore. L'acquisto dei beni e dei servizi nella pubblica amministrazione*, Series I, Quaderni di Astrid, Il Mulino publisher, Bologna 2007, Chapter IV.

<sup>29</sup> Cf. A. Sánchez Graells, *Distortions of Competition Generated by the Public (Power) Buyer: A Perceived Gap in EC Competition Law and Proposals to Bridge It*, supra note 27.

<sup>30</sup> Cf. A. Sánchez Graells, *Distortions of Competition Generated by the Public (Power) Buyer: A Perceived Gap in EC Competition Law and Proposals to Bridge It*, supra note 27.

<sup>31</sup> Cf. A. Sánchez Graells, *Distortions of Competition Generated by the Public (Power) Buyer: A Perceived Gap in EC Competition Law and Proposals to Bridge It*, supra note 27.

<sup>32</sup> Cf. OECD, *Public Procurement: The Role Of Competition Authorities In Promoting Competition*, supra note 26.

through a simple auction or tender process; ii) where there are not enough firms to sustain competition, more sophisticated arrangements may be necessary to achieve an efficient outcome. The choice of the most suitable bidding model, given the circumstances of the procurement, is therefore the starting point of any attempt to prevent collusion in public procurement<sup>33</sup>. Moreover in order to decrease the possibility of collusion, the study suggests reducing the frequency of procurement to minimize the opportunities for the parties to meet. Nevertheless the present advice also glosses over the existence of a trade-off between the need to limit the possibility of colluding and to avoid a market foreclosure in the medium to long term. In fact the European Commission warns against the risks arising from over-long award periods<sup>34</sup>. This is the case because in order to safeguard free competition, the state and other public authorities should not give individual operators the advantage of acting outside of competitive pressure<sup>35</sup>. Besides, the duration of supply is particularly important in the pharmaceutical sector because the longer the award period, the more likely it is that patented products will lose their sole selling right<sup>36</sup>. Finally, the last consideration discussed<sup>36</sup> in the OECD's Report is the possibility of training public agencies to recognize potential collusive behaviours among competitors. This idea was inspired by countries such as Canada, Switzerland and the United States where proper check-lists have been developed to help procurement entities to stop instances of possible collusion. A similar investment could be expensive in terms of resources and time, but could produce significant benefits in the long term. The advice given by the OECD's Report does not represent guidelines that must be applied by procurement entities. Nevertheless it shows that it is not enough for public procurement rules, such as transparency and publicity principles, to be correctly enforced but they must also be balanced and adapted to suit the conditions required by each actual case.

### **3.2 – Second general criterion, the selection of companies and the increase of participation in tenders through a temporary consortium of contractors.**

Actual and potential entry of new competitors in a market is probably the most important force that at the same time limits collusion and spurs a greater competition. According to Sánchez Graells<sup>37</sup>, the public procurement procedure would introduce an unjustified restriction on the “free market” because

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<sup>33</sup> Cf. OECD, *Public Procurement: The Role Of Competition Authorities In Promoting Competition*, supra note 26, p. 8

<sup>34</sup> European Commission, *Pharmaceutical Sector Inquiry. Final Report*, 8 July 2009, supra note 2, § 1605.

<sup>35</sup> Cf. G. della Cananea, *Dalla concorrenza per il mercato alla concorrenza nel mercato: gli appalti pubblici nei servizi di comunicazioni elettroniche*, 2005, supra note 22, p. 139.

<sup>36</sup> Serafino S., *Problematiche antitrust nel settore farmaceutico: le gare come strumento per incentivare la concorrenza*, September 2008, available at [http://www.assogenerici.org/articolhome/II\\_Congresso\\_Nazionale/Presentazione\\_Stefania\\_Di\\_Serafino.pdf](http://www.assogenerici.org/articolhome/II_Congresso_Nazionale/Presentazione_Stefania_Di_Serafino.pdf).

This author states that in Italy tenders include revision clauses (the so-called renegotiation procedures) of the contracted prices, according to which pharmaceutical prices can be renegotiated if their patent expires during the award period. However in the author's opinion, the same possibility of renewing the contract or of awarding a particularly long contract, could constitute an obstacle to entry of generic drugs and an advantage for the original manufacturers.

<sup>37</sup> Cf. A. Sánchez Graells, *Distortions of Competition Generated by the Public (Power) Buyer: A Perceived Gap in EC Competition Law and Proposals to Bridge It*, supra note 27.

it is based on rules that restrict the ability of potential suppliers to take part in a tender: this statement is basically true but needs to be mitigated. In fact, it is indisputable that tendering procedures, as designed, allow access only to those companies possessing certain qualifications in terms of economic, financial or technical capability. Nevertheless, in the auction the lack of selection criteria could lead to privileging businesses that do not have the skill, but are ready to present bids that are only apparently more advantageous<sup>38</sup>. Consequently, it is essential for tender auctions to specify the qualities that the firms should have in order to compete. However the guarantee of a broad participation of qualified firms is of primary importance in the pharmaceutical field because it ensures that doctors have a wide selection of pharmaceuticals from which they can choose the drugs they consider appropriate for the diseases under treatment. Considering this, on some occasions the Italian Competition Authority (the so-called AGCM) has intervened with advice aimed to steer selection procedures towards what is reasonable and impartial. In general, the Authority has explained that in order for public tenders to become a useful tool to promote competition and prevent anticompetitive behaviour, it is essential that the principles of equal treatment and proportionality should be respected and also that procurement officials must refrain from providing further qualifications other than those fixed by the law<sup>39</sup>. Another way to encourage greater participation of companies in tendering, suggested by AGCM, is to allow firms to join a temporary consortium of contractors (the so-called ATI). However, in AGCM's opinion<sup>40</sup>, the temporary consortium of contractors should not be permitted if 1) each firm has the economic, financial and technical capabilities to supply on its own the procured products and/or 2) the firms produce the same goods or services. In order to protect competition, the AGCM hopes that the use of ATI would be limited to really indispensable events, in order to increase, and not to reduce, the number of the participants in a tender<sup>41</sup>. In fact the temporary consortium of contractors is admissible only when the pooling of the resources and the sharing of the business risk produces efficiencies in the

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<sup>38</sup> Cf. M. Libertini, *La tutela della concorrenza ed i giudici amministrativi nella recente giurisprudenza*, note 18.

<sup>39</sup> In particular after a careful observation of some selection criteria included in the auctions of ASL (Local Health Agencies) and hospitals, the AGCM has outlined a set of parameters that should be followed in preparing the notification of auctions. In order to ensure the broadest participation of the stakeholders in the selection process it is necessary that:

1 – Decisions on the admission of the firms to the tender are taken not only in relation to their turnover. The Authority condemns all those clauses which require either a minimum sales ceiling disproportionate to the extent of the tender or a turnover calculated on the specific geographic market in which the tender takes place. In fact these forecasts tend to exclude smaller firms from the tender and those capable of performing the requested service on the basis of the experience gained in different geographic markets. Indeed in the pharmaceutical sector the companies' suitability for supplying pharmaceuticals is certified by a complex system of marketing authorizations, consequently the level of turnover cannot be a binding criterion for participation and award of a tender.

2 – The fact that the firms have previously supplied other public bodies should not be taken into account. In fact the only effect of this forecast is to favour those firms that have already worked for the public administration and to unjustifiably exclude both the remaining categories of companies and potential competitors who want to enter the market. (Cf. AGCM, advice AS097, *Gare pubbliche per le forniture di prodotti sanitari*, in bulletin No. 29/1997; Cf. AGCM advice AS187, *Bandi di gara in materia di appalti pubblici*, in bulletin No. 48/1999; Cf. AGCM advice AS251, *Bandi predisposti dalla concessionaria servizi informatici pubblici – CONSIP S.P.A.*, in bulletin No. 5/2003).

<sup>40</sup> Cf. AGCM advice AS187, supra note 39; Cf. AGCM advice AS251, supra note 39.

<sup>41</sup> Cf. AGCM advice AS187, supra note 39.

market, otherwise the same consortium could be considered a cartel<sup>42</sup>. The AGCM's concerns are very important in the hospital setting, in fact in this field there are many examples of agreement during tenders with the purpose of sharing the market between the firms<sup>43</sup>. Nevertheless it is interesting to note that doctrine<sup>44</sup> and jurisprudence<sup>45</sup> have recently taken a more indulgent position than that expressed by AGCM on ATI<sup>46</sup>. In particular, the supporters of the recent position suggest abandoning general and *a-priori* rules which consider ATI an anticompetitive agreement and state the need to evaluate the possible distortion created by the ATI case by case<sup>47</sup>. Finally it is important to repeat that the observations made so far are general; they summarize the concerns of the AGCM which often originate from pharmaceutical auctions but they are enforceable in all tenders. The following will highlight the peculiar features of pharmaceutical products that should influence the choices of the procurement officials in composing pharmaceutical lots and on selecting award criteria more appropriate to the object of the tender.

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<sup>42</sup> Cf. M. Libertini, *La tutela della concorrenza e i giudici amministrativi nella recente giurisprudenza*, supra note 18.

<sup>43</sup> Cf. AGCM of 17 October 2002, in Case 11305 – *Test diagnostici per il diabete*, available at bulletin No. 42/2002; Cf. AGCM of 26 April 2006, in Case 15393 – *Prodotti disinfettanti*, available at bulletin No. 17/2006; Cf. AGCM of 03 March of 2007, in Case 17135 – *Gare per la fornitura di dispositivi per stomia*, available at bulletin No. 30/2007.

<sup>44</sup> Cf. P. Piselli, *I raggruppamenti temporanei fra le esigenze di tutela della concorrenza nelle pubbliche gare e salvaguardia della libertà di iniziativa economica*, in Riv. Trim. degli Appalti, 2006, pp. 133-151; Cf. T. Fiorella, *ATI e disciplina antitrust*, in Urbanistica e appalti No. 7/2009 pp. 829-835

<sup>45</sup> Cf. ECJ of 19 May 2009, in Case C-538/07 – *Assitur*, [GU C 153 04.07.2009 p.9](#); Cf. State Council, sect. IV, sent. of 25 March 2009, No. 1796; Cf. State Council, sect. VI, sent. of 25 January 2010, No. 247.

<sup>46</sup> In particular, the advice No. AS251 (supra note 39) of the AGCM provides two restrictive statements. According to the first statement, only in exceptional cases properly justified in the auction, can the temporary consortium of contractors be permitted even if the participant firms produce the same goods or services. According to the second statement, firms that have monitoring or connection relations (as stated by Article 2359, paragraphs I, II and III of the Italian Civil Code) cannot compete in the same tender, either as individual firms or as participants in the temporary consortium of contractors.

<sup>47</sup> With regard to the prohibition of association for companies that produce the same goods or services, according to some authors (i.e. P. Piselli, *I raggruppamenti temporanei fra le esigenze di tutela della concorrenza nelle pubbliche gare e salvaguardia della libertà di iniziativa economica*, supra note 44; T. Fiorella, *ATI e disciplina antitrust*, in Urbanistica e appalti, supra note 44), the imposed restriction would limit the freedom of economic initiative which is guaranteed by Article 41 of the Italian Constitution. In fact the concept of ATI allows participant companies not only to achieve the requirements stated by the auction, but also to introduce a higher efficiency in the organization of its activities. For example, the temporary consortium of contractors allows both the business risk on the individual contract to be reduced and the business resources to be split over a greater number of orders.

Whereas with regard to prohibition imposed on firms with monitoring or connection relations from competing in the same tender, some scholars (Cf. M. Libertini, *La tutela della concorrenza e i giudici amministrativi nella recente giurisprudenza*, supra note 18; Cf. L. Fiorentino, *Lo Stato compratore. L'acquisto dei beni e dei servizi nella pubblica amministrazione*, supra note 28) welcome the restriction imposed by the Authority because they think that the existence of a control relationship between firms is a-priori capable of favouring, in competition terms, the participant firms which are referable to a single centre of interests. However according to a recent jurisprudential direction (Cf. ECJ of 19 May 2009, in Case C-538/07 – *Assitur*, [GU C 153 04.07.2009 p. 9](#)): on this judgement is modelled the sentence of Council of State, sect. VI, of 25 January 2010 No. 247) “Community law precludes a national provision which, while pursuing legitimate objectives of equality of treatment of tenders and transparency in procedures for the award of public contracts, lays down an absolute prohibition on simultaneous and competing participation in the same tendering procedure by undertakings linked by a relationship of control or affiliated to one another, without allowing them an opportunity to demonstrate that that relationship did not influence their conduct in the course of that tendering procedure... Such legislation, which is based on an irrebuttable presumption that tenders submitted for the same contract by affiliated undertakings will necessarily have been influenced by one another, breaches the principle of proportionality in that it does not allow those undertakings an opportunity to demonstrate that, in their case, there is no real risk of occurrence of practices capable of jeopardising transparency and distorting competition between tenders ( See paras 23, 28-30 and operative part of the ECJ decision of 19 May 2009, in Case C-538/07).

### 3.3 – First specific criterion, the composition of the tender lots

The composition of the tender lots represents the heart of the problem in the public procurement of pharmaceuticals, in this regard the competition Authority has also provided guidelines. Advice notes AS187 and AS251<sup>48</sup> say that in order to allow the competitive development of the tender, the object of the same cannot be artificially expanded or restricted. In fact the AGCM clarify that if the lot was expanded too much, those firms that can furnish only a single supply would be excluded; on the other hand, if the tender object was subdivided this could allow procurement entities to evade the application of EC regulations and consequently to exclude the participation of foreign firms. Finally the Authority advises careful definition of the tender object which must be highly qualified in technical and economic terms, but at the same time must not bear identifying marks or references to a specific brand or patent. However if these indications are sufficient to guide the activities of the procurement officials in most of the market, they are not sufficiently adapted to suit the drug supply setting where it is necessary to consider various other constraints that come into play. In general it can be argued that in the pharmaceutical sector the need to ensure the selection of a large number of products guarantees doctors a greater choice in selecting the most suitable drug for each disease. Furthermore, the difficulty of a drug in being successful in hospital tenders has repercussions on the diffusion of the same also in the retail market, given the existing continuity between hospital and home therapy<sup>49</sup>. Therefore to provide hospitals with a product is particularly important for pharmaceutical companies because it is also a form of marketing that will be useful for the success of the same drugs in the retail market<sup>50</sup>. However, what criteria should be enforced to establish a balance between cost containment and the availability of appropriate, effective and innovative treatment is under discussion.

With regard to the composition of pharmaceutical lots, in Italy rules that can direct the activities of procurement officials in the pharmaceutical sector do not exist, so sentence number 549 of 2003 of Emilia Romagna TAR (Regional Administrative Court) can be considered the only guidelines. According to the administrative court, it is hoped that a single tender lot includes medicines composed of different active substances but belonging to the same therapeutic class ATC<sup>51</sup>. This stance is

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<sup>48</sup> AGCM, advice AS187, *Bandi di gara in materia di appalti pubblici*, supra note 39; AGCM, advice AS251, *Bandi predisposti dalla concessionaria servizi informatici pubblici – CONSIP S.P.A.*, supra note 39.

<sup>49</sup> Cf. AGCM, Advice AS440, *Procedure di acquisto di farmaci tramite gare a pacchetto*, in bulletin No. 48/2007.

<sup>50</sup> The existence of a relationship between hospital market and retail market is recognized by doctrine and jurisprudence. In this matter, see the decision of the director general of fair trading No. CA98/2/2001 of 30 March 2001, *NAPP pharmaceutical holdings and subsidiaries (NAPP)*, available at: [http://www.ofc.gov.uk/shared\\_ofc/ca98\\_public\\_register/decisions/napp.pdf](http://www.ofc.gov.uk/shared_ofc/ca98_public_register/decisions/napp.pdf). In this decision fines were imposed on a pharmaceutical company by the UK competition authority for selling its products to hospitals at very low prices, whilst selling the same products via pharmacies at very high prices to patients, a strategy that could be sustained as doctors were found to be strongly influenced by the brands used in hospitals.

<sup>51</sup> According to the Anatomical Therapeutic Classification (the so-called ATC: the classification system adopted by the Nordic Council on Medicines of Uppsala), pharmaceuticals with the same therapeutic properties are included in the same ATC third level: they are considered as substitutes for the treatment of the same disease.

justified by the fact that the above-mentioned criterion of homogeneous therapeutic categories<sup>52</sup> - stated by Article 8, paragraph 10/13 of the Act of 1993 No 537 - is used to define the list of medicines reimbursable by the NHS and consequently it could be considered an effective criterion also to settle on a single award lot. In reality the criteria adopted to establish a list of reimbursable medicines are very different from those criteria required to define a group of drugs which will come into direct competition. In fact, building a homogeneous category of medicines, considered deserving of being reimbursed for the same price, means that all products in this category will be reimbursed under the same conditions. Instead, if drugs belonging to the same category are in competition with each other, only the selected product will be purchased and consequently will have access to the market<sup>53</sup>. Indeed, in the pharmaceutical field the identification of mutually replaceable products represents the result of a very complex operation. As regards to that, the Italian competition Authority has established<sup>54</sup> that the ATC3 therapeutic class is the most used to define the “market of product”. This means that, in general, the drugs belonging to the ATC3 class can be considered substitute products. Nevertheless, the Authority has also specified that this rule does not always work, since the ATC3 class medicines sometimes have important different features. For example, the problem of precisely assembling a group of interchangeable drugs in order to limit the “market of the product” is particularly significant within parallel imports of pharmaceuticals<sup>55</sup>. On this matter, there are many decisions which define the relevant market in very different way; in particular, in order to detect the existence of a dominant position, some Courts qualify the relevant market as that one constituted by medicines belonging to the same ATC3 class<sup>56</sup>. Nevertheless, in other decisions, the relevant market coincide sometimes with the ATC4 class<sup>57</sup>, sometimes with the individual branded pharmaceutical<sup>58</sup>, or with the single drug prescribed by the physician<sup>59</sup>. Certainly, the *ratio* governing the two branches of the law is very different. In fact, in the regulation of parallel imports the definition of the relevant market is a preliminary step to

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<sup>52</sup> In particular, the concept of homogeneous therapeutic categories is defined also by the CUF (Single Italian Pharmaceutical Commission) as a group of drugs (active substances and their pharmaceutical preparations) which, in relation to their main therapeutic indications, have a common mechanism of action and are characterized by the same clinical efficacy and side-effects, although they can also have different additional therapeutic indications. A therapeutic category includes drugs composed of perfect dosage form, unit dose and number of dosage units which allows doctors to make the same therapeutic intervention, in terms of intensity and duration.

<sup>53</sup> Cf. F. Massimino, *Gare pubbliche di farmaci, novità applicative e aspetti critici*, in *Sanità pubblica e privata* No. 1/2004, pp. 63-82, note 7.

<sup>54</sup> AGCM, *Indagine Conoscitiva nel Settore Farmaceutico*, 1997, § 1.2, available at [http://www.agcm.it/agcm\\_ita/DSAP/DSAP\\_IC.NSF/0/3a250fe3093bed4ac12564c3004594a7/\\$FILE/Ic14.pdf](http://www.agcm.it/agcm_ita/DSAP/DSAP_IC.NSF/0/3a250fe3093bed4ac12564c3004594a7/$FILE/Ic14.pdf)

<sup>55</sup> Cf. Guglielmino M., *Il mercato rilevante nel settore farmaceutico: quando è la singola specialità medicinale a determinarlo*, 2005, available at [http://www.law-economics.net/public/App.%20MI%20Petronc%20c.%20Pfizer\\_2005.pdf](http://www.law-economics.net/public/App.%20MI%20Petronc%20c.%20Pfizer_2005.pdf)

<sup>56</sup> Cf. European Commission, Jdgmt 96/478/CE – *Adalat*, in GU L 201 of 9.8.1996, p. 1–81 and Court of Appeal of Milan ordinanza 26 April 2005 – *Soc. Farmacie Petrone / c. Soc. Pharmacia Italia e Pfizer Italia*, in *Foro it.*, 2005, I, 1885, (for a detailed comment of this decision see *Rass. Di Dir. Farm.* No. 5/2005, p. 952/968).

<sup>57</sup> Cf. European Commission, Jdgmt 2006/857/CE – *AstraZeneca*, in GU L 332 del 30.11.2006, p. 24–25.

<sup>58</sup> Cf. Court of Appeal of Milan, ordinanza 23 July 2005 – *Soc. Farmacie Petrone / c. Soc. Pharmacia Italia e Pfizer Italia*. For a detailed comment of this decision see *Rass. Di Dir. Farm.* No. 1/2006, p. 15/33.

<sup>59</sup> Cf. Conseil de la Concurrence, Jdgmt 04-D-05 of 24 February 2004, point 4, available at [www.conseilconcurrence.fr/](http://www.conseilconcurrence.fr/).

determine whether the investigated firm holds a dominant position in a given market; on the opposite, within the composition of tender lots choosing a group of interchangeable medicines represents a fit tool to guarantee a balance between the availability and lower prices of suitable medicines. Furthermore, in the mentioned case law, the existence of Courts' different definitions of substitute medicines shows that an aprioristic classification of drugs does not allow to identify a perfect replaceability within the medical products because it is always necessary to take into account the circumstances of rules application. With reference to tender system, the conflation of medicines on the basis of the ATC3 class – according to which all drugs designed for the treatment of the same disease are interchangeable, regardless of the active substance of which they are composed or the patent coverage – seems rather generic. Surely in the short term, this choice could trigger enormous competition between the specialties with similar but non-identical features and as a consequence it could lead to a larger containment of costs, but there are many other variables to consider. First according to reliable doctrine<sup>60</sup>, lots which include large equivalence classes risk making products which are differentiated in terms of active ingredients, phase of life cycle, research content and existence of a patent, homogeneous in the eyes of consumers. In other words, the most innovative medicines would establish themselves more slowly in a market in which they are considered more or less equivalent to other medicines which have been available for much more time and consequently are cheaper than the former. Besides the doctors would be forced to prescribe indifferently non-identical drugs because only those have been selected.

Moreover, to tell the truth, the competitive confrontation between in-patent and off-patent drugs does not necessarily achieve a cost saving in the short run. With regard to this, it is interesting to consider specific tenders which are called “package tenders”<sup>61</sup>. In “package tenders” the suppliers can group some or all pharmaceuticals included in a lot and grant an initial discount on the price of the individual drug and an additional one on the price of the entire package made up of in-patent drugs and drugs with expired patents. This practice is inefficient because it is not favourable for those firms that produce only generic drugs: in fact manufacturers of generics have little opportunity to offer both in-patent and off-patent products at a competitive price. Instead the Authority recommends distinguishing lots constituted by off-patent drugs from those composed of drugs under patent protection that are considered substitutable by the scientific community. In this way: i) from the competitive confrontation between expired patent drugs, in the short run, the maximum discount on these types of drugs could be achieved and, in the long run, a lowering of price and a larger distribution of the generics at a competitive price; ii) from the competition between active substances with the same therapeutic properties but covered by patent, a larger distribution of innovative medicines and even cost savings in

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<sup>60</sup> Cf. F. Pammolli e C. Bonassi, *Prezzi di riferimento diversi tra regioni. Un commento al comunicato Aifa n. 50 del 2007*, Editoriale CERM No. 4/2007, available at <http://www.snamid.org/Prezzo%20di%20riferimento%20tra%20diverse%20regioni.pdf>.

<sup>61</sup> Cf. AGCM, advice AS440, *Procedure di acquisto di farmaci tramite gare a pacchetto*, supra note 49 .

the short run could be achieved. Nevertheless even in this respect, some doubts arise about the selection criteria that would be fairest to apply where, for example, a tender lot was composed of a single patented molecule distributed by different manufactures connected by a co-marketing contract<sup>62</sup>. In general the co-marketing agreement amounts to a common interest of the contracting firms. Using this strategy, pharmaceutical companies adopt promotional policies oriented both to obtaining greater popularity of the same molecule in the medical class and also to increasing the competition with other different active substances which have the same therapeutic efficacy but are made by other companies<sup>63</sup>. However, while in the “ordinary” market the competitive strategies of the co-marketing firms are based both on marketing differentiation and on different prices, in public tenders the only competitive leverage between these type of companies is the sale price. Certainly the author agrees with the assertion that where there are companies in co-marketing relations, stimulating competition between patented drugs leads to lowering the price of the same<sup>64</sup>. However it is necessary to reflect on the fact that this type of competition is altered because the licensor and the licensee companies do not compete on an equal footing. In fact, the marketing authorisation holder will sell its molecule (or the finished product) to the licensee at a price that it considers remunerative to itself, inclusive of the costs incurred: this means that it will be very difficult for the licensee to present a more favourable bid. This problem is the result of a short-circuit in the Italian market, which was created as a consequence of an automatic acceptance by the internal authorities of trade practices such as co-marketing, without subjecting the same to a legislative model that could regulate the effects of competition. Under present conditions, the benefit of lower prices in the short term derives from price competition but it has the implicit risk of the licensee exiting from the market in the long term. However what is still not clear is whether this possible exit of licensees from the market in the long term could be classified as a loss of efficiency for the market or, on the contrary, as a sustainable sacrifice to ensure an application of the competition dynamics in which companies that are better able to organize their activities prevail<sup>65</sup>.

With regard to the constitution of lots, a final comment is needed about the situation in which the ASL (Local Health Agency) buys truly innovative in-patent medicines, which are considered by the scientific

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<sup>62</sup> The co-marketing relationship is defined by doctrine as a marketing strategy whose aim is to use the powers of two or more competitors to sell the same active ingredient. First it was developed in the ‘80s and after the patentability of the drugs it was recognised. In fact it was created as a way for foreign multinational companies to more easily and promptly obtain marketing authorizations for their product through their Italian partners’ collaboration.

This definition is extrapolated from the AGCM decision No. 7337 of 1999, in Case *Servier Italia – Istituto Farmaco Biologico Stroder*, point 2.2, available in bulletin No. 26/1999. It is one of the three AGCM decisions existing on co-marketing strategy, the others are: AGCM, decision No 6927 of 1999, in Case *Byk Gulden Italia-Istituto Gentili*, available at bulletin No. 8/2009; AGCM, decision No 6928 of 1999, in Case *Istituto Gentili-Merck Sharp & Dohme -Neopharmed-Sigma Tau industrie farmaceutiche riunite-mediolanum farmaceutici*, available in bulletin No. 8/1999.

<sup>63</sup> Cf. AGCM decision No. 7337 of 1999, in Case *Servier Italia – Istituto Farmaco Biologico Stroder*, point 2.2.

<sup>64</sup> Cf. F. Massimino, *Gare pubbliche di farmaci: novità applicative e aspetti critici*, supra note 53, p. 69, nt 9.

<sup>65</sup> For a critical view of co-marketing contracts see M. Sorrentino, *La strategia di co-marketing nel settore farmaceutico*, in *L’impresa* No. 10/1992, pp. 49-57; See A. Grandi, V. Odorici, M. Sobrero, *I gruppi strategici cognitivi nell’industria farmaceutica italiana*, in *L’industria* No. 2/2000, pp. 263-287; See C. Piria, *Un riesame critico del co-marketing farmaceutico (in margine ai provvedimenti dell’Autorità garante della concorrenza e del mercato)*, in *Rass. di diritto farmaceutico*, 2000, pp. 718-735.

community as not replaceable or replaceable only with obsolete or less effective products. These types of medicines should be purchased through private negotiated procedure. In fact in these situations the principle, often affirmed also by AGCM<sup>66</sup>, that the widest application of the tendering procedure ensures the highest degree of competition between firms operating on a market, should be debunked. The doubts about the negotiated procedure can derive from the mistrust towards the discretionary decisions of public procurement officials and not from competition reasons. In fact, in the market being analyzed – characterized by differentiated products and continuous flows of innovation – individual negotiation represents normal economic trade and as such is subjected to the conditions of natural competition<sup>67</sup>. Besides Article 57, II paragraph, letter b) of Legislative Decree No 163/2006<sup>68</sup> specifically provides for the negotiated procedure when, by way of technical or artistic nature or relating to the protection of exclusive rights, the contract may be given only to a particular economic operator<sup>69</sup>.

### 3.4 – Second specific criterion, how to award the contract

Articles 53 and 55 of Directive 2004/18/EC regulating the award criteria for the bid are embodied in Italian law in Articles 81, 82 and 83 of the Procurement Code (Legislative Decree No 163/2006). According to the law, the best bid can be selected on the basis of the lowest price or the most economically advantageous bid criteria. In the first case, the bid will be considered for its price; whereas in the second case other factors are considered such as price, performance, delivery time and service, in order to reconcile economic and the qualitative aspects. According to the AGCM opinion<sup>70</sup> and with a view to promoting competition, the lowest price criterion tends to be more appropriate where the object of the contract is standardized; whereas in situations in which the qualitative aspects of the bid contribute to better satisfaction of the public interest, a more complex evaluation<sup>71</sup> would be hoped for. Besides, in order to consider the bids, IV paragraph, of Article 83, of the Procurement Code states that contractors can designate experts to draw up the criteria, weights, scores and the specifications which must be indicated in the auctions.

Unfortunately in pharmaceutical tendering, only one of the two criteria, the lowest price, is usually considered. However on the basis of a differentiation proposed in literature, the enforcement of the

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<sup>66</sup> Cf. AGCM, advice AS285, *Selezione delle imprese interessate al ciclo di produzione di bollini autoadesivi per i prodotti farmaceutici*, in bulletin No 46/2004; Cf. AGCM, advice AS187, supra note 39.

<sup>67</sup> See M. Libertini, *Organismo di diritto pubblico, rischio d'impresa e concorrenza: una relazione ancora incerta*, in *Contratto e impresa*, No. 6/2008 pp. 1201-1227; see also M. Libertini, *La tutela della concorrenza e i giudici amministrativi nella recente giurisprudenza*, supra note 18.

<sup>68</sup> The Article 57, II paragraph, letter b) of the Legislative Decree No 163/2006 implements the Article 31 of Directive 2004/18/EC.

<sup>69</sup> Cf. R. De Simone, *Procedura negoziata senza bando per unicità del prestatore: una deroga obbligata al principio della concorrenza*, in *Lexitalia.it*, June 2009.

<sup>70</sup> AGCM advice AS251, *Bandi predisposti dalla concessionaria servizi informatici pubblici – CONSIP S.P.A.*, supra note 39.

<sup>71</sup> With regard to the choice of the best award criteria see also R. Caponigro, *La motivazione della scelta del contraente negli appalti aggiudicati con il criterio dell'offerta economicamente più vantaggiosa*, supra note 22.

three existing criteria is suggested. Of note, some scholars<sup>72</sup> divide drugs into three distinct categories: 1) branded or un-branded off-patent drugs; 2) in-patent drugs that are less innovative either because they have been available for a long time in the market or because they constitute incremental innovations; 3) in-patent drugs with new compositions which introduce significant innovation. It is possible to apply different award criteria to each category as follows.

First, some observations on the trend of generic drugs<sup>73</sup> suggest that the lowest price criterion is appropriate only for making a choice within the pharmaceuticals belonging to the first category. In fact competition on price has a positive impact on off-patent molecules<sup>74</sup> because they can be truly considered as identical copies in terms of active substance, dosage, pharmaceutical shape, modality of release and medication. In cases like these, promoting *à la Bertrand* competition could mean encouraging an alignment of the marginal costs of production<sup>75</sup> and consequently a decrease in selling price and a larger diffusion of the same products<sup>76</sup>. Instead for drugs considered substitutes and belonging to the second category mentioned, the proposal is to use the most economically advantageous criterion. In fact, as stated above, these products are often perfect substitutes only for main therapeutic indications because they present some additional specific features. Consequently where this type of competition can be enforced, it should be based primarily on the added value that each product, or each manufacturer who supplies the product, is able to provide. According to an expert<sup>77</sup>, in the pharmaceutical field the qualitative assessments on advantageous bids can concern: the logistic integration between the manufacturer and the purchaser's administration, the pharmaco-economy, the equipment or the courses that are directly or indirectly aimed at the medication and other cognitive or practical support which allows public bodies to exercise their therapeutic function optimally. However to safeguard the impartiality of the choice, procurement entities must list which of the additional qualifications justified the award of the contract. In fact, European Court of Justice has ruled<sup>78</sup> that the contractors can choose the award criterion which is the most appropriate to the tender object, but at the same time they are obliged to indicate the assessment methods and to

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<sup>72</sup> The tripartition of pharmaceuticals is freely inspired by the draft: F. Pammolli, C. Bonassi, M. Riccaboni, N. Salerno, *Regolazione di prezzo, innovazione, ciclo di vita dei prodotti: per una riforma del sistema di pricing nel settore farmaceutico*, published in *La regolazione del ciclo e dei prezzi dei prodotti farmaceutici e il sostegno dell'innovazione e della ricerca. Confronti europei e proposte di riforma* – July 2007, available at <http://www.astrid-online.it/farmaci/Paper-farm/index.htm>.

<sup>73</sup> Cf. C. Jommi, *Il confronto internazionale tra prezzi dei farmaci: aspetti metodologici, principali risultati in letteratura e studio osservatorio farmaci*, published in *La regolazione del ciclo e dei prezzi dei prodotti farmaceutici e il sostegno dell'innovazione e della ricerca. Confronti europei e proposte di riforma* – July 2007. available at <http://www.astrid-online.it/farmaci/Paper-farm/index.htm>.

<sup>74</sup> Cf. C. Jommi, *Value base pricing per i farmaci: quali opportunità? Quali rischi?*, 2009, available at [http://www.astrid-online.it/rassegna/04-12-2009/Jommi\\_Value-Based-Pricing\\_06\\_11\\_09.pdf](http://www.astrid-online.it/rassegna/04-12-2009/Jommi_Value-Based-Pricing_06_11_09.pdf).

<sup>75</sup> Cf. F. Pammolli, C. Bonassi, M. Riccaboni, N. Salerno, *Regolazione di prezzo, innovazione, ciclo di vita dei prodotti: per una riforma del sistema di pricing nel settore farmaceutico*, supra note 72.

<sup>76</sup> The same opinion is expressed by the European Commission *Pharmaceutical Sector Inquiry. Final Report*, 8 July 2009, supra note 2 and by OECD Health Policy Studies, *Pharmaceutical Pricing in a Global Market*, supra note 5, p. 150.

<sup>77</sup> F. Massimino, *pubbliche di farmaci: novità applicative e aspetti critici*, supra note 53, p. 71

<sup>78</sup> Cf. ECJ of 7 October 2004, in Case C-247/02 - *Sintesi c. Autorità Vigilanza Lavori Pubblici*, in *Giust. civ.*, 2004, p. 2893, with critical note of R.B.

explain the reason that led them to deviate from the lowest price criterion. Finally, as already specified, the drugs belonging to the third category should be excluded from the tendering process and be purchased through private negotiated procedure because they are truly irreplaceable with other kinds of products.

## Conclusions

In the light of research conducted in the Italian field, the purchasing of pharmaceuticals by tendering procedure could be an effective tool both in containing public spending and, at the same time, in protecting patient health. Nevertheless this efficient result could be achieved only on the condition that procurement entities adapt public procurement rules to the specific needs of the market in question. In fact, the public agencies should pay attention to the correct application both of general criteria enforceable on all tenders such as: i) the degree of transparency in the tender process and ii) the guarantee of maximum participation; and of those criteria particularly influenced by the features of the pharmaceuticals such as: i) the correct definition of the tender lots composition and ii) the selection of the appropriate award criteria of the bid.

In particular the procurement entities should guarantee the transparency of the product selection, considering that the same rules which limit the discretion of their choices could be an incentive for the exchange of information and the collusion between competitors. Moreover in order to prevent tenders from becoming a tool of unjustified exclusion of any firm, the procurement entities should ensure maximum participation avoiding enforcing qualifications that are too restrictive for the firms which want to compete. With regard to the composition of the lots, it would be opportune to consider that including a homogeneous class of drugs in the same lot is not the most appropriate way of stimulating competition, because a homogeneous class could result in a container of products with different features in terms of efficiency, innovation and sensitivity to competition. In fact the use of this system risks encouraging a price reduction in the short run, against certain negative effects in the long run such as: i) a smaller spread of truly innovative drugs, ii) a general homogenization in the use of drugs that are equal only for the main therapeutic indications, iii) a levelling out of competition which is unfavourable to the spread of generics and the lowering of their prices. Similarly, the criteria selected for the award of the bid should not be restricted to the lowest price. In fact price competition is certainly effective for branded or un-branded off-patent drugs<sup>79</sup>, but the same conclusion cannot be reached for in-patent drugs with different features which require a more complete and complex handling. In conclusion the author believes the observance of the listed criteria could allow tendering procurement to be an effective tool in stimulating the competition dynamics between companies. The

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<sup>79</sup> Cf. C. Jommi, *Il confronto internazionale tra prezzi dei farmaci: aspetti metodologici, principali risultati in letteratura e studio osservatorio farmaci*, supra note 73.

hoped-for effects are: lowering of medicine prices, wider distribution of generic products, rise in competition between less innovative drugs, achievement of adequate remuneration for the truly innovative drugs, serving as an incentive to further research and allowing patients a ready availability of suitable drugs.

Finally it is important to highlight that the remarks made are the result of an analysis of Italian legislation and practices, in which tendering is used mainly to supply the pharmaceutical requirement of hospitals. The same conclusions might not have been reached if it had considered tendering procedures as a tool to supply the retail market, a hypothesis also observed in the study by ÖBIG-FP<sup>80</sup>. In fact a feature of the tender is to provide for a single winning bidder, which means that the exclusion of some competitors from hospital procurement could be considered a bearable compromise for the market. Whereas if the winning bidder were also the only company that could enter the retail market, as happens in Germany, further observations would be required. For example with regard to German and Dutch reimbursable medicines, the tender would also affect decisions on reimbursement, because in pharmacies, consumers can only purchase the drugs that are selected by the tendering procedures at the reimbursable price. For this reason the comments put forward have overall value, but would require further specification if the foreign markets under analysis were regulated differently from the Italian market.

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<sup>80</sup> ÖBIG-FP, *Tendering of pharmaceuticals in Europe and EEA countries*, supra note 6.

## Bibliography

- AGCM, *Indagine Conoscitiva nel Settore Farmaceutico*, 1997, available at [http://www.agcm.it/agcm\\_ita/DSAP/DSAP\\_IC.NSF/0/3a250fe3093bed4ac12564c3004594a7/\\$FILE/Ic14.pdf](http://www.agcm.it/agcm_ita/DSAP/DSAP_IC.NSF/0/3a250fe3093bed4ac12564c3004594a7/$FILE/Ic14.pdf)
- AGCM, advice AS097, *Gare pubbliche per le forniture di prodotti sanitari*, 1997, in bulletin No. 29/1997;
- AGCM, advice AS187, *Bandi di gara in materia di appalti pubblici*, 1999, in bulletin No. 48/1999;
- AGCM, advice AS251, *Bandi predisposti dalla concessionaria servizi informatici pubblici – CONSIP S.P.A*, 2003, in bulletin No. 5/2003;
- AGCM, advice AS285, *Selezione delle imprese interessate al ciclo di produzione di bollini autoadesivi per i prodotti farmaceutici*, 2004 in bulletin No. 46/2004;
- AGCM, advice AS333, *Previsioni sul modello di gara da adottare per l'evoluzione della rete unitaria per la pubblica amministrazione (rupa) nell'ambito del sistema pubblico di connettività*, 2006, in bulletin No. 8/2006;
- AGCM, advice AS440, *Procedure di acquisto di farmaci tramite gare a pacchetto*, 2007, in bulletin No. 48/2007;
- Bedau M. and Tugendreich B., *Are German health insurers obliged to purchase drugs by public tender?*, August 2007, available at [http://www.pharmacist.or.kr/webapps/attach/data/pds03/Aug07\\_Euralex\\_MBedau\\_BTugendreich.pdf](http://www.pharmacist.or.kr/webapps/attach/data/pds03/Aug07_Euralex_MBedau_BTugendreich.pdf);
- Caponigro R., *La motivazione della scelta del contraente negli appalti aggiudicati con il criterio dell'offerta economicamente più vantaggiosa*, Report on IGI conference on corrective 3 to the public contracts code, held in Rome October 14 of 2008, available at [http://www.giustizia-amministrativa.it/documentazione/Caponigro\\_Motivazione.htm](http://www.giustizia-amministrativa.it/documentazione/Caponigro_Motivazione.htm);
- Dawson C. (European Social Insurance Platform member), *Cost Containment in the pharmaceutical sector*, July 2008, available at <http://www.peer-review-social-inclusion.eu/peer-reviews/2008/cost-containment-in-the-pharmaceutical-sector-innovative-approaches-to-contracting-while-ensuring-fair-access-to-drugs/stakeholder-esip/download>;
- della Cananea G., *Dalla concorrenza per il mercato alla concorrenza nel mercato: gli appalti pubblici nei servizi di comunicazioni elettroniche*, 2005, p. 136, available at [www.iisa.it/documenti/atti%2028.01.05/Della%Cananea\\_PPPiisa\\_BUP.pdf](http://www.iisa.it/documenti/atti%2028.01.05/Della%Cananea_PPPiisa_BUP.pdf);
- De Simone R., *Procedura negoziata senza bando per unicità del prestatore: una deroga obbligata al principio della concorrenza*, in Lexitalia.it, June 2009;
- D'Alberti M., *Interesse pubblico e concorrenza nel codice dei contratti pubblici*, in Dir. Amm. No. 2/2008, pp. 297-311;
- European Commission, *COMMUNICATION FROM THE COMMISSION, Guidelines on the applicability of Article 101 of the Treaty on the Functioning of the European Union to horizontal co-operation agreement*, 4 May 2010, available at [http://ec.europa.eu/competition/consultations/2010\\_horizontals/index.html](http://ec.europa.eu/competition/consultations/2010_horizontals/index.html);
- European Commission, *Pharmaceutical Sector Inquiry. Final Report*, 8 July 2009, available at <http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/index.html>;
- Fidone G., Gambuto S., Mele G., *Meccanismi elusivi e limitazione della concorrenza nella prassi amministrativa degli appalti pubblici*. Biennial reports of the CSC, Centro Studi Confindustria, edited by Cipolletta I., Micossi S., Nardozzi G., Trento S., March 17 of 2006 Biennial Conference, Rome. Document available at [http://www.confindustria.it/AreAtt/DocUfPub.nsf/3087977852662c0ac1256f65003aa57c/5bf88442620420eac1257132005edcc1/\\$FILE/PAPER\\_7d.pdf](http://www.confindustria.it/AreAtt/DocUfPub.nsf/3087977852662c0ac1256f65003aa57c/5bf88442620420eac1257132005edcc1/$FILE/PAPER_7d.pdf);
- Fiorella T., *ATI e disciplina antitrust*, in Urbanistica e appalti No. 7/2009, pp. 829-835;
- Fiorentino L., *Lo stato compratore. L'acquisto dei beni e dei servizi nella pubblica amministrazione*, Series I, Quaderni di Astrid, Il Mulino publisher, Bologna, 2007;

- Grandi A., Odorici V., Sobrero M., *I gruppi strategici cognitivi nell'industria farmaceutica italiana*, in *L'industria* No. 2/2000, pp. 263-287;
- Guglielmino M., *Il mercato rilevante nel settore farmaceutico: quando è la singola specialità medicinale a determinarlo*, 2005, available at [http://www.law-economics.net/public/App.%20MI%20Petronc.%20Pfizer\\_2005.pdf](http://www.law-economics.net/public/App.%20MI%20Petronc.%20Pfizer_2005.pdf)
- High Level Pharmaceutical Forum 2005-2008, *Final conclusions & recommendations of the HLPF*, October 2008, available at <http://ec.europa.eu/pharmaforum>;
- Jommi C., *Il confronto internazionale tra prezzi dei farmaci: aspetti metodologici, principali risultati in letteratura e studio osservatorio farmaci*, in *La regolazione del ciclo e dei prezzi dei prodotti farmaceutici e il sostegno dell'innovazione e della ricerca. Confronti europei e proposte di riforma* – July 2007, available at <http://www.astrid-online.it/farmaci/Paper-farm/index.htm>;
- Jommi C., *Value base pricing per i farmaci: quali opportunità? Quali rischi?*, 2009, available at [http://www.astrid-online.it/rassegna/04-12-2009/Jommi\\_Value-Based-Pricing\\_06\\_11\\_09.pdf](http://www.astrid-online.it/rassegna/04-12-2009/Jommi_Value-Based-Pricing_06_11_09.pdf);
- Kanavos P., Seeley L. and Vandoros S. LSE Health London School of Economics, *Tender systems for outpatient pharmaceuticals in the European Union: Evidence from the Netherlands, Germany and Belgium*, October 2009, available at [http://ec.europa.eu/enterprise/sectors/pharmaceuticals/files/docs/study\\_pricing\\_2007/tendering\\_systems\\_en.pdf](http://ec.europa.eu/enterprise/sectors/pharmaceuticals/files/docs/study_pricing_2007/tendering_systems_en.pdf);
- Lacava C., *I contratti pubblici tra Stato e Regioni e la tutela della concorrenza*, in *Giorn. di Dir. Amm.* No. 6/2008, pp. 624-632;
- Libertini M., *La tutela della concorrenza e i giudici amministrativi nella recente giurisprudenza*, in *Giornale di Diritto Amministrativo* No. 6/2007 pp. 632-642;
- Libertini M., *Organismo di diritto pubblico, rischio d'impresa e concorrenza: una relazione ancora incerta*, in *Contratto e impresa* No. 6/2008, pp. 1201-1227;
- Massimino F., *Gare pubbliche di farmaci, novità applicative e aspetti critici*, in *Sanità pubblica e privata* No. 1/2004, pp. 63-82;
- OECD, *Public Procurement: The Role Of Competition Authorities In Promoting Competition*, 2007, available at <http://www.oecd.org/dataoecd/25/48/39891049.pdf>;
- OECD Health Policy Studies, *Pharmaceutical Pricing in a Global Market*, September 2008;
- Pammolli F., Salerno N. C., *Il prezzo di riferimento e le gare sui farmaci off-patent: quanta confusione anche tra esperti*, CERM, SHORT NOTE N. 2/2010 ;
- Pammolli F., Bonassi C., Riccaboni M., Salerno N., *Regolazione di prezzo, innovazione, ciclo di vita dei prodotti: per una riforma del sistema di pricing nel settore farmaceutico*, published in *La regolazione del ciclo e dei prezzi dei prodotti farmaceutici e il sostegno dell'innovazione e della ricerca. Confronti europei e proposte di riforma*, July 2007, available at <http://www.astrid-online.it/farmaci/Paper-farm/index.htm>;
- Pammolli F. e Bonassi C., *Prezzi di riferimento diversi tra regioni. Un commento al comunicato Aifa No. 50 of 2007*, Editoriale CERM No. 4/2007, available at <http://www.snamid.org/Prezzo%20di%20riferimento%20tra%20diverse%20regioni.pdf>;
- Piria C., *Un riesame critico del co-marketing farmaceutico (in margine ai provvedimenti dell'Autorità garante della concorrenza e del mercato)*, in *Rassegna di diritto farmaceutico*, 2000, pp. 718-735;
- Piselli P., *I raggruppamenti temporanei fra le esigenze di tutela della concorrenza nelle pubbliche gare e salvaguardia della libertà di iniziativa economica*, in *Riv. Trim. degli Appalti*, 2006, pp. 133-151;
- Polo M., *Un ministro comprensivo*, 25.06.2010, WWW.LAVOCE.INFO Sanità/ Concorrenza e Mercati, available at [http://www.lavoce.info/binary/la\\_voce/articoli/cache\\_pdf/UN-MINISTRO-COMPENSIVO-1001799.pdf](http://www.lavoce.info/binary/la_voce/articoli/cache_pdf/UN-MINISTRO-COMPENSIVO-1001799.pdf);
- Sánchez Graells A., *Distortions of Competition Generated by the Public (Power) Buyer: A Perceived Gap in EC Competition Law and Proposals to Bridge It*, August 2009, available at [http://papers.ssrn.com/sol3/papers.cfm?abstract\\_id=1458949](http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1458949);
- Serafino S., *Problematiche antitrust nel settore farmaceutico: le gare come strumento per incentivare la concorrenza*, September 2008, available at

[http://www.assogenerici.org/articolihome/II Congresso Nazionale/Presentazione Stefania Di Serafino.pdf](http://www.assogenerici.org/articolihome/II_Congresso_Nazionale/Presentazione_Stefania_Di_Serafino.pdf);

- Sorrentino M., *La strategia di co-marketing nel settore farmaceutico*, in *L'impresa* No. 10/1992, pp. 49-57;
- ÖBIG-FP, *Tendering of pharmaceuticals in Europe and EAA countries*, June 2008, available at [http://ppri.oebig.at/Downloads/Publications/Final\\_Report\\_Tendering\\_June\\_08.pdf](http://ppri.oebig.at/Downloads/Publications/Final_Report_Tendering_June_08.pdf).