

Romania: new legislation with impact on the drug/medical equipment supply contract award, enforced at the beginning of the second quarter 2013¹

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On April 2nd 2013 the Romanian Parliament passed a new law for implementing the EU Directive 2011/7/UE on combating the late payment in commercial transactions, i.e. Law no. 72/2013 on combating the late payment in contracts between professionals and contracts between professionals and contracting authorities.

This new Law provides for certain imperative payment terms, that are mandatorily applicable also to the state hospitals and other public medical institutions in Romania, including the Romanian Health Ministry, with the occasion of preparing and publishing bidding documentations for drugs, vaccines or any other medical equipment acquisitions. These payment terms were considerably shortened compared to the current practice on the drug and vaccines supply market, so that each and every contracting authority that is organizing a bid for such acquisition must observe the new payment terms (of 60 days, compared to the former standard term of minimum 180 days).

Another reform brought by this law is the establishment of a mandatory minimum legal interest, as a penalty for the late payments of hospitals to private suppliers, below which no hospital is allowed to go. This is another provision that hugely impacts the current practice regarding the penalties for late payments, which are usually set by hospitals at a very low rate (between 0,01%/day the minimum and 0,1%/day the maximum accepted). Under the new Law, the minimum penalty is composed of two elements: the Romanian National Bank's reference interest rate, plus 8 percentage points/year (this giving now a penalty of 13,25%/year).

Selective overview on the drug supply contract awards in Romania:

The award of public contracts in Romania is governed by the Government Emergency Ordinance no. 34/2006, which regulates all stages of a tender, from publication of the initial announcements (either of intention or of participation) and up to performance of the award drug supply contracts.

In case of state hospitals and/or other public medical institutions, these are obliged to organize public tenders for acquisitions of drugs in values exceeding a certain threshold, which currently is of Euro 15.000 for all lots of drugs contained in the tender documents. In case the overall value of the acquisition exceeds a certain ceiling, the respective hospital/medical institution has the obligation to publish the tender announcement and documentation in the Official Journal of the European Union as well (in addition to publishing them in the national electronic tender system, called SEAP (RO: "Sistemul Electronic de Achizitii Publice") – www.e-licitatie.ro).

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Tender documents and the main information published in the SEAP and the European Union Official Journal (if the case):

The tender data sheets must contain the following main information, for interested bidders:

- A description of the contracting authority and of the CPV classification of the drugs to be purchased from the drug importers and/or distributors;
- The minimum and maximum estimated total value of the funds to be allocated for drugs to be purchased, for all lots contained in the tender data sheet;
- Duration of the frameworks agreement and of the subsequent agreements that are concluded for each and every order of drugs, with the winning bidder;
- The conditions for participation (participation guarantee value, good performance guarantee value, documents attesting bidder's capacity to participate and provide the respective drugs/medical equipment under the conditions in the tender documents including the tender book – namely personal conditions, technical and professional conditions, economical conditions);
- The public sources of funding the acquisition; almost all state hospitals are funded by the National Health Insurance House (CNAS), subordinated to the Health Ministry; some hospitals dispose of internal funds, a case which is obligatorily mentioned in the tender documents as well;
- The type of acquisition procedure – i.e. if it is an offline or a online bid, if it is a public auction or a limited public auction – usually all state hospitals are using the procedure of public auction;
- The award criteria – in all cases involving state hospitals or other public medical institutions, the award criterion is the lowest price offered; if the procedure involves an electronic bid as well (as final stage of the procedure) the bidders have the possibility to offer discounted prices compared to those offered in the financial proposal, under certain terms and conditions;
- Details regarding the way the offers must be submitted, terms for validity of the offers;
- Details regarding the governmental body that is competent to settle the tender related disputes and other relevant information in this respect.
- Details regarding each lot of drugs, including the estimates minimum and maximum values, way of presentation, etc.
- A copy of the draft framework agreement and of the subsequent supply agreement, with all clauses that can be negotiated and those which cannot be negotiated, **including clauses regarding the term of payment and accepted penalty rates.**

Impact of Law no. 72/2013 over the tenders to be further organized by state hospitals, other public medical institutions, including the Romanian Health Ministry:

As it is mentioned in the preamble of this Law, it was designed to implement in Romania the European Parliament and Council Directive 2011/7/EU on combating the late payment in commercial transactions.

Article 6 para 4 of this Law imposes the hospitals and other public medical institutions to pay for the acquired drugs or other medical products or equipment within a maximum period of time of 60 days, running from three different moments, namely:

- The date the invoice or the payment request is issued;
- The date the drugs are handed-over, if this date is subsequent to the date the invoice is received or the invoice's date is not exactly regulated in the contract;

- The date the products are verified prior to payment, for evaluating the conformity of those products, if such a procedure is provided in the tender documents; in this case the evaluation procedure cannot exceed 30 days from receipt of the products, with certain exceptions.

However, according to article 7 of this Law, the contracting authority has the possibility to include in the tender documents a payment term that is longer than 60 days, with two conditions:

- This longer term must be objectively justified considering the particulars of that tender and
- Such clause must not be considered by Law 72/2013 an “abusive clause” in the sense that it is obviously un-equitable towards the supplier.

Law 72/2013 provides that it is not applicable to those supply contracts concluded before its enactment, and which shall continue to run based on the details valid in the tender documents at the time the tender was started.

As for those contracts that are not yet concluded (but the tender was finalized and the winner should sign the exact draft of contract provided in the tender documents, that is no longer compliant with the new Law) Law 72/2013 does not offer any explicit transitory solution.

In this case, the hospitals shall have the option to directly modify the respective draft-contracts, in order to make them compliant with the new Law (thus deviating however from the tender documents, which is not allowed by GEO 34/2006) or they have to conclude them as they are, with the consequence of some of their clauses being at risk of annulment in court as being abusive (if, for example, they contain a payment term of 180 days instead of 60), or the hospitals can be forced to cancel the whole tender and re-initiate another tender, that would observe the new legal provisions regarding the payment terms and legal interest.

With respect to the legal interest, any clause included in the tender documentation that would provide for a legal interest lower than the minimum legal interest (mentioned in the head of this article) shall be seen as abusive by operation of law and the court may annul such clause.

In all cases, Law no. 72/2013 does not apply to those contracts concluded between pharmaceutical companies, drug/medical equipment importers/distributors and consumers, as well as between such companies and other companies under judicial insolvency procedures (i.e. receivables to be collected within a judicial insolvency procedure).

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