Competition Council
Republic of Latvia

Price Formation of Medicines and Alleged Competition Restrictions that Affect Financial Availability of Medicines

Sector inquiry
2019

Conclusions

1 Reimbursable and non-reimbursable medicines in Latvia have different pricing mechanisms. If the same medicines are sold in a pharmacy both as reimbursable and non-reimbursable, they have a different price. If a medicine is listed as reimbursable and is sold within the reimbursement system, its price forms in accordance with the Regulation of the Cabinet of Ministers No. 899[1] (hereinafter – Regulation No. 899). If the medicine is included in the list of reimbursable medicines (hereinafter – the List), but is sold outside the reimbursement system due to, e.g., different diagnosis of patient, the price through wholesaler and pharmacy mark-ups forms in accordance with the Regulation of the Cabinet of Ministers No. 803[2] (hereinafter – Regulation No. 803). In this case the price is higher than the price that forms according to the Regulation No. 899.

2 The regulatory framework does not clearly state that the price of medicines that are included in the List and sold outside the reimbursement system has to be formed in accordance with the Regulation No. 803, instead of the Regulations No. 899. It is an interpretation of the parties involved in the application of the regulatory framework. As a result of such interpretation, medicines that are included in the List and are sold outside the reimbursement system, are more expensive for patients.

3 Inclusion of medicines in the List facilitates price reduction not only when these medicinal products are ensured for patients within the framework of the reimbursement system, but also when they are sold outside the reimbursement system, because the manufacturer price, on which the pricing is based, is reduced.

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[1] 31.10.2006. the Regulation of the Cabinet of Ministers No. 899 – Procedures for the Reimbursement of Expenditures for the Acquisition of Medicinal Products and Medical Devices Intended for the Outpatient Medical Treatment. See: https://likumi.lv/ta/en/en/id/147522-procedures-for-the-reimbursement-of-expenditures-for-the-acquisition-of-medicinal-products-and-medical-devices-intended-for-the-outpatient-medical-treatment

[2] 25.10.2005. the Regulation of the Cabinet of Ministers No. 803 – Regulations Regarding the Principles for the Determination of the Price of Medicinal Products. See: https://likumi.lv/ta/en/en/id/120074-regulations-regarding-the-principles-for-the-determination-of-the-price-of-medicinal-products

Price formation for non-reimbursable medicines in Latvia

4 The wholesale and pharmacy mark-ups are formed (partially) as a percentage of the manufacturer price, which *prima facie* can motivate wholesalers and pharmacies to distribute more expensive medicines. The situation is different in the prescription and non-prescription segment, considering that the doctor may indicate in the prescription the general name of medicine as a result the pharmacy will sell to the patient the cheapest one. Whereas the mark-up mechanism existing for non-prescription medicines motivates wholesalers and pharmacies to sell more expensive medicines, which affects the financial accessibility for patients.

5 If the manufacturer price in the price interval from 1 to 2 000 *euros* is assumed as 100%, the total mark-up intended for the wholesaler and pharmacy above the manufacturer price 100% is from 65% to 31%. When the end price of medicine is assumed as 100%, the structure of the end price depending on the manufacturer price (in the price interval from 1 to 2 000 *euros*) is: manufacturer share and pharmacy share – from 26% to 8%.

6 Considering the applicable mark-ups in their absolute terms depending on the manufacturer price (in the interval from 1 to 2 000 *euros*), the wholesale mark-up is from 0.18 to approximately 200 *euros*. The pharmacy mark-up is from 0.47 to 223 *euros*.

7 In general, considering the mark-ups applicable to medicines in their absolute terms, it can be concluded that they are high, and in the segment of more expensive medicines the mark-up level, probably, is not objectively justified with costs related to distribution.

8 The Competition Council (hereinafter – the CC) has already previously concluded that manufacturers use to apply discounts to wholesalers, and wholesalers can apply discounts to pharmacies, which are basically related to the procurement volume and the total procurement basket. In order for a pharmacy to be granted with a discount, the paying discipline of the pharmacy as a customer is significant. However, such discounts may not influence the financial accessibility of medicines, because these discounts do not actually reach the patient.

9 At the same time, if existence and survival of pharmacy is almost completely dependent on discounts granted by another merchant for the volume of acquired medicines, fulfilment of marketing activities etc., holder of the pharmacy licence should carefully reconsider its economic activity in order to optimise the operational processes.

Comparison of price formation of non-reimbursable medicines in the Baltic states

10 The impact on price differences in Latvia, Lithuania and Estonia is made by a different Value Added Tax (hereinafter – VAT): in Latvia – 12%, in Lithuania – 5%, and in Estonia – 9%. However, the information obtained during the sector inquiry and the conducted comparison lead to a conclusion

that the differences of the pricing mechanism applied to medicines in the Baltic states affect the end price of medicines significantly.

11 One of the most significant differences in the regulatory framework of Latvia, Lithuania and Estonia as regards wholesale and pharmacy price and mark-up formation is that a maximum fixed mark-up or so-called ceiling is determined for a wholesaler and pharmacy in Lithuania and Estonia. According to the mechanism implemented in Latvia, the wholesale mark-up is set proportionally to the manufacturer price. Upon the manufacturer price increasing, the wholesale mark-up, although decreases in terms of percentage, continues to increase in monetary terms. The wholesale and pharmacy mark-up in Latvia always, i.e., regardless the procurement price, increases proportionally to the procurement price.

12 Mark-ups of non-reimbursable medicines in Lithuania and Estonia are lower than in Latvia. This results in a situation that the wholesale and pharmacy prices in Lithuania and Estonia are lower than in Latvia, except the segment of cheapest medicines, where the impact of mark-ups is insignificant. At the wholesale level, the difference compared to Lithuania can reach up to 80 *euros*, and at the pharmacy level (including VAT) – even up to 270 *euros*.

13 Since the regulatory framework of Latvia does not provide for the mark-up ceiling, the wholesale mark-up in Latvia in monetary terms is higher than in Lithuania and Estonia, regardless the manufacturer price. For example, if the manufacturer price in Latvia is 25 *euros*, the wholesaler's profit from sales of one medicine package is 3.34 *euros*, which is almost 2.7 (mark-up in Lithuania is 1.25 *euros*) times more than in Lithuania and 4.5 (mark-up in EE is 0.75 *euros*) times more than in Estonia.

14 If the manufacturer price in Latvia is 50 *euros*, the wholesaler's profit from sales of one medicine package is 5.84 *euros*, which is 2.4 (mark-up in Lithuania is 2.50 *euros*) times more than in Lithuania and almost 4 (mark-up in Estonia is 1.50 *euros*) times more than in Estonia. Whereas if the manufacturer price in Latvia is 213 *euros*, the wholesaler's profit from sales of one medicine package is 22.14 *euros*, which is approximately 2 times more than in Lithuania and 3 times more than in Estonia. In the segment of expensive medicines, the differences between wholesaler mark-ups in the Baltic states are significant, which additionally shows that wholesalers in Latvia have a possibility to set relatively high and seemingly disproportionate mark-ups. At the same time, it makes a negative impact on the end price of medicines and, consequently, the financial accessibility of them.

15 As regards pharmacy revenue, the situation with non-reimbursable medicines is similar as at the level of wholesalers – if the manufacturer price is 25 *euros*, the pharmacy profit in Latvia comprises 5.74 *euros*, in Lithuania – 3.94 *euros*, and in Estonia – 3.86 *euros*. If the manufacturer price is 50 *euros*, the pharmacy profit in Latvia comprises already 8.50 *euros*, in Lithuania – 7.88 *euros*, and in Estonia – 5.11 *euros*. If the manufacturer price is 213 *euros*, the pharmacy profit in Latvia is 26.43 *euros*, in Lithuania – 17.38 *euros*, and in Estonia – 5.11 *euros*. In the segment, where the highest number (volume) of packages is sold, i.e., the

segment of medicines with a price up to 50 *euros*, and the segment of expensive medicines, the pharmacy mark-up in Latvia is the highest among the Baltic states.

16 Assessing the permitted revenue (mark-up) differences for non-reimbursable medicines in the Baltic states, namely, considering the profit opportunities in the intermediate stages in Latvia, one should take into consideration differences of other profit affecting factors in the Baltic states. However, it does not justify the application of the proportionality mechanism, considering the condition that it is not objectively substantiated and also does not promote the financial accessibility of medicines for patients in Latvia.

17 Such differences show that the regulatory framework in Latvia allows the intermediate stages of distribution of medicines – wholesalers and pharmacies – to apply *prima facie* disproportionally high mark-ups and provides for higher profit opportunities than in Lithuania and Estonia. It has to be indicated that such mark-up differences and their proportionality are not related to the fact that the more expensive medicines have different pricing components, namely, different pharmacist consultations or storage/logistics (with separate exceptions). The negative impact of such mark-up system involves vertical integration (desire of related market participants to distribute specific medicines on the market), and dependence of pharmacists (regardless the linkage of pharmacy with a wholesaler, etc.).

18 The segment of non-reimbursable non-prescription medicines has to be considered as the most sensitive segment of medicines in such a mark-up system in terms of price, where market participants have the widest freedom of action, concurrently with existence of vertical integration and insufficient independence of pharmacists.

19 At the same time, one should take into consideration that the price differences are not pronounced in all price segments. The differences are less pronounced in the segment of cheap medicines, and more pronounced in the segment of expensive medicines. Moreover, the situation can be different in various pharmacies, and the permitted mark-up for some pharmacies may be sufficient and can ensure good profit and development opportunities, for some pharmacies – only enough to cover costs, whereas for some other pharmacies – insufficient (also considering the different assortment and demand of pharmacies). The different situation among pharmacies arises also due to other aspects, for example, depending on whether it is a network pharmacy or independent pharmacy, integrated with a wholesaler or independent, whether it is located in a densely populated area or less populated area, in a territory of hospital, whether it receives discounts from suppliers, etc.

Formation of prices and mark-ups of reimbursable medicines in Latvia

20 The regulatory framework provides for a different procedure of formation of wholesale and pharmacy mark-up – the wholesale mark-up is formed proportionally to the manufacturer price in all price segments, whereas for

pharmacies the mark-up becomes fixed for the manufacturer price over 100 *euros*. Moreover, in the price segments over 300 *euros* it gradually becomes significantly lower than the wholesale mark-up.

21 The pharmacy mark-up is higher than the wholesale mark-up in the price segment up to the manufacturer price of 200 *euros* (corresponds to reimbursement base price of 206 *euros*), but, when assessing the proportionality of mark-up breakdown, the differences in turnovers of wholesalers and certain pharmacies has to be taken into account. At the manufacturer price of 200 *euros*, the wholesale and pharmacy mark-ups (in absolute terms) equalise. Further, upon increase of the manufacturer price, the wholesale mark-up continues to increase, whereas the pharmacy mark-up becomes fixed, as already mentioned before. After reaching the segment with the manufacturer price over 200 *euros*, the wholesale mark-up increases in the range from 6 *euros* to 20 *euros* per each sold package of medicines. Consequently, in the price segment over 200 *euros* the mark-up increases for one involved party, whereas for the other – does not change and gradually becomes significantly lower. For example, at the manufacturer price 500 *euros*, the wholesale mark-up is 15 *euros* per package, and the pharmacy mark-up is 6.05 *euros* per package.

22 Such differences indicate that the mark-up among intermediate stages *prima facie* is distributed unevenly and can be disproportionate. At the same time, this also promotes dependence of pharmacies on wholesalers (through applied discounts and more or less successful cooperation).

23 The regulatory framework of pricing of reimbursable medicines has a contradictory effect on the motivation of market participants to reduce the price of medicines. There exist mechanisms, which promote reduction of the manufacturer price, and, on the other hand, there are mechanisms, which do not promote reduction of prices of medicines. This effect depends on the pricing and profit formation at the wholesale level. Determination of profit proportionally to the manufacturer price promotes motivation of wholesalers (including through vertical integration – with medical treatment institutions/pharmacies) to distribute more expensive medicines alongside analogues. The regulatory framework on price reduction, when medicines are transferred from the List B to the List A[3], and when competing analogues emerge in the List A, promotes offering of cheaper medicines. At the same time, it has to be noted that such a situation is partially prevented by amendments to the Regulations No. 899 on the use of the general name of medicines in prescriptions, made in 2019.

24 The regulatory framework on how the price of medicines included in the List has to be determined, if a patient's diagnosis does not correspond to the List, is ambiguous. This allows a situation, where two pricing algorithms can concurrently exist for reimbursable medicines and, respectively, two pharmacy prices. This situation is contrary to the interests of patients and is more favourable for the interests of intermediaries – wholesalers and pharmacies.

[3] The list of reimbursable medicines in Latvia consists of three parts – List A, List B, and List C. The Regulation of the Cabinet of Ministers No. 899. explains the difference among these parts.

25 The distribution of revenue at the wholesale and pharmacy level is disproportionate. The regulatory framework provides for significantly higher revenue of wholesaler in the segment of expensive medicines compared to revenue of pharmacies, which facilitates dependence of pharmacy as a link of distribution chain on the wholesaler.

26 As regards prices of parallel distributed and imported medicines, if these medicines are included in the List, Paragraph 30^1 of the Regulation No. 899 sets a requirement that these prices shall be lower than the price of reimbursable medicines, regarding which the parallel distribution or import is implemented. A quantitative criterion for the price difference is not determined. Non-existence of quantitative criterion influences the pricing process. However, the price changes that are promoted by parallel import, can be ineffective in general, because the administrative resources that are used for respective procedures can cost for the state more than the said price reduction (considering that the parallel importers and distributors can set a minimum price difference of 0.01 *euros*, thus formally complying with the requirement stipulated by the Regulation No. 899). Therefore, the effect of parallel import has to be assessed systematically, i.e., assessing not only the direct impact on the budget savings due to the reduced price, but also the required administrative resources.

27 As regards reimbursable medicines, a positive effect on the financial accessibility for patients can be generated by the amendments to the Regulation No. 899, which will henceforward stipulate that when prescribing medicines the general name intended for the respective diagnosis shall be indicated. Whereas a pharmacy is obliged to issue the cheapest medicines according to the general name, and only in separate, justified cases, when use of medicines do not give the desired therapeutic effect, the medical person shall prescribe another medicines, starting with the lowest price within the respective general name. Such a condition increases the competition pressure among manufacturers, which also creates additional motivation for manufacturers to maintain their products as the cheapest in the List, thus ensuring higher sales volumes.

Comparison of pricing and mark-up formation of reimbursable medicines in the Baltic states

28 The regulatory framework in the Baltic states differs significantly, and differences are also determined by the fact that the situation is more favourable for various intermediate stages in different states. For example, comparing the regulatory framework on pricing of reimbursable medicines in Latvia and Lithuania, it can be concluded that the mechanism existing in Lithuania provides higher mark-ups for pharmacies, thus ensuring more independence of pharmacies in the case of vertical integration.

The wholesale prices of reimbursed medicines in the segment of cheapest medicines are similar in Latvia, Lithuania and Estonia, whereas in the segment of expensive medicines Latvia and Lithuania have considerably higher prices than in Estonia. In Latvia, wholesale prices (excluding VAT) are lower at the manufacturer price 1-7 *euros*. The wholesale profit in the

segment of cheapest medicines can be higher in Latvia, Lithuania or Estonia, depending on the manufacturer price, and in the segment of expensive medicines wholesalers in Latvia have the highest profit in the Baltic states. In the segment of medicines that cost over 100 *euros*, Latvia has higher prices and the difference is already more noticeable – up to 15 *euros* per package, which significantly influences the use of state funding within the framework of reimbursement system for expensive medicines.

29 In the segment of prices of expensive medicines, profit of wholesalers in Latvia is practically always higher, and, although it does not exceed 5% in the end price, considering that the end price is high (several tens or hundreds of *euros*), also this relatively small mark-up percentage comprises an amount of up to 21 *euros* and makes a considerable impact on the financial accessibility of medicines for patients. The higher is the manufacturer price, the more the wholesale price in Latvia exceeds prices in Lithuania and Estonia.

30 Differences in pharmacy prices are not so pronounced among the Baltic states. The pharmacy mark-up in Lithuania in monetary terms is higher than in Latvia and Estonia, and the difference is significant. This means that in Lithuania the conditions for gaining profit by pharmacies is *prima facie* more favourable than in other states.

Comparison of actually applied prices of medicines in the Baltic states

31 Assessing the data on 18 medicines, compiled during the market surveillance, and comparing their manufacturer prices and pharmacy prices in Latvia and Lithuania, it can be concluded that:

- manufacturer prices for 15 out of 18 medicines in Latvia are lower than or equal to prices in Lithuania. If lower prices are set in Latvia, the difference exceeds 10% on average;
- out of these 15 medicines (100%) with manufacturer prices in Latvia being lower than or equal to prices in Lithuania, only for six of them (or 40%) also the pharmacy price in Latvia is lower than in Lithuania. Respectively, in nine cases (or 60%) the pharmacy price is higher in Lithuania.

32 Comparing (19 medicines) manufacturer prices and pharmacy prices in Latvia and Lithuania, the following can be concluded:

- manufacturer prices for 16 out of 19 medicines in Latvia are lower than or equal to manufacturer prices in Estonia. If lower prices are set in Latvia, the difference exceeds 10% on average;
- out of these 16 medicines (100%) with manufacturer prices in Latvia being lower than or equal to prices in Estonia, only for six of them (or 37%) the pharmacy prices in Latvia are lower than in Estonia. In another five cases (or 31%) prices in Latvia can be lower or higher than in Estonia – depending on the particular pharmacy in Estonia. And in eight cases (or 50%) the pharmacy price in Latvia is higher than in Estonia.

33 It leads to a conclusion that manufacturers in Latvia mostly set lower prices of medicines than in Lithuania and Estonia, whereas prices in pharmacies in Latvia are mostly higher. This shows that also in practice mark-ups during distribution stages (intermediary mark-ups) in Latvia are higher than in Lithuania and Estonia.

34 There are no grounds for a comprehensive statement that all medicines in Latvia are more expensive than in Lithuania and Estonia. In approximately 40% of cases in the group of medicines assessed during the sector inquiry, prices of medicines in pharmacies in Latvia are lower than in Lithuania and Estonia.

35 In correlation with other circumstances, which were identified during the inquiry concerning the factors significant for manufacturers during the pricing procedure, for example, the market volume, the differences of Latvian, Lithuanian and Estonian markets are not as significant to make the prices differ considerably in general.

36 The differences in prices of medicines in pharmacies are various, and the most significant differences can be observed in the cases, when medicines, that have to be compared, have a different status in terms of reimbursement (are or are not included in the List), which influences the pricing mechanism and its application in practice.

Suggestions

37 Taking into consideration the conclusions drawn and aspects identified during the sector inquiry, which affect the financial accessibility of medicines and opportunities for increasing this accessibility, the Ministry of Health in cooperation with other responsible institutions in the sector has to revise pricing mechanisms, also using comparison among the Baltic states both in terms of pricing of non-reimbursable and reimbursable medicines.

38 The following principles have to be observed while developing a new pricing model:

- purpose of the mechanism – to reduce the end prices for patients, facilitating the financial accessibility/to increase the financial accessibility within the framework of state reimbursement system, i.e., assessing it from the perspective of more efficient spending of the state budget funds;
- to assess the possibility of excluding the direct proportionality of wholesale price and pharmacy price to the manufacturer price. The possible solution could be introduction of fixed payment per one sold package of medicines;
- to provide such distribution of mark-up between the wholesaler and the pharmacy, which mitigates dependence of pharmacies on the wholesaler, i.e., to consider the possibility of increasing the pharmacy profit in separate segments or changing the numerical value of mark-ups in favour of the pharmacy level;

- when setting intervals and mark-ups, to take into account the price segment up to 50 *euros*, which has higher volume of sales and accordingly highest consumption;
- to set the maximum amount of the patient's co-payment in *euros*.

39 The responsible institutions in the sector have to consider making amendments to regulatory enactments concerning application of the Regulation No. 803 and the Regulation No. 899. It should be stipulated that, if medicines are included in the List, the pharmacy price shall be set according to the mechanism provided for in the Regulation No. 899.

40 The possibility of applying a single pricing mechanism to reimbursable and non-reimbursable medicines has to be considered.

41 A systematic assessment of the effect of parallel import has to be carried out, considering the fact that the administrative resources employed for the respective procedures (inclusion in the List, price assessment, etc.) can cost more to the state than the said price reduction. Not only the direct impact on the budget savings due to the price reduction (reduced price per one package, potential sales volume) should be assessed, but also the required consumption of administrative resources for implementation of such activities. Respectively, amendments to Paragraph 30^1 of the Regulation No. 899 have to be considered – the requirement that the prices of parallel distributed and imported medicines shall be lower than the price of those medicines, regarding which such parallel distribution or import is carried out.

42 Considering that applying of discounts concurrently with existence of vertical integration can negatively affect the motivation of manufacturers to offer new medicines/include them in the List, as well as independence of pharmacists, thus also having negative impact on the accessibility for patients, the possibility of restricting the discount granting system has to be considered at all levels of distribution of medicines, building a system, which is transparent and easy to monitor by the responsible institutions.