European Diagnostic Manufacturers Association

EDMA position paper

UNIT-PRICE, RESULT-BASED CONTRACTS FOR THE SUPPLY OF DIAGNOSTIC SYSTEMS

"Cost per Test" or "Cost per Result"

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PURPOSE OF THIS POSITION PAPER

The bases upon which the calculation of the price for the supply of *In Vitro* Diagnostic (IVD) medical devices depend to a large extent on what products / services are required to be supplied and the various obligations that each of the parties to the supply agreement undertakes. The purpose of this Position Paper is, firstly, to draw Members' attention to the very significant differences between two bases for price determination what have come to be called "Cost per Test" and "Cost per Result", and to indicate some of the management and control difficulties that are inherent in the "Cost per Result" basis. The second purpose is to point out certain legal considerations concerning the "Cost per Result" basis that may not be readily apparent to a supplier.

DIAGNOSTIC SYSTEMS: DEFINITION AND ANALYSIS OF A SPECIFIC CONTRACTUAL RELATIONSHIP

The diagnostic system comprises diagnostic kits, instruments and consumables in addition to the provision of assistance and maintenance services. We are dealing, therefore, with a complex set of goods and services designed to carry out diagnostic analyses (i.e. tests) on human biological samples.

Given that the legal instruments governing the supply of diagnostic systems are extremely varied, in this document we shall focus on the contractual relationship most commonly used by health services – particularly public ones – to acquire such systems.
Following on from the above, we shall consider this set of goods and (associated) services – commonly termed a "diagnostic system" – as an indivisible "whole".

Diagnostic systems are governed by complex contracts, including different contractual arrangements (e.g. supply, leasing, sale, loan for use, etc.), which may be combined in different ways depending on the requirements of the parties (or the specifications of the public service concerned).

The aim is to enable the laboratory to carry out its work – i.e. perform diagnostic tests on biological samples of patients/clients – as effectively as possible. We shall term this work, performed for an individual client, the diagnostic result.

It should be highlighted, first and foremost, that the supplier of the system does not take part in the laboratory's activities and is not involved in materially performing the tests in any capacity whatsoever. The supplier merely supplies the equipment required to carry out the tests.

In general, also when comparing systems in a competitive context, the criterion for assessing the performance of the systems is the test itself.

The test is in fact the system's "basic unit of measurement". The concept of quality and the comparison of the machines on offer are based on it. The test or diagnostic analysis or examination consists of the procedure

followed to carry out the measurement of a single analytic parameter with the relevant diagnostic apparatus.

The diagnostic result is the intellectual procedure whereby the responsible expert in the lab, on the basis of the results of one or (as is often the case) several (repeated) biological sample tests, formulates (or confirms) a diagnosis.

The laboratory's activity follows specific analytical protocols which are in all cases alien to the system's productive process, and these protocols may involve the repetition of the analytical process and hence of the test.

The diagnostic result is therefore the outcome of intellectual elaboration, of a specific, specialised skill, and of an assessment and evaluation process which in no case can be "delegated" to the machine (nor, more generally, to the system). The system is therefore the means, whereas the diagnostic result is the end.

The diagnostic result is the outcome of a healthcare procedure which is carried out by duly authorised personnel (medical doctors, chemists, biologists, etc.).

UNIT-PRICE, RESULT-BASED SUPPLY CONTRACTS

We are referring to contracts whereby some healthcare institutions are requiring their suppliers (from the diagnostic sector) to base the supply on the diagnostic result at a standard price, without defining materials required.
In other words, the laboratory, which uses the diagnostic system under its own exclusive responsibility and without the supplier being involved in the management process in any capacity, requests (or requires) the supplier to provide (the material resources of) the system under a contract whereby the supplier's remuneration is based on the diagnostic result as the basic "calculation unit" – i.e. the supplier's remuneration does not depend on the equipment used, but is agreed in advance on the basis of a fixed price per each diagnostic result.

The supplier must therefore provide the client (the laboratory) with all the equipment and materials required to carry out the task in question, while the client is required to inform the supplier of the number of diagnostic results carried out in order to calculate the supplier's remuneration.

Thus the characteristics of the equipment and materials used by the system to achieve the goal in question (the diagnostic result) become irrelevant. The use of said resources is defined, if at all, on the basis of a fixed unit-price.

Two possible reasons seem to have led some healthcare institutions to adopt unit-price, result-based contracts:
- Firstly, they transfer the system's management risk from the laboratory to the supplier, and
- Secondly, they make the supplier responsible for possible anomalies in the system, or rather in the machine which is at the heart of the system (such as for example, functioning problems), by regarding such malfunctions in terms of a unit-price and hence a priori ("ex ante") contractual definition. In this case, too, the control process is "diverted".

From a supplier's point of view, the first reason is problematic because it entrusts the control and proper management of the laboratory's activity to an external agency, i.e. to the supplier, without however enabling the latter to effectively intervene in the process.
Similarly, the second reason is problematic because it adopts a disproportionate and potentially damaging instrument to correct any anomalies arising in the contractual relationship, in spite of the fact that such anomalies can be remedied with ordinary contractual instruments.

KEY CONSIDERATIONS

Unit-price, result-based supply contracts can be criticised from several perspectives:

a. Management: The supply of unit-price, result-based diagnostic systems is a makeshift, "hybrid" solution between direct production and the outsourcing of healthcare procedures and cannot easily be reconciled with the basic quality assurance and process control criteria applicable to healthcare services;

b. Contractual relationship: The supply of unit-price, result-based diagnostic systems introduces a great deal of haphazardness in the contractual relationship, and this can have a significant impact on the supply cost structure. But even more clearly, it demotivates the client (laboratory) from putting in place the necessary control instruments to ensure the efficiency of its own activities. In theory, such control instruments become the responsibility of the supplier who nevertheless, not being in a position to intervene in the management of the clients' activities, sees his efforts (to control the process) completely thwarted by the absence of any powers to implement them effectively.
Another possible consequence of such an arrangement is the transformation of a healthcare equipment supply relationship into a healthcare service supply relationship – i.e. a kind of outsourcing of diagnostic procedures;

c. Fiscal implications: Calculating the supplier's remuneration "a posteriori", on the basis of a fixed "unit price", seems to be inconsistent with current tax regulations..

a. Management aspects

The basic principle underlying this kind of choice is the "make or buy" principle, i.e. certain ancillary, technical support, administrative or healthcare services can either be directly produced or outsourced.

There are many different arguments for and against outsourcing but, in any case, there is no automatic correlation between outsourcing and increased efficiency.

In fact, for outsourcing to be actually advantageous, the following main conditions must be fulfilled:
- Competition between potential suppliers and/or actual possibility of opting for own production within reasonable timescales;
- Effective ability to manage internal redundant processes/equipment;
- Access, on the part of the purchasers of the service, to adequate information on costs;
- Good contracting ability on the part of the purchasers of the service;
- Definition of effective penalties in the event of the supplier not complying with the provisions of the contract.

The choice between own production and outsourcing is at any rate a basic choice which should be clear-cut and well-defined, and which does not allow for half-baked solutions such as, for example, "purchasing consumables and paying on the basis of the services directly provided" or, more specifically, "purchasing diagnostic systems and paying on the basis of the diagnostic results produced by the laboratory". If it is decided to purchase a service as such, then the service should be remunerated (and hence no production costs will be incurred). Conversely, if it is decided to purchase the factors of production in order to produce the required service, then said factors should be paid for proportionally to actual consumption, rather than proportionally to the number of results obtained.

It is questionable, furthermore, that the supply of unit-price, result-based diagnostic systems can ever be compatible with basic good management and quality assurance criteria. In fact, effectively monitoring the appropriateness of the services provided – as well as of all related processes – has been a key element of the policies implemented in recent years to make

healthcare centres and hospitals more accountable.

Control of healthcare processes (including laboratory medicine in particular) is based precisely on identifying the main processes (involved in the performance and analysis of a test) in order to define adequately-controlled and reproducible characteristics (operational procedures). This includes all the organisational, administrative and medical/healthcare aspects that need to be controlled to ensure the quality of the overall service provided.

The IVD equipment industry has always promoted and supported the development and implementation of methods and measures to ensure high quality standards in test laboratories. However, the industry is neither responsible for, nor capable of drawing up the operational procedures on which quality assurance is based. This task is obviously the responsibility of the agencies in charge of supervising and managing the relevant equipment, personnel and overall organisation.

IVD equipment/materials are neither commodities nor mass consumption goods. Rather, they are sophisticated and complex factors of production, used in equally sophisticated processes and organisations that are essential to ensuring the quality of the healthcare services provided to the public.

This is why diagnostic companies specialise in the manufacture of such products and are capable of guaranteeing their quality. In order to ensure the highest possible quality standards for the client, it is important that companies in the sector are asked to do their job, rather than take on responsibility for someone else's job.

In order to optimise resources and overall purchase costs (as well as to ensure a quality service) it is therefore essential to approach the relevant technologies taking into account their specificities.

b. Contractual aspects

The kind of unit-price supply contract (or *"contrat à forfait"*, in French) briefly outlined above can include or exclude different provisions which may vary to a greater or lesser extent from one contract to another.

However, the minimum common denominator of such an approach is the calculation of the supplier's remuneration on the basis of the results achieved, and in some cases the "unit-price principle" may even be applied to the equipment itself.

In the latter case, the contractual relationship undergoes a fundamental change, acquiring all the characteristics of a contract for the provision of health services. What is involved here is a kind of outsourcing of healthcare services, which however is aberrant since it cannot be fully implemented, given that the supplier is not responsible for the management of the laboratory, in spite of being held responsible for the results. In other words, the laboratory's obligations to the supplier depend exclusively on the process of certification of the results.

As already shown above, the actual logical relationship between equipment supplied and results obtained is obscured. The former variable is independent of the latter.

Key elements such as the organisation of the laboratory and the diagnostic protocols, which are responsible for variations in the performance of the means employed (materials, equipment, etc.), are dropped out of the equation. The losses of reagents have in any cases to be supported by the supplier (misuse by the laboratory staff, fraudulent use, etc.).

The greater the variations, the more haphazardness become a major ingredient of the contractual relationship. Uncertainty affects the value and cost of the services.

Another adverse effect of this approach is the basic loss of ability, on the part of the client (the laboratory), to perform the tests, including the process of checking its own efficiency, for which the supplier is arbitrarily held responsible. All of this undermines the economic viability of the relationship and the efficiency of the laboratory.

If the principle of haphazardness is taken to its extreme, it can be said that the price paid for the diagnostic result completely loses its link with the performance of the system and becomes the price of a risk which the laboratory has passed on to the supplier.

c. Fiscal aspects

Also under a unit-price supply contract, invoicing must be based on the contractually agreed and actually delivered quantities of goods or services.

Article 63 of Council Directive 2006/112 EC on the Common System of Value Added Tax establishes that in general *"VAT shall become chargeable when the goods or services are supplied".*

It follows that invoicing cannot take place "*a posteriori*", on the basis of the diagnostic results certified by the laboratory, but must be carried out following the delivery of the equipment or materials in the specified quantities and at the specified unit prices.

Otherwise the supplier would find himself invoicing amounts different from (i.e. smaller or larger than) those specified in the accounting documents, thus clearly failing to comply with tax regulations.

PROPOSAL

The solution put forward to improve control over the supply without however shifting responsibility improperly on to the supplier consists in drawing up a contract for the supply of "test-based" systems.

Each of the bidding competitors and, subsequently, the chosen supplier should specify the consumption of the diagnostic test system supplied. Given that the materials/equipment are supplied in the shape of kits conforming to pre-established quantities, including specified quantities of the associated consumables, the bidder/supplier is required to establish, for each kit (and associated consumables), the number of tests that can be carried out (e.g. 1 kit = 100 tests).
The calculation of the quantity of equipment/materials should take into account the needs of the system in terms of consumables (start-up, rinsing, etc.).

This also makes it possible to compare different bids on the basis of the number of tests per kit – an efficient method not only to evaluate bids but also to monitor supplies.

Any deviation from the expected successful test rate will (or might) indicate an anomaly in the production process, and such an anomaly might in turn be attributed either to a malfunction in the system or to its misuse by the laboratory staff. Mutual feedback with the supplier will enable such anomalies to be corrected and will also help improve the efficiency of the laboratory.

LEGAL CONSIDERATIONS

Apart from the implications of Article 63 of Council Directive 2006/112 EC mentioned above, it should be noted that in at least one Member State, (Spain) several courts have ruled that it is not permitted to include in public tender contracts clauses incorporating a "Cost per Result" basis. Examples of such court decisions are:-

- 10th of December 2003 and 17th March 2004, by ***the "Sala de lo Contencioso Administrativo del Tribunal Superior de Justicia de Galicia"***
- 27th of October 2003, by ***the "Juzgado de lo Contencioso Administrativo N°7 de Sevilla"***

- 29th June 2004, by ***the "Tribunal Superior de Justicia de Andalucía"***.

The main reasons given by these courts for their decisions (and which have already been alluded to in this Paper) were the following:

The supplier has the right to set the price of the products actually supplied to and formally received by the hospital.

The price must be based on the material supplied, and cannot be left to be determined by reference to subsequent activities or inactivities by the hospital which are entirely outside the supplier's power and control. Blind trust cannot be required of a supplier.

The supplier can guarantee the quality of the product he supplies, but in no way can he guarantee or be responsible for its future storage and control when it is in the hospital or its future use by hospital staff.

It is up to the personnel of the hospital to guarantee the efficiency of the operations, the correct handling of the reagents and other material. The hospital is responsible for any bad practises it may adopt such as:
- Human failures in the handling of the product,
- Misuse of the material supplied or functioning of the instruments
- Losses, fraudulent use, damage or deterioration of the material
- Inadequate or inappropriate storage of the material (reagents removed from the fridge or fridge switch off)
- Wrong management of expiry dates (vial with short expiry date opened and used only once etc.)

The constant monitoring of a hospital's activities or those of its laboratories cannot be an additional obligation imposed on a supplier since that would constitute an impossible deviation of power and control and an unacceptable transfer of management risk.

EDMA would like to thank FENIN, the association representing the IVD industry in Spain, for sharing with EDMA members their legal experience and providing us reference cases and ASSOBIOMEDICA, the Association representing the IVD industry in Italy, for sharing with EDMA members a Position Paper developed in Italy, which is the basis of this document. EDMA would also like to encourage other NAMs to benefit from ASSOBIOMEDICA and FENIN work by translating / adapting this Position Paper if the same problems are met in other countries.

EDMA Tenders Task Force