

**DIRECTORATE FOR FINANCIAL AND ENTERPRISE AFFAIRS
COMPETITION COMMITTEE**

Excessive Pricing in Pharmaceutical Markets – Note by Lithuania

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Lithuania

1. Introduction

1. In Lithuania, the pharmaceuticals sector is subject to regulation. In addition to the Pharmacy Law of the Republic of Lithuania,¹ there are a number of substatutory legal acts (such as the decisions of the Government of the Republic of Lithuania (hereinafter: the Government of Lithuania), Orders of the Ministry of Health of the Republic of Lithuania (hereinafter: the Ministry of Health)), which contain more detailed regulatory provisions in the pharmaceutical sector.

2. The Competition Council of the Republic of Lithuania (hereinafter: the Competition Council) closely observes the pharmaceutical sector and actively participates in the public debate.² Within the scope of its competences, the Competition Council contributes to the regulatory framework in this sector, for example, by submitting opinions on the various legal drafts. Also, it is noteworthy that, for example, in August 2016, the Competition Council started the investigation on the Order of the Ministry of Health (hereinafter: the Order),³ which listed the space requirements for pharmacies, such as, for example, the requirement that the space of a pharmacy operating in a city could be no less than 60 square meters, the space of a charity pharmacy – no less than 30 square meters, whereas no space requirements were set for pharmacies operating in the villages.⁴ The concern of the Competition Council was that such regulatory requirements could unjustifiably restrict the economic activity of pharmacies. In February 2017, the Ministry of Health amended the Order.⁵ In the latter, it was stated that space requirements for pharmacies had to be such that a pharmacy could guarantee the performance of pharma activities, the storage of pharmaceuticals and the provision of pharma services to

¹ The Pharmacy Law of the Republic of Lithuania, 22 June 2006, No. X-709 (with later amendments).

² See the press releases of the Competition Council, for example: “*J. Šovienė. Kompensuojamieji vaistai: kur dingsta sutaupyti milijonai?*” (27 March 2018, available at: <http://kt.gov.lt/lt/naujienos/j-soviene-kompensuojamieji-vaistai-kur-dingsta-sutaupyti-milijonai> (in Lithuanian)); An interview with Jūratė Šovienė, the Council Member and the Deputy Chairperson of the Competition Council: “*Paaškinio, kodėl, užuot pigė, vaistai iš tikrųjų pabrango*” (7 August 2017, available at: <http://kt.gov.lt/lt/naujienos/paaiskino-kodel-uzuot-pige-vaistai-is-tikruju-pabrango> (in Lithuanian)); “*Konkurencijos taryba nepitaria iniciatyvai kurti valstybinių vaistinių tinklą*” (20 June 2017, available at: <http://kt.gov.lt/lt/naujienos/konkurencijos-taryba-nepitaria-iniciatyvai-kurti-valstybiniu-vaistiniu-tinkla> (in Lithuanian)).

³ The Order of the Ministry of Health of the Republic of Lithuania on the approval of the requirements of pharmacies’ premises and inventories, 7 January 2003, No. V-7.

⁴ *Ibid.*, Point 8.

⁵ The Order of the Ministry of Health of the Republic of Lithuania on the amendment of the Order of the Ministry of Health of the Republic of Lithuania as of 7 January 2003, No. V-7 on the requirements of pharmacies’ premises and inventories (13 February 2017, No. V-132).

consumers, including the guarantee to preserve their confidentiality.⁶ In light of the amendment of the Order, the Competition Council terminated the investigation.⁷

3. Up to date, there are no remarkable abuse of dominance cases, including those on excessive pricing, in the pharmaceutical sector in Lithuania. For the sake of precision, it could be noted that, in 2009, the Competition Council refused to start the investigation on the alleged abuse of a dominant position (a refusal to supply) pursuant to a complaint, basically due to insufficient information to start the investigation.⁸ The decision of the Competition Council was upheld by the Lithuanian courts.⁹

4. The Competition Council conducted two market studies in this sector, one of them concerning parallel imports (2013), and the other - reimbursable pharmaceuticals (2016).

2. Market studies conducted by the Competition Council

5. The Competition Council has conducted two market studies with regard to the pharmaceutical sector: a market study on the parallel import of pharmaceuticals and the market study on reimbursable pharmaceuticals.

2.1. Market study on the parallel import of pharmaceuticals¹⁰

6. In 2012, the Competition Council started a market study on the parallel import of pharmaceuticals. The aims of the market study were, firstly, to evaluate the situation of the parallel import market of pharmaceuticals in Lithuania, secondly, to determine the main factors causing a low market share of pharmaceuticals brought to Lithuania by way of parallel import, and thirdly, to assess whether the competition in the Lithuanian pharmaceuticals' sales market could be increased by promoting parallel import and, if the answer were in the affirmative, to prepare relevant recommendations.¹¹

⁶ *Ibid.*, Point 8.

⁷ Decision of the Competition Council of the Republic of Lithuania on the termination of the investigation on compliance of the requirements of pharmacies' premises and inventories approved by the Order of the Ministry of Health of the Republic of Lithuania on the approval of the requirements of pharmacies' premises and inventories, 7 January 2003, No. V-7 with Article 4 of the Law on Competition of the Republic of Lithuania, 24 February 2017, No. 1S-21 (2017).

⁸ Decision of the Competition Council of the Republic of Lithuania on a refusal to start investigation on compliance of actions of UAB "GlaxoSmithKline Lietuva" with the requirements of Article 9 of the Law on Competition of the Republic of Lithuania, 26 February 2009, No. 1S-28.

⁹ Judgement of Vilnius District Administrative Court, 16 July 2009, Case No. I-1465-473/2009; Judgement of the Supreme Administrative Court of Lithuania, 27 September 2010, Case No. A-444-996/2010.

¹⁰ Decision of the Competition Council on the concluded market study on the parallel import of pharmaceuticals, 25 September 2013, No. 6S-31.

¹¹ *Ibid.*, para. 3.

7. In order to achieve these goals, the Competition Council, first of all, analysed the regulatory framework of the pharmaceutical sector in Lithuania.¹² In particular, legal provisions related to the distribution and sales of pharmaceuticals were scrutinized. It was stated that, according to the Pharmacy Law, pharmaceuticals could be grouped into two groups, i.e. firstly, a prescription medicine and non-prescription medicine, and secondly, reimbursable and non-reimbursable medicine.¹³ Referring to the legal provisions of the Pharmacy Law, it was said that medicine is considered a prescription medicine on the basis of the decision of the State Medicines Control Agency or the European Agency of Pharmaceuticals,¹⁴ whereas reimbursable medicine was said to be such which is included in the reimbursable pharmaceuticals' list and the purchase costs of which are wholly or partially reimbursed to the patients, who are insured by the compulsory health insurance, from the budgetary resources of the Compulsory Health Insurance Fund.¹⁵ The Competition Council noted that, considering that part of the price of reimbursable pharmaceuticals is funded by the Compulsory Health Insurance Fund, these pharmaceuticals are subject to specific rules, including the decision of the Government of Lithuania,¹⁶ and are strictly regulated.¹⁷

8. The Competition Council explained that an undertaking seeking to bring pharmaceuticals to Lithuania by means of parallel import had to have a license for wholesale distribution of pharmaceuticals and, according to the requirements of the Pharmacy Law, the pharmaceuticals concerned had to be registered on the List of Parallely Imported Pharmaceuticals and in respect of which a permission had been granted for parallel import.¹⁸ The permissions for parallel import were granted by the State Medicines Control Agency.¹⁹ However, it was noted in the market study that the permission could be granted only to such pharmaceuticals, which were identical to the pharmaceutical registered in Lithuania or were sufficiently similar to such pharmaceutical according to the relevant criteria (such as, for example, the same active ingredient etc.).²⁰ It was stressed that, in case an undertaking bringing a pharmaceutical to Lithuania by way of parallel import wanted it to be taken on the reimbursable pharmaceuticals' list, the rules applicable to reimbursable pharmaceuticals applied.²¹ Importantly though, it was said that, according to the rules

¹² *Ibid.*, paras 5-20.

¹³ *Ibid.*, para. 6.

¹⁴ *Ibid.*, para. 7.

¹⁵ *Ibid.*, para. 8.

¹⁶ Decision of the Government of the Republic of Lithuania on the approval of the rules on calculating the base price of medicinal products for outpatient treatment, the acquisition costs of which are compensated from the Compulsory Health Insurance Fund, 13 September 2005, No. 994 (with later amendments).

¹⁷ Decision of the Competition Council on the concluded market study on the parallel import of pharmaceuticals, 25 September 2013, No. 6S-31, para. 9.

¹⁸ *Ibid.*, para. 13.

¹⁹ *Ibid.*, para. 14.

²⁰ *Ibid.*, para. 15.

²¹ *Ibid.*, para. 16.

adopted by the decision of the Government²² (hereinafter: the Rules), point 19, pharmaceuticals brought to Lithuania by way of parallel import could be taken on the reimbursable pharmaceuticals' list only if the difference between the declared price of such a pharmaceutical and the identical registered pharmaceutical (i.e. a pharmaceutical provided by market authorization holders) was no less than 4 to 10 percent.²³

9. The Competition Council noted that parallel import of pharmaceuticals in Lithuania has been legalized since 2007, when the Minister of Health adopted the Rules on parallel import.²⁴ However, it was stated, that the first pharmaceuticals were brought to Lithuania by means of parallel import only in 2009.²⁵ The Competition Council drew attention to the fact that the market share of the pharmaceuticals brought to and distributed in Lithuania by way of parallel import was rather small. Relying on the study carried out upon the request of the State Medicines Control Agency "The Effect of the European Pharmaceutical Legislation (Policy) on Accessibility of Medicines in Lithuania", it was noted that, in 2010, the wholesales of pharmaceuticals brought to Lithuania by way of parallel import amounted only to 0,15 percent of all the market for pharmaceuticals, whereas assessing the sold packages, such a number amounted only to 0,12 percent.²⁶

10. Thus, the Competition Council analysed the potential hurdles to competition in terms of, firstly, the regulatory framework,²⁷ and secondly, the price level of pharmaceuticals in Lithuania compared to other countries of the European Economic Area.²⁸

11. The Competition Council concluded that, whereas the legal rules in the case of non-reimbursable pharmaceuticals were the same for both parallelly imported pharmaceuticals and the pharmaceuticals offered in the market by market authorization holders, the Rules, which were applicable in the case of reimbursable pharmaceuticals set conditions, which were different for parallelly imported pharmaceuticals and the pharmaceuticals offered by market authorization holders.²⁹ In particular, it was stated that Point 19 of the aforementioned Rules, which said that the declared price of a parallelly imported pharmaceutical had to be lower than the declared price of a reference medicine, could unjustifiably restrict the activities of parallel importers, thereby possibly impacting the

²² Decision of the Government of the Republic of Lithuania on the approval of the rules on calculating the base price of medicinal products for outpatient treatment, the acquisition costs of which are compensated from the Compulsory Health Insurance Fund, 13 September 2005, No. 994 (with later amendments).

²³ Decision of the Competition Council on the concluded market study on the parallel import of pharmaceuticals, 25 September 2013, No. 6S-31, para. 17.

²⁴ Order of the Ministry of Health of the Republic of Lithuania on the approval of the rules on the parallel import of pharmaceuticals, 30 March 2007, No. V-228.

²⁵ Decision of the Competition Council on the concluded market study on the parallel import of pharmaceuticals, 25 September 2013, No. 6S-31, para. 24.

²⁶ *Ibid.*, para. 25.

²⁷ *Ibid.*, paras 37-48.

²⁸ *Ibid.*, paras 49-52.

²⁹ *Ibid.*, paras 54-55.

competition between parallel importers and market authorization holders.³⁰ It was explained that a market authorization holder may be not incentivized to lower the declared price as the established requirement of 4-10 percent difference in price, essentially, guaranteed a certain price level, which (when maintained), could make it possible to avoid additional competition with the parallel importer.³¹ The Competition Council said that the annulment of such a requirement in Point 19 was likely to increase competition and, as a result, consumers would benefit and the expenses of the Compulsory Health Insurance Fund may be reduced.³² Moreover, it was said that competition was likely to be intensified also due to the availability of pharmaceuticals that were not parallelly imported at the time for the failure to meet the conditions laid down in Point 19.³³ Therefore, the Competition Council suggested removing from the aforementioned Rules the requirement laid down in Point 19, which said that the declared price of a parallelly imported pharmaceutical had to be 4 to 10 percent lower than the declared price of a reference medicine, since such a requirement, according to the Competition Council, unjustifiably restricted competition of pharmaceutical companies.³⁴

12. In this regard, it is noteworthy that the Government of Lithuania modified Point 19 of the aforementioned Rules in November 2015³⁵ and removed the statement, which said that the declared price of a parallelly imported pharmaceutical had to be 4 to 10 percent lower than the declared price of a reference medicine.

2.2. Market study on reimbursable pharmaceuticals³⁶

13. In 2015, the Competition Council, taking account of the importance of reimbursable pharmaceuticals for consumers and seeking to assess whether the regulatory framework for the entry into the market for reimbursable pharmaceuticals and for the functioning therein do not pose competition problems, commenced a market study on reimbursable pharmaceuticals.³⁷ It was said that, if the latter concern were confirmed, it might be that neither consumers nor the state did take full advantage of the benefits

³⁰ *Ibid.*, para. 56.

³¹ *Ibid.*, para. 56.

³² *Ibid.*, para. 57.

³³ *Ibid.*, para. 57.

³⁴ *Ibid.*, para. 60.

³⁵ Decision of the Government of the Republic of Lithuania on the amendment of the Decision of the Government of the Republic of Lithuania as of 13 September 2005, No. 994 on the approval of the rules on calculating the base price of medicinal products for outpatient treatment, the acquisition costs of which are compensated from the Compulsory Health Insurance Fund (11 November 2015, No. 1178).

³⁶ Decision of the Competition Council on the conclusions of the market study on reimbursable pharmaceuticals, 6 December 2016, No. 3S-92 (2016).

³⁷ *Ibid.*, para. 1.

generated by competition, such as lower prices, an increased choice of pharmaceuticals as well as an effective use of the Compulsory Health Insurance Fund's budget.³⁸

14. During the market study, the Competition Council scrutinized the rules approved by the decision of the Government of Lithuania³⁹ (hereinafter: the Rules), particularly, Point 7 and Point 8, with the following aims: firstly, to conduct the analysis of the market for reimbursable pharmaceuticals, secondly, to assess the impact of Point 7 and Point 8 on the market for reimbursable pharmaceuticals, and thirdly, to identify competition problems in the market for reimbursable pharmaceuticals and to suggest possible solutions to such problems ensuring effective competition.⁴⁰

15. Since Point 7 of the aforementioned Rules was related solely to generics, namely, the question when a generic may be taken on the reimbursable pharmaceuticals' list, the Competition Council sought to clarify what impact the regulatory requirements could have on generics. The Competition Council explained that, according to Point 7, a generic could be taken on the reimbursable pharmaceuticals' list, if its declared price was – by a certain percentage point – lower than the price of the cheapest pharmaceutical, which was already on the list. The percentage point depended on the question of whether the pharmaceutical had to be added to the list for the first time or subsequently. In case the pharmaceutical had to be added to the list for the first time, the declared price of the generic had to be 50 percent lower, whereas in the case of the second and third time - 15 percent lower, the fourth and the fifth time – 5 percent lower etc.⁴¹ Furthermore, in the case of the second and any subsequent additions of the pharmaceutical to the list, the condition had to be fulfilled not to exceed 95 percent of the average price determined by the reference to the prices of pharmaceuticals declared by the producers in other European Union's (hereinafter: the EU) Member States.⁴²

16. In this regard, it could be noted that the Competition Council explained that the calculation of the base price of the reimbursable pharmaceuticals included external price referencing, i.e. a comparison with the prices in certain other EU Member States, which were selected on the basis that they had a similar gross domestic product per capita to Lithuania.⁴³ The referenced Member States included Bulgaria, the Czech Republic, Estonia, Latvia, Poland, Romania, Slovakia and Hungary.⁴⁴ The price taken for the comparison was the average of the declared lowest prices (excluding VAT or an analogous

³⁸ *Ibid.*, para. 1.

³⁹ Decision of the Government of the Republic of Lithuania on the approval of the rules on calculating the base price of medicinal products for outpatient treatment, the acquisition costs of which are compensated from the Compulsory Health Insurance Fund, 13 September 2005, No. 994 (with later amendments).

⁴⁰ Decision of the Competition Council on the conclusions of the market study on the reimbursable pharmaceuticals, 6 December 2016, No. 3S-92 (2016), paras 2-3.

⁴¹ *Ibid.*, paras 22, 45.

⁴² *Ibid.*, paras 22, 45.

⁴³ *Ibid.*, para. 15.

⁴⁴ *Ibid.*, para. 15.

tax applied in that country) of the pharmaceuticals having the same common name in the referenced Member States.⁴⁵

17. Point 8 of the Rules stipulated the requirements for the declared price of the pharmaceutical, in order for it to maintain on the reimbursable pharmaceuticals' list, which was confirmed once a year.⁴⁶

18. When analysing reimbursable pharmaceuticals in Lithuania, the Competition Council drew attention to the fact that, although an overall number of generics on the reimbursable pharmaceuticals' list was growing till 2015, a number of the applications of new generics to be taken on the list started declining in 2012 and after.⁴⁷ According to the Competition Council, it was likely that the decreasing number of generics' applications was related to the aforementioned requirements enshrined in Point 7.⁴⁸ Also, the Competition Council found that, in 2013-2015, the part of the price of reimbursable pharmaceuticals, which had to be paid by the patients themselves, increased.⁴⁹ The Competition Council further observed that the requirements laid down in Point 7 were altered several times in the period between 2008 and 2014, yet, they became stricter over time.⁵⁰ The Competition Council also found that in the years of 2009-2015 a number of the applications of new generics to be taken on the list were rejected, although in all of these applications the prices of generics were lower than of the pharmaceuticals already on the list. According to the Competition Council, this showed that, due to the requirements in Point 7, cheaper pharmaceuticals did not enter the market.⁵¹

19. Following the results of its analysis, the Competition Council concluded that the requirements laid down in Point 7, firstly, hindered less expensive pharmaceuticals to be taken on the reimbursable pharmaceuticals' list, and when the pharmaceuticals were added to the group for the 4th time and subsequently, this did not contribute to the decrease in prices, secondly, the requirements in Point 7 were not based on any extensive economic analysis, and thirdly, the regulatory requirements in Point 7, by hindering the possibility of pharmaceuticals to be taken on the reimbursable pharmaceuticals' list, restricted competition of pharmaceuticals.⁵² According to the Competition Council, a regulatory framework should not restrict, but, instead, should incentivize the entry of the pharmaceuticals into the aforementioned list, and in such a way increase their competition by way of incentivizing them to stay on the list.⁵³

20. As regards the maintainance of generics and non-generics on the reimbursable pharmaceuticals' list, Point 8 was scrutinized. It was explained that Point 8 set out the

⁴⁵ *Ibid.*, para. 16.

⁴⁶ *Ibid.*, para. 24.

⁴⁷ *Ibid.*, paras 33-34, 61.

⁴⁸ *Ibid.*, paras 35, 62.

⁴⁹ *Ibid.*, para. 41.

⁵⁰ *Ibid.*, para. 47.

⁵¹ *Ibid.*, paras 63-64.

⁵² *Ibid.*, para. 67.

⁵³ *Ibid.*, para. 68.

conditions for the determination of the price of generic and non-generic pharmaceuticals in order for a pharmaceutical to remain on the reimbursable pharmaceuticals' list.⁵⁴ According to these conditions, if the pharmaceuticals' group comprised pharmaceuticals (of the same common name) of more than three producers, only pharmaceuticals could be maintained on the list, the price of which was no more than 40 percent higher compared to the average price of the two cheapest pharmaceuticals of the same group.⁵⁵ According to the Competition Council, the differences between the declared prices and factual prices (i.e. prices, which could factually be reduced through the mechanism of a "classifier") distorted the application of Point 8, since the latter referred to the declared prices, although in reality these were not the real prices.⁵⁶ Furthermore, the requirements in Point 8 were applied once a year when the reimbursable pharmaceuticals' list was approved, whereas it was not applicable for any newly entered pharmaceuticals throughout the year – the circumstance, which was said to question the efficiency of the application of Point 8.⁵⁷ The analysis⁵⁸ of the Competition Council revealed that differences existed between the declared and factual prices of pharmaceuticals with the result that the differences in factual prices were much higher than the ones set in Point 8, and still such pharmaceuticals were kept on the reimbursable pharmaceuticals' list.⁵⁹ In turn, it was stated that the application of the requirements in Point 8 relating to the declared prices was possibly inappropriate due to the significant discounts applied through the "classifier".⁶⁰ In this regard, the Competition Council concluded that Point 8 did not sufficiently promote price competition between pharmaceuticals.⁶¹ First of all, it was said that the 40 percent threshold might have been too high to adequately promote competition between the pharmaceuticals already on the reimbursable pharmaceuticals' list. Secondly, due to the application of discounts, the difference in actual prices of pharmaceuticals often exceeded the 40 percent threshold (which was calculated according to the declared prices), so that competition between the pharmaceuticals in the group was not encouraged. Thirdly, the calculation of the base prices of pharmaceuticals according to the declared prices was said to be flawed, first and foremost, because it might be that the base price was not calculated according to the factually lowest price due to the application of the discounts via the "classifier".⁶²

21. The Competition Council analysed the "classifier" in more detail. It was explained that detailed information concerning the pricing of reimbursable pharmaceuticals

⁵⁴ *Ibid.*, para. 69.

⁵⁵ *Ibid.*, para. 25.

⁵⁶ *Ibid.*, para. 77.

⁵⁷ *Ibid.*, para. 78.

⁵⁸ *Ibid.*, paras 82-101.

⁵⁹ *Ibid.*, para. 90.

⁶⁰ *Ibid.*, para. 93.

⁶¹ *Ibid.*, para. 100.

⁶² *Ibid.*, para. 100.

was accessible via the classifier.⁶³ This information included retail and base prices of reimbursable pharmaceuticals after the reduction via the classifier, the amounts of patients' premium payments as well as the duration of the application of discounts.⁶⁴ Importantly, this information was accessible to all registered users.⁶⁵ Thus, the producers of pharmaceuticals, to whom the discounts via the classifier applied, could see not only their own pricing information, but also that of the competitors.⁶⁶ In this regard, the Competition Council stressed that the exchange of sensitive information (including, information about prices) between competitors may restrict competition.⁶⁷ Having assessed the information available on the classifier, the Competition Council held that, due to the nature of the information to be found in the classifier, the exchange of such information could restrict competition. It was said that such information could be regarded as strategically important, as it included information regarding the individual prices applied by each competitor. Further, the pricing information was not merely of historical nature. The classifier included not only current but also future prices and the period of time of their application. Moreover, such information was exchanged frequently and regularly - once a month.⁶⁸ Overall, the Competition Council concluded that making such commercially sensitive information available on the classifier, particularly, in the market, which was already very transparent due to legal regulation, could have a negative effect on competition between the producers of pharmaceuticals as well as the prices of reimbursable pharmaceuticals, so that the Competition Council said that such possibility for the registered users to obtain detailed and relevant pricing information of the competitors via the classifier should be removed.⁶⁹

22. In the conclusions of this market study, the Competition Council found that Point 7 was a regulatory obstacle to the entry into the reimbursable pharmaceuticals' market, while Point 8 was said to have protected pharmaceuticals, which were already in the market, from competitive pressure of new pharmaceuticals.⁷⁰ Such regulation was said to be restricting competition in the pharmaceuticals market with a likelihood that the prices of pharmaceuticals were higher, the choice was decreased and the budget of Compulsory Health Insurance Fund was not used effectively.⁷¹

23. Overall, the conclusions of the Competition Council in this market study can be summarized as follows. Firstly, it was said that competition could be restricted due to the

⁶³ *Ibid.*, para. 107.

⁶⁴ *Ibid.*, para. 107.

⁶⁵ *Ibid.*, para. 107.

⁶⁶ *Ibid.*, para. 107.

⁶⁷ *Ibid.*, paras 108-112.

⁶⁸ *Ibid.*, para. 113.

⁶⁹ *Ibid.*, para. 115.

⁷⁰ *Ibid.*, para. 132.

⁷¹ *Ibid.*, para. 132.

regulatory restrictions to enter the market of reimbursable pharmaceuticals.⁷² Secondly, it was said that the regulatory conditions for maintaining on the reimbursable pharmaceuticals' list did not ensure effective competition.⁷³ Thirdly, the regulatory system when the prices of pharmaceuticals were reimbursed on the basis of the declared – not factual – prices was said not to promote and not to guarantee effective competition.⁷⁴ Fourthly, competition may be restricted as the average prices in referenced states were taken into account when calculating the amount of the reimbursement for a pharmaceutical.⁷⁵ Fifthly, due to the lack of objective information about pharmaceuticals, effective competition may be not promoted and ensured.⁷⁶ Sixthly, competition may be weakened due to the exchange of sensitive information.⁷⁷

24. On this basis, the Competition Council provided recommendations to the Parliament of the Republic of Lithuania, the Government of the Republic of Lithuania and the Ministry of Health of the Republic of Lithuania on how competition in the market for reimbursable pharmaceuticals could be incentivized and promoted. In particular, the Competition Council suggested promoting the entry of generic pharmaceuticals into the market; shaping the regulation of reimbursable pharmaceuticals on the basis of an economic analysis; considering to remove the restrictions enshrined in Point 7; promoting the entry of analogous pharmaceuticals into the reimbursable pharmaceuticals' list and encouraging competition for remaining on this list; calculating the base price according to the actual prices instead of the declared prices; reconsidering the usefulness of external price referencing; making the requirements enshrined in Point 8 stricter and/or using other methods to incentivize the producers/suppliers to offer the least expensive product; removing the possibility for market participants to become aware of commercially sensitive pricing information via the classifier or other means; informing the public more effectively about the interchangeability of the generic and non-generic pharmaceuticals etc.⁷⁸

25. The Competition Council remained active also after the market study. Specifically, the Competition Council, within the scope of its competences, issued opinions⁷⁹ on the

⁷² *Ibid.*, para. 135(1).

⁷³ *Ibid.*, para. 135(2).

⁷⁴ *Ibid.*, para. 135(3).

⁷⁵ *Ibid.*, para. 135(4).

⁷⁶ *Ibid.*, para. 135(5).

⁷⁷ *Ibid.*, para. 135(6).

⁷⁸ *Ibid.*, para. 136.

⁷⁹ See, for example, the Opinion of the Competition Council of the Republic of Lithuania on the legal draft of the decision of the Government of the Republic of Lithuania No. 17-3705 (6 April 2017) (available at: <https://e-seimas.lrs.lt/portal/legalAct/lt/TAK/a34e9d801ac411e79f4996496b137f39?positionInSearchResult=65&searchModelUUID=8fcf5538-15bc-4a1e-8628-e59959de69cb> (in Lithuanian)); the Opinion of the Competition Council of the Republic of Lithuania on the “Approval of the Guidelines on the Policy of Pharmaceuticals” No. 17-7356 (4 July 2017) (available at: <https://e-seimas.lrs.lt/portal/legalAct/lt/TAK/b9fe770260b811e7a53b83ca0142260e?positionInSearchResult=65&searchModelUUID=8fcf5538-15bc-4a1e-8628-e59959de69cb> (in Lithuanian)).

proposals submitted by the Ministry of Health to amend the legal provisions, such as the aforementioned Point 7 and Point 8. *Inter alia*, the Competition Council advocated for a systemic change of the regulatory framework for reimbursable pharmaceuticals and argued that partial amendments may do more harm than good.⁸⁰ The decision of the Government of the Republic of Lithuania on the amendments was adopted on 17 January 2018.⁸¹

3. Conclusions

26. In conclusion, the above described market studies conducted by the Competition Council as well as its active role, within the scope of its competences, in contributing to the regulatory framework in the pharmaceutical sector show that the Competition Council takes a serious approach towards the pharmaceutical sector and puts efforts in that pharmaceuticals' markets remain competitive.

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⁸⁰ The Opinion of the Competition Council of the Republic of Lithuania on the project of the decision of the Government of the Republic of Lithuania No. 17-3705 (6 April 2017), para. 5.

⁸¹ Decision of the Government of the Republic of Lithuania on the amendment of the Decision of the Government of the Republic of Lithuania as of 13 September 2005, No. 994 on the approval of the rules on calculating the base price of medicinal products for outpatient treatment, the acquisition costs of which are compensated from the Compulsory Health Insurance Fund (17 January 2018, No. 59).