



# Wholesale and retail mark-ups in ved trading: price regulation and state procurement

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VEGAS LEX

### WHERE DO WE FACE THESE LEGAL REGULATIONS?

Federal law dated 5 April 2013 No. 44-FZ "On the contract system in the area of procurement of goods, works, and services for state and municipal needs" (hereinafter referred to as the "Law No. 44-FZ") first consolidated in federal legislation special rules governing the purchase of vital and essential drugs (VED). Nevertheless, already during the first year of application of these provisions, we saw conflicting interpretations arise on the part of state customers, regulators, and market participants. In particular, the wording of the new law caused controversies concerning the possible application of wholesale and retail mark-ups in the formation of the maximum starting price of contract (MSPC) for drugs included in the VED list.

Thus, Part 10 of Article 31 of the Law No. 44-FZ says that the customer, during the procurement of drugs included in the VED list, has the right to refuse to conclude a contract with the tender winner, if the proposed price of the purchased products exceeds their "maximum selling price" and the tender participant refuses to lower the proposed price. At the same time, the concept of the "maximum selling price" is not used in current legal instruments, and the Federal Law of 12 April 2010 No. 61-FZ "On Circulation of Medicines" (hereinafter referred to as "Law No. 61-FZ") uses the term "maximum selling price established by the manufacturer".

In accordance with Law No. 61-FZ, manufacturers bringing to the market a drug included in the VED list, are required to register its price in the State Register of Maximum Selling Prices. Pharmaceutical distributors, in the meantime, calculate the selling price of the drug based on the actual manufacturer's selling price (which cannot exceed the registered price) and regional mark-up, the amount of which is regulated. With the use of a mark-up, distributors have the ability to offset their costs, in particular as-

sociated with the delivery and transportation of drugs to the regions of Russia.

Nevertheless, the current wording of Law No. 44-FZ does not expressly indicate that the customer is entitled to take into account the size of the regulated mark-up when determining the MSPC of the drug included on the VED list. This had led to a restrictive interpretation of the law, as reflected, in particular, in the Letter from the Russian Ministry of Economic Development dated 23 April 2014 No. D28p-548, according to which, the customer is not entitled to form the MSPC by taking into account the size of the regional price mark-up.

The presence of contradictory wording in Part 10 of Article 31 of the Law No. 44-FZ, allows for dual interpretation, as well as the existence of a restrictive (though not having the character of a regulatory act) clarification, led to the formation of a controversial law enforcement practices on this issue.

### LAW ENFORCEMENT PRACTICE: MORE QUESTIONS THAN ANSWERS

On 22 October 2014, Kemerovo OFAS issued a decision on Case No. 337/3-2014, in which it supported the demand of the customer to have the pharmaceutical distributor, who won the auction, reduce his proposed price of the contract to the level of the manufacturer's registered maximum price. Moreover, the Kemerovo OFAS explained the procedure for calculating the MSPC, by the customer, in the following way: "The price offered by the tender participant, who is a VAT payer, is composed of the 'price of the drugs' (this is actually the selling price + regional mark-up) and the VAT amount, charged to the buyer in addition to the price of the drugs. Thus, in accordance with Law No. 44-FZ, the customer must deduct from the proposed price of the tender participant, the amount of VAT (except in the case that the customer becomes aware that the tender participant is

not a VAT payer), and then compare the remaining part of the proposed price of the tender participant with a registered maximum selling price of the drug. If the price of the drugs (the actual selling price + mark-up) exceeds the registered maximum selling price, the tender participant is obliged to reduce his price (most likely dropping the regional mark-up). If the price of the drug (the actual selling price + regional mark-up) does not exceed the registered price, the contract is concluded at the proposed price of the tender winner, and the regional mark-up, in this case, is preserved".

Nonetheless, on 27 November 2014, the Kemerovo OFAS issued a decision that differs from the preceding one<sup>1</sup> on the same subject. According to the results of an audit, the antitrust authority found that the tender documentation contained a reference to the right of the customer to reduce the proposed price of the tender participant, to the level of the maximum selling price of the manufacturer. However, in this case, the Kemerovo OFAS concluded that the customer has no legal grounds to make a price reduction for a drug on the VED list, to the level of the maximum selling price, as Part 10 of Article 31 of the Law No. 44-FZ provides a different regulatory mechanism<sup>2</sup>.

At the same time, in law enforcement practice, one can also meet different approaches to the interpretation of Law No. 44-FZ<sup>3</sup>.

Thus, on 22 September 2014, the general prosecutor ordered the Regional Ministry of Health to eliminate violations of contract system legislation. When holding tenders in the region, the customer determined the starting price of the tender without taking into account the wholesale mark-ups, which led to the failure of more than 20 tenders for drugs – as the potential tender participants refused to participate in tenders that would lead to losses for them. In its order, the general prosecutor bluntly pointed out that the purpose of wholesale mark-ups – was to compensate suppliers for the cost of shipping and transportation of drugs. Accordingly, the order contains the following logic for formation of the MSPC. If the contract price is determined by excluding mark-ups, then the place of delivery should be determined not by the location of the customer, but by the location of the producer of drugs. In this case, the customer must conclude an additional contract for the transportation and delivery of drugs to the location of the customer. If the delivery is to be made to the location of the customer, then the contract price must include a maximum mark-up to cover transport and other costs of the suppliers.

On the possibility of taking into account mark-ups during formation of the MSPC, it is also indirectly provided for by the Decision of Ulyanovsk Region OFAS, dated 5 December 2014, in Case No. 11645/03-2014. The sub-

<sup>1</sup> The decision of the Kemerovo OFAS dated 27 November 2014 on Case No. 403/3-2014.

<sup>2</sup> In particular, it allows the customer to refuse to conclude a contract with the tender winner, if the offered price of drugs exceeds their maximum selling price, and the tender participant refuses to reduce it (moreover, the indicated regulation contains no direct wording allowing the price to be reduced by the customer).

<sup>3</sup> In practice, we see broad interpretations of the concept of "maximum selling price" and the subsequent need for justification of the size of mark-ups during formation of the MSPC. In accordance with the requirements of Article 22 of Law No. 44-FZ, to justify the MSPC, one can also use the tariff method. The tariff method is to be applied if, in accordance with the legislation of the Russian Federation, prices of purchased goods, works and services for state and municipal needs, are subject to state regulation, or are established by municipal regulations. In this case, the MSPC is determined by regulated prices (tariffs) for goods, works, and services. On the other hand, the prices of drugs are regulated in accordance with Law No. 61-FZ (such regulation implies the need to register the maximum selling price of the producer, and the establishment, on the level of subject of the federation, limited sizes of wholesale and retail mark-ups on the actual selling prices, established by the producers). In this regard, the MSPC is formed in accordance with the prices registered in the State Register of Maximum Selling Prices <http://grls.rosminzdrav.ru/pricelims.aspx> (Article 60 of Law No. 61-FZ), including VAT (10%), as stipulated in Paragraph 2 of Article 164 of Part II of the RF Tax Code, and the maximum mark-ups on the actual selling price of the manufacturer, in accordance with local legal and regulatory acts adopted in the corresponding subject of the Russian Federation. (We could not find examples of proceedings, in which such a procedure for the determination of MSPC was contested. However, as long as the current regulation is subject to varying interpretations, we cannot exclude the risk of such proceedings occurring).

ject of procurement in this case, however, was not the supply of drugs, but the provision of services to ensure that certain categories of citizens can obtain drugs and medical devices<sup>4</sup>. This service includes not only the purchase of drugs, but also their receipt, storage, delivery to pharmacies, and dispensing to citizens via prescriptions. The customer conducted an analysis of the market using the comparable market prices method, by issuing requests for price information from suppliers that had experience of providing such services. Commercial offers were received from three suppliers, and taken into account were the amounts of mark-ups on maximum prices of producers for drugs on the VED list. At the same time, the customer, to justify the MSPC, assumed the minimum value of the proposed mark-up, which was recognized as lawful by the OFAS Ulyanovsk Region.

### CONCLUSIONS

Today, it is obvious that conflicts would arise due to legal regulation of the pro-

curement of drugs, included in the VED list, and it is already having a negative impact on the market. Thus, those customers who wish to avoid risks and adhere to the letter of the law, may face failed tenders, and the inability to provide patients with necessary drugs. On their part, market participants that win tenders, could face forced reductions of their proposed contract prices.

It is difficult to unambiguously predict the future direction of this vector, which determines the formation of the legal practice. In this regard, the best way to eliminate the risks described above, is to make amendments to Law No. 44-FZ. An alternative would be the publication by relevant state agencies (in particular, the Ministry of Economic Development of Russia, the Federal Antimonopoly Service of Russia and the Russian Ministry of Health) of official informational letters, containing broad interpretations of current legal regulations.

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<sup>4</sup> During the procurement of complex services for the provision of certain categories of citizens with drugs (which includes not only the supply but also the storage and dispensing of drugs, as well as prolonged servicing of the population), legal enforcement practice, as a rule, grants exemptions from rigid regulations, which apply during the conclusion of state contracts, the subject of which is only the supply of drugs.

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