# PART X

## HEALTH SECTOR PROCUREMENT

# IMPROVING PHARMACEUTICAL PROCUREMENT: AVCP GUIDELINES FOR ITALIAN PUBLIC HEALTH STRUCTURES

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**ABSTRACT.** Public health structures in Europe procure pharmaceuticals following the procedures established in the EU Directive 2004/18. In Italy, lowest price sealed-bidding with lots division is the most adopted method. This paper illustrates several issues related to medicine procurement and illustrate the guidelines provided by the AVCP (Italian Authority for the Supervision of Public Contracts) to contracting authorities after specific sector inquiry. The guidelines deal with "zero/almost-zero price bids", quality of drugs, lots division of active ingredients, reserve prices, re-awarding rules after drug patent expiration, and uncertainty of quantity/length of the contracts. As many issues do not appear specific to the Italian context, AVCP guidelines might inform medicines acquisitions of contracting authorities in other countries.

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## INTRODUCTION

In many countries a relevant fraction of the public budget is allocated to purchase medicines.† For instance, in 2006 more developed countries' pharmaceutical expenditure accounted on average for 1.5% of GDP and 20% of total health expenditure, 63% of which financed by the public sector.‡

There is much difference in total expenditure between countries. For instance, Luxembourg, Denmark and New Zealand spend less than 1% of GDP to acquire medicines, while the United States spend about 2%. In major OECD countries, more than 50% of the total expenditure is financed by public sector. The countries in which the government spend more are the Netherlands and Germany (about 80%)§.

In 2010 the Italian pharmaceutical expenditure was 26 billion of euro, 1,24% of GDP, 12% of total (public and private) health care spending.** The purchase of medicines is largely financed by the public sector (75%).

Medicines that are directly provided to consumers/patients by public health structures, such local health districts (ASL) and public hospital (PH), amount to 7 billion of euro, 27% of the total pharmaceutical expenditure and about 0,25% of the Italian GDP.††

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† We will use drugs, medicines and pharmaceuticals interchangeably. The paper does not deal with vaccines, contraceptives and medical supplies.

‡ See WHO, *World Medicine Situation* (2011).

§ Eurostat, *Health Statistics* (2012).

** More data are in Farmindustria (2011), Evoluzione del settore farmaceutico. See also OSMED (2011), *L'uso dei Farmaci in Italia*, Rapporto nazionale anno 2010.

†† In 2009, public contracts for drugs procurement represent 7,5% of total public contracts above €150.000. *For more details on the market of public procurement in Italy, see* AVCP (2009), *Relazione Annuale al Parlamento.*

Regions are charged by the Italian constitution and other lower-rank laws to manage and provide health services‡‡.

Within Regions operate many different public bodies that purchase and dispense medicines to final consumers. At the beginning of the 2000' such institutional arrangement did not appear efficient for several reasons: huge differences in drug prices inter and intra regions; difficulties in achieving scale economies; many tendering procedures for the same medicines with different procurement/awarding rules. Moreover, several regions were experiencing (and still experience) high deficit in the health financial budget.

In the last year, several initiatives of Italian governments aimed at simplifying the fragmentation of purchasing units and bodies and at further strengthening the power of Regions by encouraging centralization of medicines acquisition procedures. These policies were also accompanied with the imposition of commitments to reduce health deficits.

Centralization of purchases was incentivated by the creation of regional procurement agencies. These agencies are in charge to aggregate demand of different health structures facing with common needs (drugs, human vaccines, medical equipments, surgical instruments, etc.) and thus achieving potentially large economies of scale.

Demand aggregation also aimed at harmonizing purchasing prices and to define standardized costs that contracting authorities should have adopted for the calculation of the estimated value of the public contracts.

Despite such institutional evolution towards more centralization, encouraged by the introduction of the 2004/18 EU Directive and its transposition into the Italian legislations in 2006, procurement practices of contracting authorities (also CAs) still appear different and often far from full compliance with the law. To some extent, the phenomenon is favored by an area of administrative, operative and technical discretion that, however,

‡‡ In Italy the administrative powers are split between Central Government, 20 Regions, more than 100 Provinces and more than 8.000 Municipalities.

has been considerably limited by several updates of the national procurement laws in the years 2007-2011.§§

Within its institutional activity, the Italian Authority for the Supervision of Public Contracts (AVCP)*** has received numerous complaints from economic operators that show a significant heterogeneity in contracting authorities practices as well as distortions in the application of the procurement laws.

One important complaint was submitted in 2009 by "Farmindustria", the association of all firms producing originator/innovative pharmaceutical products.

As we will see in more detail in the next paragraphs, Farmindustria claimed the existence of several distortions in drug procurement procedures of Italian public health structures. These include the problems of extremely low bids, reserve prices set on the basis of the best price obtained in the previous tender, uncertainty in the contract length and in the quantity to be purchased within the contract.

The AVCP carried a specific sector inquiry on the pharmaceutical procurement with the aim to investigate the potential distortions signaled by economic operators and to verify whether bidding documents and procurement practices are respectful of the law.

The final target was the improvement of drug procurement by providing CAs with indications on how to draft bidding

§§ To reduce corruption and increase monitoring in public-private movements of money, recent reforms introduced the full traceability of payment refereed to public contracts and obliged contractors to activate specific bank accounts dedicated to receive invoices payment from CAs.

*** The AVCP was created in 2006 by the law 2006/163 of transposition of the EU Directives 2004/18 and 2004/17. Art. 6,7,8 of the law established the institution of a specific Authority for the supervision of supply contracts for works, supplies, and services. The mission of the Authority is to monitor the market for public contracts and to ensure that tendering procedures are run in compliance with the basic principles established by the 2006/163 law. Special attention is dedicated to transparency and efficiency of procurement procedures and to the prevention of distortions in the application of the law.

documents fully compliant with the law. The results of this inquiry are published in the guidelines object of the present article.†††

The paper is structured as follows. The next section illustrates major policies/guidelines adopted by international organizations and in particular those providing grants for the purchase of pharmaceuticals to less developed countries (to our knowledge the only international institution that issued guides on the topic). The third section shows the results of the AVCP national enquiry of pharmaceutical procurement. After illustrating the methodology followed in the enquiry, the paper will focus on issues emerged and indications provided by the AVCP. The last section presents the concluding remarks.

## OVERVIEW OF MAIN EXISTING POLICIES ON PHARMACEUTICAL PROCUREMENT

In this section we briefly survey the major existing policies/guidelines in pharmaceutical procurement at international level.

While we do not have information that more developed countries have issued specific guidelines to "regulate" pharmaceutical public procurement, there are several international institutions linking the funds they grant countries to the compliance of some basic principles and procurement rules. To date, guidelines mainly deal with pharmaceutical procurement of less developed countries and for humanitarian purposes funded by international institutions such as the, the World Bank, the World Health Organization (WHO) and the European Union.

The "regulation" of funds for drug procurement is particularly relevant for less developed countries because medicines are considered a key vehicle to combat deathly illnesses (such malaria and other infective diseases) as well as to reduce poverty and improve welfare conditions of target populations. The issue is of vital importance as local weak

††† The Italian version of the guidelines is available in Italian at the following link.

institutions and legislations, and the lack of capacity to perform transparent and efficient procurement may compromise the effectiveness of drug procurement and thus prevention against illnesses.

As we will see below, WB/WHO and the EU guidelines typically suggest to procure pharmaceutical by means of competitive procedures avoiding, at the same time, that competition may have adverse effects on the quality/safety of selected products. Pre-qualification is thus recommended as the preliminary and fundamental step in order to ensure that only "qualified" suppliers, i.e., those fulfilling international manufacturing and quality standard, are admitted to compete for the procurement contract.

To our knowledge, no other institution issued guidelines as those of AVCP providing CAs with practical rules to be adopted to improve procurement procedures and bidding document. In this context, we believe that, *mutatis mutandis*, AVCP guides may inform medicine acquisitions of CAs in other countries and work as complement indications for countries running drug procurement funded by the WB/WHO/EU or other international institutions.

On key guide document issued by the WHO is the *Operational principles for good Pharmaceutical procurement* (1999) which has drawn objectives and principles to improve pharmaceutical procurement practices in countries served by the Interagency Pharmaceutical Coordination group (IPC) members (the IPC includes all OECD nations and many developing countries).

By assessing the main problems connected to procurement of pharmaceuticals – which include offices with little experience and skills, absence of a comprehensive procurement policy, lack of rules and regulation – the document emphasizes the importance of some broad principles that any public or private organizations should apply in the development of drug procurement procedures. Essential principles recommend to ensure drugs and reliability of supplier products and to achieve the cost-effectiveness of medical treatments.

The respect of such principles crucially depends on the application of some practical rules, many of which have been already translated in many OECD procurement legislations in the last decade.

In particular, the WHO focuses the attention on the following issues:

- *Transparency*, namely the compliance of bidding documents with procurement legislation and with explicit and clear award criteria.
- *Knowledge, skills and experience.* Too often procurement officials have little or no specific training in pharmaceutical procurement.
- *Planning and monitoring.* The procurement process must be heavily supported by IT tools and infrastructures in order to track and report the contract's information as well as on suppliers' performance.
- *Quantities.* Accurate estimation of procurement needs and requirements are necessary to avoid overstocks or wastes.‡‡‡ Moreover, suppliers are expected to offer lower prices if they believe that quantities are estimated accurately.
- *Competition* is a general rule to awards pharmaceutical contracts, except for emergency or very small purchases.
- *Quality assurance*, that is pre-qualification of supplier (e.g., by adopting restricted tendering procedures) on the basis of capacity and reputation, and post-qualification that includes the assurance that the drugs purchased are compliant to international standards.

In the *Medicines Strategy 2002-2003* (2000), the WHO highlights the considerable impact of essential drugs on governments and households health budget in developing countries. One key policy indications arising from the MS 2002-2003 is the adoption of "pooled procurement", namely demand/need aggregation. Aggregation of needs should result in expected lower prices and thus in an increased affordability medicines.

‡‡‡ On this issue, see also WHO (1995), *Estimating drug requirements: a practical manual*.

Another WHO document worth mentioning is *Practical Guidelines on Pharmaceutical Procurement for Countries with Small Procurement Agencies* (2002).

The guidelines provide indications on most appropriate requirements that should be provided for in bidding documents in order to ensure quality, safety and efficacy of imported pharmaceutical products. This aspect is particularly important for countries with no local pharmaceutical industry and/or that cannot rely on drugs authorization/registration systems. The concern for the issue stems from the fact that in small countries regulation authorities often lack the capability to evaluate the quality of pharmaceutical products with the result that one department/agency may be called to carry out both drug control and procurement. The two functions are usually separated. In Europe, for instance, the European Medicines Agency (EMEA) is responsible for the scientific evaluation of medicines developed by pharmaceutical companies for use in the European Union but not for the procurement of drugs which is in charge of the single CA in each country.

In a context of "weak" regulation, the benefits from adopting international competitive bidding may vanish with potential worsening of quality standards. To cope with this issue, on major indications of the WHO is that small procurement agencies can ensure drugs quality by conducting restricted procedures to which are invited only prequalified suppliers.

*Procurement of goods, works, and non-consulting services under IBRD loans and IDA credits & grants by world bank borrowers* (May 2004, last revision January 2011), is the major World Bank publication regulating the acquisitions carried out within projects that are financed by the Bank. It is well known that the WB grants developing countries money for various purposes among which projects involving the award of procurement contracts.

To ensure that WB-financed procurements are undertaken in compliance with key recognized principles, such as transparency and efficiency, the guidelines establish that borrowers shall select the most appropriate method for the specific procurement. International Competitive Bidding (ICB), i.e., open competition among all potential suppliers fulfilling

requirements established by the WHO, is in many cases a suitable (and recommended) method.§§§

Recommendations apply to all contracts for goods, works, and non-consulting services financed by a Bank loan; pharmaceutical products are therefore subject to the application of the guidelines whenever their purchase is financed by the Bank.

In the *Standard Bidding Documents – Procurement of Health Sector Goods* (2004, revised in 2008), in line with the mentioned general guidelines for works, goods and services, the WB illustrates in detail the basic elements that any bidding drug-related document should contain. For this purpose, bidding documents should be prepared on the basis of templates for the technical specifications, bid data sheet and special conditions of contract. The templates have been prepared by the WB for use by borrowers and their implementing agencies in the procurement of pharmaceuticals (including vaccines, condoms and nutritional supplements) by means of open-international competitive procedures.

In the context of the EU there are no specific guidelines on pharmaceutical procurement, expect the guide-book for humanitarian aid. The *Review of Quality Assurance (QA) Mechanisms for Medicines and Medical Supplies in Humanitarian Aid* (2006) is the first guide-book of the European Commission in the health sector for emergency/humanitarian aid. The guidelines propose recommendations to NGO Partner of the European Commission's Directorate-General for Humanitarian Aid (DG ECHO) as how to manage the medicine cycle during emergency situations and to assist them to operate in accordance with international standards.

The *Guidelines for the award of Procurement Contracts within the framework of Humanitarian Aid Actions financed by the*

§§§ Other methods are the "limited international bidding", by which competition is restricted to a pool of bidders previously invited to the procedure, and "national competitive bidding" where only domestic firms are qualified to bid.

*European Union* (2011) offers a more comprehensive approach to health procurement under humanitarian interventions.

Similarly to the WB, these guidelines provide indications on the driving principles that are at the basis of the award of contracts in humanitarian actions financed, in whole or in part, by the European Union.

Since the provision of health supplies and services is considered an essential function in the achievement of the objectives of the humanitarian actions, it is argued that procurement must be performed with timeliness of the response and the quality/safety of the purchased products. One major message of the book is that procurement agencies should use restricted tenders conducted by direct invitation to all pre-qualified suppliers.

Pre-qualification involves screening suppliers before they are considered eligible for procurement in humanitarian actions. To this purpose, contracting authorities may rely on available lists, such as that of medicinal products used for HIV/AIDS, malaria, tuberculosis and for reproductive health issued by the WHO, or on indications/scientific assessment of international authorities as the European Medicines Agency.

Another key indication of the book is that in comparing the costs of pharmaceutical products, CAs should consider the cost of the whole care treatment in the place of the cost per unit of product, as this cost can be influenced by other factors such as transportation charges, storage requirements and shelf-life.

## PHARMACEUTICAL PUBLIC PROCUREMENT IN ITALY

As we have seen in the previous sections, availability of drugs, quality/safety and timely deliveries are considered essential elements of effective pharmaceutical acquisitions.

However, any procurement process should optimally trade-off the above elements with cost sustainability for the health systems.

In balancing these aspects, the CA is called to manage several key factors such as selecting a comprehensive list of drugs, namely "active ingredients"[****], estimating accurately the needs, evaluating products with commercial authorization, assessing market prices, managing deliveries and stocks, etc..

One fundamental step is to check whether or not the listed drugs are covered by patent. Despite the progressive entry of so called "generic" products in recent years, today many drugs are still *in-patent*. While in-patent drugs are provided by only one supplier (the patent's owner) and thus force the CA to negotiate the contract terms with her, remaining *off-patent* drugs are usually produced by two or more suppliers and can therefore be purchased through standard competitive procedures. Information on existing patents is thus essential to decide on the most appropriate tender procedure.

As in all EU member states, in Italy drugs dispensed to people by are purchased by the ASL, PH and the other public health structures in compliance with the awarding procedures indicated in the EU Directive 2004/18, which has been transposed in the Italian legislation in 2006. As well known, open, restricted and negotiated procedures can be used according to the value of the contract and on the type of good/service to be procured.[††††]

According to the legislation, except for those covered by patent, that can be purchased through direct negotiation with the sole producer or the exclusive national trader, drug procurement contracts must be awarded following the standard open or restricted procedures if the value of the contract is above the EU threshold (€200.000 for 2012).

In 2011 the AVCP concluded a national enquiry focused on the topic of drug procurement in the public sector. In carrying out its institutional activity, which is also based on reports and inquiries from CAs and economic operators, the Authority

[****]We will use, active principles, active ingredients and molecules interchangeably.

[††††] For a survey of tendering procedures adopted to procure drugs in the main EU countries, see Habl, Leopold, and Vogler (2008).

registered potential distortions in the application of the national and European procurement laws by part of Italian CAs.

In this context, the AVCP decided to launch a national enquiry with the aim of surveying common procurement practices followed by CAs, addressing potential distortions in the application of procurement laws and identifying possible solutions.

The analysis of many bidding documents and the interviews with CAs and economic operators highlighted the existence of several critical points and scope for tender design improvements. The issues addressed in the enquiry include key aspect as the set-up of reserve prices, the division of active ingredients contract into lots, the management of patent expiration during the execution of the contract, the submission of very low bids.

### *Methodology followed in the enquiry*

The first step was the interview to six central purchasing bodies operating at regional level and to the main pharmaceutical sector's trade associations, namely "Farmindustria" and "Assogenerici", representing, respectively, the firms producing originator and generic products.

The interviews to the central purchasing bodies aimed at collecting bidding documents, contracts as well as information of main procurement practices. The interviews to trade associations were focused on collecting information about main critical aspects that economic operators experience in participating to tender procedures.

The second step was the analysis of the **legal/regulatory** framework.

One first characteristics of the Italian health system is that drugs are classified into three categories, A,H,C; each drug is classified in one of the three categories according to the dispensing channel (pharmacy or hospit/ASL) and the level of reimbursement guarantee by the SSN. In particular drugs classification is as follows.

- **Type A.** Drugs included in this category are reimbursed by the SSN. These drugs are typically purchased in pharmacy, but could also be dispensed by hospitals. If purchased through a pharmacy, full reimbursement apply only to the least cost product (so called "reference price") while the consumer pays the difference between the market price and the reference price if a more expensive product is chosen.

- **Type C.** This category includes all drugs whom costs are fully beard by consumers (e.g., painkillers). They are purchased by hospitals/ASL and they are sold by pharmacies.

- **Type H.** These drugs are used and dispensed by hospitals, they cannot be sold by pharmacies.

As in main EU member States (except of Germany where pharmaceuticals prices are freely determined in the market),‡‡‡‡ in Italy the price of drugs is regulated by the National Drug Agency (AIFA). The price evaluation procedure takes into account several aspects such as the quality/innovativeness of the treatment, existence of substitutes in the market, price of similar drugs already in the market, etc. Drugs subject to price regulation are those included in categories "A" and "H", i.e., drugs whose cost is beard by the SSN.

A second important characteristic is that producers must provide drugs to public hospital applying at least a 50% (33,35% for some products) of discount on the drug market price, i.e., the price determined by AIFA.

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‡‡‡‡ For an overview of pharmaceutical regulation policies, see *Pharmaceutical Pricing Policies in a Global Market*, OCED (2008) at http://www.oecd.org/document/44/0,3746,en_2649_37407_41382764_1_1_1_37407,00.html. See also Garattini, Cornago, De Compadri (2007), for a comparative analysis of regulation schemes in Europe and alternative improving solutions.

The guidelines provided by the AVCP involve all drugs (except vaccines) procured by hospitals/ASL or other public health structures.

The third step was the audition of the regulatory agency AIFA and the Ministry of Health. Such auditions aimed at collecting more information on the regulatory framework and on instruments that are in use to monitor the market of drugs, with particular focus on the quality of medicines and criteria followed by AIFA to regulate prices and release authorizations.

The last step was the analysis of all information collected in the enquiry, the discussion of main as critical issues emerged, and the draft of the final documents containing indications and guidelines for Italian CAs.

### *Issues Emerged in the Enquiry and Policy Indications*

Before discussion in detail the issued emerged and indications provided by AVCP it is important fixing how Italian CAs usually purchase drugs.

CAs typically adopt the open tendering procedure in which all potential producers/distributors satisfying requirements indicated in bidding documents are allowed to present a tender. The lowest price is arguably the most adopted awarding criteria. The most advantageous offer is used rarely and only in specific situations in which there are some qualitative elements that are of relevant interest for the CA (for instance, in the acquisition of particular types of human vaccines).

The aim of the purchasing procedure is not the selection of a brand or a specific type of drug, rather the single active ingredient or molecule of which is composed any drug in commerce. In fact, each drug is produced with a combination of several ingredients and additives: the most important ingredients is the main molecule (or combinations of molecules) that is "in charge" to contrast one particular illness or pathology.

When the active ingredient/molecule to be procured is covered by patent, the CA directly negotiates price and other

contract conditions with the producer (or distributor) of the molecule.

Tendering procedures for drugs procurement are typically split into many lots. When the number of active ingredients to purchased is high the procedure can even be launched with hundreds or thousands of lots, each of them is dedicated to a single specific molecule.

In what follows we describe the issues emerged the enquiry and indication that the AVCP provided to CAs.

*Active ingredients and lots division*

Italian CAs typically buy many different types of molecules within the same tendering procedure. One procedure may comprehend hundreds or even thousands molecules. To each molecule is usually associated a specific lot. Not rarely, Italian contracting authorities bundle in one lot different molecules, typically substitutes/similar molecules.

Adequate lots division is important to obtain a good tender design.§§§§ The need for lot-splitting stems, in particular, from the market structure. Depending on the producing firms' technologies or marketing strategies, drugs may be put produced and sold in different (pharmaceutical) forms/solutions.

The elements characterizing drugs production are: the pharmaceutical forms (e.g., tablets, syrup, injections, etc.), the dosage (ml, mg., etc) and the packaging (number of pieces in each pack/box).

For example, "paracetamol", which is a widely used drug for the relief of fever or pains associated with many parts of the body, is produced by several firms with different final product solutions. The table below illustrates the some solutions existing on the market.

§§§§ For an in-depth analysis of the competitive effects of lots division, see Grimm, Pacini, Spagnolo and Zanza (2006).

| Characteristics of Paracetamol | | |
|---|---|---|
| **Pharmaceutical form** | **Dosage (mg.)** | **Packaging** |
| Tablets | 125, 150, 250, 500, 1.000, ... | 10,15,20 ... tablets |
| chewable tablets | | 10,15,20 tablets |
| Syrup | | 100 ml, 250 ml, .... |
| Injections | | 10, 20, .. |
| Sachets | | 15, 20, 25 sachets |

While many firms are endowed with production systems able to cover all combinations of forms and dosages, some firms can be specialized in one or a limited number of combinations, with the result that only a small number of economic operator is allowed participate to a tendering procedure in which one single lot comprehends all pharmaceutical forms and dosages required.

Since drugs may come in different form/dosage combinations, appropriate lots division becomes a critical element of the procurement design.

CAs should, however, bear in mind costs and benefits of lots division. On the one hand, additional lots tend to increase the costs of the tendering procedure in terms of offer evaluation as well as ex-post contract management; on the other hand, additional lots may increase the number of potential bids per lot and thus competition among firms. Such a trade-off is solved in favor of more lots when the benefits of higher expected competition (price reduction) overwhelms expected transaction/procedure costs.

One major indication provided by the AVCP to CAs is to **avoid bundling of molecules**. The basic rule for the AVCP is therefore “one molecule one lot”.

To ensure that tendering procedure are fully compliant with the principle of open competition to all potential suppliers,

the AVCP suggested that lots division should operate also at the pharmaceutical form level. Therefore, if the CA needs to procure one specific molecule in several different forms, e.g., tablets and syrup, she must further split the tendering procedure as in many lots as the number of different pharmaceutical forms existing on the market for that molecule.

Another reason supporting the lots division at pharmaceutical form level attains to the issue of price measures. Suppose, for instance, that the interested pharmaceutical forms for paracetamol are tablets and syrup. As tablets and syrup come with different unit measure (mg. and ml.), the one-lot solution complicates the design of the tender as the CA should appropriately define the weight for each single pharmaceutical form to be included in the lot. Instead, with separated lots, the CA simply defines the unit price over which competitors are required to bid: in the example of paracetamol, the CA will ask supplier the price per mg. for tablets and the price per ml. for syrup. The bid will be the unit price per ml./mg. multiplied the estimated quantity of mg./ml.

The CA can freely evaluate costs and benefits of further lots division with respect to the element of dosage and packaging. The CAs must, however, evaluate, on a case-by-case basis, the circumstances in which the drug with a particular dosage appears necessary in relation to the level of medical treatment to be ensured. In this case, separated lot for each different dosage may be appropriate, even though suppliers are not specialized in any particular dosage. For instance, tablets of paracetamol should be purchased in different dosages as each of them may be appropriate according to the particular type or seriousness of illnesses to be treated (e.g.,1.000 mg. are good for adults' fever but not for that of newborns). This is not the case, instead, for paracetamol in syrup, as any dosage solution appears easily adaptable to different, "spoon-based", medical treatments.

*Set-up the reserve price*

One important aspect emphasized by economic operators is that very often the reserve price is set equal to the best price obtained in the most recent tender. As the awarding unit price for

some active ingredient can be extremely low, sometimes even less than €1, suppliers claim that this policy prevents some firms to participate to the tender.

The enquiry shows the existence of a certain variety of solutions adopted in the set-up of the reserve price. While for some CA the benchmark parameter is the price fixed by the regulatory Agency (AIFA), which is the official market price for many drugs, for others the benchmark is the regulated price minus the discount provided for by the law (usually 33,35% or 50% depending on the type of active ingredient). Not rarely, however, the reserve price is fixed according to the average prices or the best prices obtained in previous tenders.

Which is the most appropriate policy?

The AVCP suggests that reserve price should reflect the real market values of drugs. In particular, the AVCP recommends using all price information available on the molecules of interest. Therefore, the reserve price for each single molecule should be set taking into account the following information:

- the regulated price;
- the minimum discount indicated by the law;
- the prices submitted by all participating suppliers in previous tenders;
- the reserve price and contract prices obtained by other CAs;
- the price of all close substitute molecules including the price of generic products (if any).

The use of all available information should help the CA identifying a value or a range of values within which choosing the reserve price. As a result, the reserve price might be “binding” for example in the case of limited dispersion in submitted prices of more recent tenders, and when these prices result steadily below the regulated price (net of law discounts). Confirmation of this trend in outcomes of other CAs purchasing the same molecule in similar quantities gives further support to a policy by which the reserve price is set in proximity of the best awarding prices or an average of winning prices in more recent tenders. Such a rule

achieves the goal of stimulating competition among more efficient suppliers without excluding potentially competitive bidders .*****

Instead, when the price dispersion of bids is not negligible, with some bids resulting not well below the regulated price, the reserve price could be set at higher levels. This policy reduces the risk of excluding some potential efficient competitor and stimulates a large participation to the tender.

*Very low tenders*

One of the most critical point emerged in the enquiry is the phenomenon of very low tenders. In particular, trade association stressed that very often awarding prices result in a very low price or almost zero price bid and that CA miss the check of the appropriateness of the bid.

A look to some data may help focusing the issue.

In the enquiry, the AVCP analyzed one important tender run in 2009 by one big hospital of Palermo. The tender was split in a total of 2.035 different lots and overall value of 1 billion of euro. The procedure was completed for 1.353 lots, for the remaining 682 lots there were placed no bid or no appropriate bid (i.e., bid below the reserve price).

One interesting data is that for those molecules for which the law establishes that suppliers must offer a discount of at least 33,35%††††† of the regulated price, the tender registers the following results in terms of the ratio (discount offer by the tender/minimum law discount): on a total of 363 offers, 185 (51%) report a price discount of at least 66,70%; 116 (32%) report a discount of at least 80%; 64 (18%) report a price discount of at least equal to 90%.

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***** For more details on the role of reserve prices in managing participation and competition, see Albano, Dimitri, Perrigne and Piga (2006).

††††† We remind that the law requires supplier to offer discounts on regulated price that usually range 33,35%-50%, according to the type of molecule.

Data indicate that many offers are not only well below the regulated price but also well below the 33,35% minimum discount required by law.

One thing worth noticing is that in several cases the reserve price is set to very low values. For instance, the lot n.434 referred to the molecule "Perindopril" (tablet of 5 mg.) which is used to treat high pressure, was auctioned off at a reserve price of €0,50187. The tender was awarded to the discount of 90,78%, while the regulated price is €21,78 and the minimum discount required by law to suppliers is 33,35%.

The table below summarizes the outcome of the tender for the lot n. 431.

Several things are worth noting. First, the reserve price set by the CA is well below the regulated price even net of the minimum discounts required by law. As illustrated in the previous point, sometimes the reserve price is considerably different from the regulated prices and is set on a level that reflects previous awarding prices. In the case reported in the table, the results of the tender seems to support the choice of the CA; despite the reserve price is tight relative to the regulated prices net of minimum law discounts, several suppliers placed a bid well below the maximum allowed price.

| Procurement of Enalapril (Tablets, 5 mg.) | | | | | |
|---|---|---|---|---|---|
| Supplier | Regulated price | reserve price (unit price per mg.) | lot value (3 years) | % discount over the regulated price required by law | % discount offered |
| 1 | € 2,99 | € 0,07248 | € 17.552,7 | 33,35% | 36,13% |
| 2 | € 2,99 | | | 33,35% | 44,96% |
| 3 (winner) | € 4,28 | | | 50% | 90,78% |
| 4 | € 4,51 | | | 50% | 65,00% |

One point worth discussing is that 3 over 4 suppliers placed discounts ranging 36%-65%, while one supplier was

particularly aggressive reducing the price of 90%. One may wonder how CAs should behave when facing with bids that appears abnormally low, i.e., when discounts are above 80%-90%.

The fear of very low tender stems from the risk that the contractor may violate the contract requirements, therefore delivering a level of quality lower than that expected by the CAs or being unable to ensure the supply for the entire contract length. For this reason, the Italian (and the European) procurement law establishes that CAs must check whether submitted are consistent with the performance and requirement established in the contract.

This is usually operated by asking the supplier to produce any document, element or information in support of the economic sustainability of the submitted price.

In line with the procurement legislation and cases law, indications provided by the AVCP are that the evaluation of the adequateness of price bids is under the technical discretion of the CAs. In other words, each CAs should evaluate, case by case and according to the rules provided by the law, whether or not the bid may appear or not abnormally low in relation to the type of drug being procured.

However, there are elements suggesting that, despite the very low level, quasi-zero prices (as that submitted in lot 431 discussed above) reflect the real/market prices and can thus be considered appropriate tender.

Preliminarily, it must be pointed out that there are cases in which the appropriateness check over price bids is hard to be performed by CA. Many molecules are in fact still covered by patent, and there is no or little terms of comparisons to evaluate the appropriateness of the sole price offered. From interviews and documents collected from several CAs in the enquiry, it emerges that no particular problem of contractual performance has been signaled in past procurements.

One element playing a key role is that drugs cannot be placed in the market without specific authorization of the regulatory agency AIFA. All drugs are subject to tight evaluation process on the effects obtained in laboratory experiments, on the

quality of all ingredients contained in the drug, and on the manufacturing methods and processes. After rigorous positive control by the AIFA, the producer is released the authorization to place the drug in the market. Such ex-ante control prevent the risk that are placed in the market drugs dangerous for human health or drugs that are not manufactured according to the international standard of production. Drugs produced in Europe or in other countries that have market authorizations in those countries are subject to the further authorization process of the Italian regulatory agency.

CAs are therefore confident that (the intrinsic) quality of procured drugs is ensured ex-ante by the control of AIFA and that it is unlikely to be affected by with very low prices.

For these reasons, in Italy there is no need for prequalification as recommended by WHO for developing countries.

Firms' trade associations argue that very low bids might also be due to products whose active ingredients or additives are produced in extra-EU countries without adequate control standard on their quality and manufacturing methods. It is argued that this may create or worsen the vicious dynamics for which low-quality suppliers induce other suppliers to submit very low bids in tendering procedures and offering medicines of low quality. The enquiry has showed, however, that the current Italian/European legislation on the authorization process to put the drug in commerce should in theory avoid such a risk.

Beside the intrinsic quality of drugs other qualitative dimensions may be relevant in pharmaceutical procurement. The most important one is timely deliveries.

The contract structure plays a key role in delivery issues. Indeed, in contrast with the purchase of many other goods (such as PC, printers, etc.), in which the delivery occurs only once, drugs are supplied periodically. The contractor is not called to deliver all the quantity estimated in the contract, rather she delivers the type of drugs in the quantities required according to the time schedule established by the CA. Bidding documents usually ask the

contractor to deliver the drugs within 7 days from the date of request of order.

By information collected in the enquiry, however, there is no evidence of contractor late deliveries or other relevant deviation from promised product or quality. There are no reports to AVCP about suppliers contract breach for drugs purchase.

One last point emerged in the enquiry is that often low prices can be explained by the expiration of the patent. Once the patent is expired, generic producers may replicate the molecule and enter the market. Since one major manufacturing cost is associated to research and laboratory experiments, manufacturing costs for generic producer are much lower.

When generic products become available, competition often leads to significant lower prices for both the originator and generic product. According to the *Pharmaceutical Sector Enquiry* (2008) of the European Commission, the entry of generic products yields a 20-25% of average price reduction in the first years, and in some – although not frequent – cases up to 80%-90% (see also Sauri', 2012).

Price reductions may be even larger when the drugs procured by the health structure are also dispensed via pharmacy. Very often patients ending hospitalization buy in private pharmacies the medicines dispensed in the hospital. This fact further stimulates competition in the tender as the winning supplier will have the chance to sell the offered product not only to the hospital but also to the patients via pharmacy after hospitalization.

*Patent expiration*

Patents are legal titles protecting inventions and providing the holder the right to prevent third parties from making, using, offering for sale or selling the product without the holder's prior authorization. The patent is essential in the pharmaceutical sector as it represents the key incentive factor ensuring an adequate reward of R&D investments.

The patent protection may be obtained for up to 20 years.

At the end of the patent's protection period, other firms are free to exploit commercially the molecule object of invention. This phase is typically characterized by generic firms producing and selling (bio-)equivalent drugs after AIFA authorization.

Bio-equivalence requires that the product contains the same molecule of the originator product, with the same dosage and pharmaceutical form. In other words, the generic products must be indicated for the same originator's therapy use. Very often, generic products contain more ingredients or additives that make the drug suitable to treat more than one pathology.

The entry of generic products typically determines a considerable reduction of regulated prices of originator drugs. The entity of the price adjustment is fixed by the law and by the AIFA according to several parameters.

Entry of generic products and price reductions of all drugs that are considered equivalent for a certain pathology have a significant potential impact of drug procurement outcome.

It is important noticing that bidding documents usually specify that the CAs may opt for contract resolution or modification of quantity to be purchased in case of entry of generic products. In practice, CAs often require the contractor (the originator producer) a revision of price in response to cheaper products available in the market.

While such practice directly lowers procurement costs, in terms of either unit costs per drug and administrative/tender process costs, it lacks exploiting the benefit of competition and it is not fully compliant with the principles of efficiency provided for the EU directives and the national procurement laws.

In case of patent expiration, the AVCP argued that CAs should not simply ask a price revision to the contractor, rather they should re-open the competition among all potential suppliers now authorized to sell the molecule/s of interest.

The CA, on a case-by case basis, should evaluate the specific procedure to be adopted, e.g., new tender procedure, negotiated procedure with suppliers, etc.

The rule proposed by the AVCP has the clear advantage of re-opening the competition amongst all suppliers endowed with AIFA authorization for the molecule of interest (originator and generic suppliers), therefore creating the conditions for the CA to obtain price reductions that can be greater than that proposed by the actual contractor.

*Quantity and contract length*

Very often the quantity indicated in bidding documents is not considered by the CAs a commitment to buy, rather an indicative/preliminary estimate of the volume of the supply.

In other words, the CA makes herself free to increase or decrease the purchase of drugs. The variation of quantity is often linked to a sketchy list of contingencies that may arise during contract execution, such as generic product entry, new epidemic diseases, updates to the handbook of medicine to be used in hospital, etc.

The Italian procurement law allows CAs to modify quantities up to 20% of the initial estimate. An increase of quantity above 20% is allowed under exceptional circumstances to be accurately motivated. CAs usually require the contractor to maintain bidding prices for purchases increase less than 20%.

The enquiry shows, however, that in practice the quantity purchased by the CA is much greater that the initial estimate, and it is well above of 20% of increase.

This is usually motivated by unforeseen contingencies, some of which indicated above, that may force the CAs to increase the quantity of drugs to be purchase in the contract. Quantity increases are often associated with renewals that make the contract last 2-3 times the initial length (typically fixed in 2 or 3 years).

In providing indications, the AVCP accounted for two opposite interests: that of the CAs to respond to unforeseen contingencies that may impact on the quantity of drugs necessary to ensure an adequate health care of patients, and that of bidding suppliers to know *ex-ante* the quantity to be sold with sufficient precision.

Increasing the reliability of quantity estimates provided for in bidding documents allows suppliers to make more accurate price offers. Suppliers may lower the unit price if they know *ex-ante* that the CAs will purchase 2 or 3 times the quantity indicated in the bidding document. This stimulate competition with respect to incumbent suppliers that exploiting a significant informative advantage (they know precisely the quantity needed for each type of drugs) are in condition to offer (very low) prices aligned to the real larger volumes of drugs that will be ordered during the contract execution.

The AVCP indications is to estimate with accuracy the quantity that should be purchased during the contract, thus avoiding that significant deviations from the initial values result in a loss of price further reduction that might have been obtained during the tender procedure.

## CONCLUDING REMARKS

The AVCP sector enquiry shows the persistence of several critical points in the tendering procedure for the purchase of drugs, despite the formal compliance to the procedures designed by the EC Directive 18/2004. The main AVCP suggestions to CAs can be summarized as follow:

1. **active principle and lots divisions**: the AVCP considers necessary avoiding bundling of molecules, i.e. providing for the rule “one molecule, one lot”. To ensure that tendering procedure are fully compliant with the principle of open competition to all potential suppliers, lots division should operate also at the pharmaceutical form level;

2. **definition of the reserve price**: the suggestion is to use of all available information to identify a value/range of reasonable values within which choosing the reserve price. The reserve price could be fined tuned according to the level of regulated price net of minimum law discount and the degree of price dispersion in previous tenders;
3. **very low bids**: The AVCP survey shows that often low prices can be explained by several factors. In line with the procurement legislation and cases law, indications provided by the AVCP are that the evaluation of the adequateness of price bids is under the technical discretion of the CAs; check should be done on a case-by-case basis;
4. **patent expiration**: currently, CAs ask a price revision to the contractor in case of patent expiration, the AVCP argued that it should be better to re-open the competition among all potential suppliers now authorized to sell the molecule of interest;
5. **uncertainty in quantities and length of contracts**: very often the quantity indicated in bidding documents are considered an indicative/preliminary estimate of the volume of the supply, rather than a true commitment to buy. The AVCP suggests that an accurate estimation of the quantity that should be purchased during the contract could foster competition and permit to CAs to gain a better price.

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