

**DIRECTORATE FOR FINANCIAL AND ENTERPRISE AFFAIRS
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Please contact Mr Chris PIKE if you have any questions about this document
[Email: Chris.Pike@oecd.org]

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Lithuania

1. Introduction

1. According to Article 53(1) of the Constitution of the Republic of Lithuania,¹ the state cares about the health of people and guarantees medical support and services in the case of their sickness. Furthermore, the aforementioned constitutional provision states that the law determines the rules based on which free medical support is provided to the citizens in the public healthcare institutions. In Lithuania, the providers of healthcare services are public and private, so that healthcare services are both publically funded and private funded.

2. Within its competences, the Competition Council of the Republic of Lithuania (hereinafter: the Competition Council) is active in the healthcare sector. The Competition Council conducted two market studies in the pharmaceutical sector: the market study on the parallel import of pharmaceuticals (in 2013) and the market study on reimbursable pharmaceuticals (in 2016).² Also, in terms of advocacy, the Competition Council is rather active when it comes to healthcare markets.³ No less important is the fact that the Competition Council takes an active role, within its competences, when it comes to the regulatory framework of the healthcare sector. In the recent years, there were several attempts to reform healthcare markets.

2. Recent healthcare reforms or their initiatives

3. In recent years, several healthcare reforms were initiated in Lithuania. Whereas some of them, such as, for example, the establishment of hospitals' pharmacies have been implemented, others did not go through, such as, for example, an attempt to create

¹ Constitution of the Republic of Lithuania as of 25 October 1992, entered into force on 2 November 1995 (Lietuvos aidas, 1992, No. 220 (1992-11-10), Valstybės Žinios, 1992, No. 33-1014 (1992-11-30)).

² Decision of the Competition Council on the concluded market study on the parallel import of pharmaceuticals, 25 September 2013, No. 6S-31; Decision of the Competition Council on the conclusions of the market study on the reimbursable pharmaceuticals, 6 December 2016, No. 3S-92 (2016). For a more detailed description of these studies see Lithuania's Report on Excessive Pricing in Pharmaceuticals.

³ 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 pigę, 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 nepritaria iniciatyvai kurti valstybinių vaistinių tinklą*" (20 June 2017, available at: <http://kt.gov.lt/lt/naujienos/konkurencijos-taryba-nepritaria-iniciatyvai-kurti-valstybiniu-vaistiniu-tinkla> (in Lithuanian)).

regulation for concluding contracts by territorial health insurance funds with public and private healthcare institutions respectively.

2.1. The establishment of hospitals' pharmacies

4. On 5 May 2017, the draft of the amendments of the Pharmacy Law was registered.⁴ According to the draft amendments, it was suggested that Article 35 of the Pharmacy Law should be supplemented with the Section 5¹, which shall state that hospital pharmacies may be such, which perform the functions of a public pharmacy, so that such hospital pharmacies, as a division of the healthcare services institution, shall not only supply pharmaceuticals to the aforementioned institution, but shall also perform the functions of a public pharmacy. Also, the draft amendments suggested that the Pharmacy Law should be supplemented with a new chapter (Chapter 8¹), which shall elaborate on the sales of non-prescriptive pharmaceuticals by retail undertakings.

5. The Competition Council submitted its opinion on the aforementioned draft of the amendments of the Pharmacy Law.⁵

6. Firstly, the Competition Council criticized the draft amendments with regard to hospitals' pharmacies by stating that the draft amendments to the Pharmacy Law were proposed without any proper explanation of the reasons of why the participation of the state in this regard was necessary, what the long-term effect of it would be on competition and without having performed any cost-benefit analysis of the proposed system.⁶ The Competition Council drew attention to the fact that the suggested regulation allowed the establishment of hospitals' pharmacies by both healthcare institutions providing stationary services and healthcare institutions providing outpatient services and stressed that the new regulation would enable such pharmacies to perform the functions of a public pharmacy, i.e. to sell (to supply) pharmaceuticals to natural and legal persons, who/which do not have a license for pharma activity or healthcare services.⁷ The Competition Council referred to Article 46 of the Constitution of the Republic of Lithuania, according to which the freedom of economic activity is guaranteed and which states that the state shall regulate economic activity in the way that serves the welfare of its people.⁸ Accordingly, the Competition Council said that constitutional provisions state that the basis of the Lithuanian economy is private ownership and the freedom of individual economic activity, so that the role of the state is rather to promote such an activity, to support it, to safeguard and to regulate.⁹ The Competition Council stressed that only when sufficient data exists about the fact that

⁴ Project of the Law to amend Articles 2, 8, 19, 33, 35, 59¹, 68¹ of the Pharmacy Law No. X-709 and to supplement it with Chapter 8¹, 5 May 2017, No. 17-5735 (available at: <https://e-seimas.lrs.lt/portal/legalAct/lt/TAP/6ac5ab80317a11e79f4996496b137f39?positionInSearchResult=51&searchModelUUID=dcafa582-baec-46b8-b4ff-8de19cea46c5> (in Lithuanian)).

⁵ The opinion of the Competition Council of the Republic of Lithuania, 20 June 2017, No. (2.30-35) 6V-1443 (available at: <https://e-seimas.lrs.lt/portal/legalAct/lt/TAK/5044628059011e78869ae36ddd5784f?jfwid=1v569hlod> (in Lithuanian)).

⁶ *Ibid.*, para. 7.

⁷ *Ibid.*, para. 11.

⁸ *Ibid.*, para. 13.

⁹ *Ibid.*, para. 14.

particular services are essentially necessary in the society and that their provision cannot be guaranteed by effective competition among private undertakings, the state may take an initiative to provide such services. However, it was noted, that there was no grounded evidence that in the pharmaceuticals retail market there was such a “market mistake”, which could be corrected only by the intervention of the state, i.e. by the initiative of the latter to start performing economic activity.¹⁰ Furthermore, the Competition Council drew attention to the fact that the suggested regulation created conditions for the subjects of public administration simultaneously to participate in the economic activity and to enforce public administration with regard to the established undertaking – the circumstance, which, it was said, may create risks such as the conflict of interests, the problem of transparency, state aid, corruption etc.¹¹ Therefore, the Competition Council opposed to suggested regulatory amendments, according to which a chain of state pharmacies could be established.¹²

7. Secondly, the Competition Council expressed its opinion with regard to the draft amendments on the sale of pharmaceuticals by retail undertakings. Draft amendments suggested supplementing the Pharmacy Law with legal provisions on the sale of pharmaceuticals by retail undertakings. However, one of the conditions when a pharmaceutical could be included on the list of pharmaceuticals, which can be sold by retail undertakings, was the requirement that a pharmaceutical had to be registered in Lithuania and had to have been a non-prescriptive pharmaceutical for at least 5 years (draft of Article 41² of the Pharmacy Law). In the opinion of the Competition Council, there was a lack of objective justification as regards the five-year term enshrined in the draft amendments, so that the competition authority raised the question whether the criteria enshrined in the draft amendments in terms of the requirements of when a pharmaceutical could be sold by retail undertakings were objective and proportionate to the aim that was strived to be achieved.¹³

8. On 15 September 2017, further draft amendments of the Pharmacy Law were registered.¹⁴ According to draft amendments, it was suggested that Article 35(5) of the Pharmacy Law should be amended by stating that hospitals’ pharmacies may sell (supply) pharmaceuticals to the patients, to whom healthcare services are provided in the day stationary, and also that they may sell pharmaceuticals remotely. In the opinion provided by the Competition Council,¹⁵ the latter drew attention to the fact that, according to such an amendment, hospitals’ pharmacies would be able not only to provide pharmaceuticals

¹⁰ *Ibid.*, para. 18.

¹¹ *Ibid.*, para. 20.

¹² *Ibid.*, para. 23.

¹³ *Ibid.*, paras 26-27.

¹⁴ Project of the Law to amend Articles 2, 8, 19, 33, 35¹, 59¹, 68¹ of the Pharmacy Law No. X-709 and to supplement it with Chapter 8¹, 15 September 2017, No. 17-5735(2) (available at: <https://e-seimas.lrs.lt/portal/legalAct/lt/TAP/b61601709a0c11e78d46b68e19efc509?positionInSearchResults=38&searchModelUUID=dcafa582-baec-46b8-b4ff-8de19cea46c5> (in Lithuanian)).

¹⁵ The opinion of the Competition Council of the Republic of Lithuania, 26 October 2017, No. (2.30-35) 6V-2565 (available at (under the section “skenuoti originalai”): <https://e-seimas.lrs.lt/portal/legalAct/lt/TAP/643b8190e0c511e7b4d1bdd5f1a9ff0e?positionInSearchResults=30&searchModelUUID=dcafa582-baec-46b8-b4ff-8de19cea46c5> (in Lithuanian)).

to the patients of the day stationary, but also to sell them remotely to all consumers.¹⁶ In such a case, the same economic and legal risks that were mentioned in the previous Competition Council's opinion were said to remain, namely: the conflict of interests, transparency problem, state aid, the risk of corruption etc.¹⁷ According to the Competition Council, if in all healthcare institutions hospitals' pharmacies were established, this might raise the risk that such pharmacies may be the only ones, so that private pharmacies may be just pushed out and substituted by state pharmacies.¹⁸ Hence, the Competition Council stated that the suggested regulation offered the participation of the state in the business.¹⁹ However, the Competition Council reiterated that the regulation of the economic activity should be such that it creates most beneficial conditions for effective competition, based on which the benefit may go to consumers (patients) and the state as a whole. Such regulation, it was said, should not amount to overregulation or protectionism. To the contrary, it was noted, that regulation should be clear, transparent and non-discriminatory.²⁰ Accordingly, the Competition Council opposed to the suggested draft amendments as regards the establishment of the state pharmacies' chain.²¹

9. On 10 April 2018, further draft amendments to the Pharmacy Law (namely, Article 35) were registered.²² According to the draft amendments, hospitals' pharmacies could be established only by healthcare institutions and such pharmacies could sell pharmaceuticals to consumers. Also with regard to this draft amendment, the Competition Council provided its opinion,²³ in which it opposed to the draft amendments, which, according to the Competition Council, basically suggested creating a chain of state pharmacies.

10. On 30 June 2018, amendments to the Pharmacy Law were adopted.²⁴ It is noteworthy that, although not all provisions of the Law amending the Pharmacy Law are currently in force, the amendments related to hospitals' pharmacies entered into force on 1 November 2018. According to the amended Pharmacy Law, Article 35, hospitals' pharmacies are a healthcare institution's division, which supplies such a healthcare institution with pharmaceuticals. If such a healthcare institution provides also day

¹⁶ *Ibid.*, para. 14.

¹⁷ *Ibid.*, para. 15.

¹⁸ *Ibid.*, para. 22.

¹⁹ *Ibid.*, para. 22.

²⁰ *Ibid.*, para. 24.

²¹ *Ibid.*, para. 25.

²² Project of the Law amending Article 35 of the Pharmacy Law No. X-709, 10 April 2018, No. XIIIIP-1939 (available at: <https://e-seimas.lrs.lt/portal/legalAct/lt/TAP/0709add03c8211e884a38848fe3ec9e2?positionInSearchResults=17&searchModelUUID=5427e8f7-d060-4335-8df0-f0ac3f8d30cf> (in Lithuanian)).

²³ The opinion of the Competition Council of the Republic of Lithuania, 24 May 2018, No. (2.30E-35)6V-1347 (available at: <https://e-seimas.lrs.lt/portal/legalAct/lt/TAK/5e53c5005ff311e896f6c1beca8cd3a8?jfwid=-k3id7kqzp> (in Lithuanian)).

²⁴ Law amending Articles 2, 8, 19, 33, 35, 35¹, 59¹, 68¹ of the Pharmacy Law No. X-709 and supplementing this Law with Chapter 8¹, 30 June 2018, No. XIII-1408 (available at: <https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/40d27d917dd611e89188e16a6495e98c?positionInSearchResults=5&searchModelUUID=5427e8f7-d060-4335-8df0-f0ac3f8d30cf> (in Lithuanian)).

stationary services, hospital pharmacy may sell (supply) pharmaceuticals to the patients of the day stationary. However, according to the amended Article 35 of the Pharmacy Law, hospitals' pharmacies cannot sell pharmaceuticals remotely.

2.2. Healthcare insurance

11. On 24 May 2018, draft amendments of the Law on Health Insurance were registered.²⁵ According to the draft amendments, territorial health insurance funds shall conclude contracts for healthcare services with healthcare institutions, which belong to the state or municipality healthcare institutions' network, whereas contracts with other healthcare institutions shall be concluded only if the aforementioned institutions cannot provide the service or only to the extent such service is not provided. Also with regard to these draft amendments the Competition Council submitted its opinion.²⁶ According to the Competition Council, the suggested regulation created different conditions for healthcare institutions by prioritizing healthcare institutions, which belonged to the state or municipality healthcare institutions' network.²⁷ The Competition Council pointed out that healthcare institutions, which did not belong to the aforementioned network, would be discriminated.²⁸ The Competition Council stressed that any restriction of an economic activity should be objectively justified and should also be proportionate to the aim, which it strives to achieve. In this regard, the Competition Council referred to the case-law of the Constitutional Court of the Republic of Lithuania,²⁹ according to which any restrictions or the prohibition of an economic activity have to comply with four conditions: firstly, economic activity can be restricted only by law, secondly, such restrictions are necessary in the democratic society pursuing to protect the rights and freedoms of other persons, the values enshrined in the Constitution of the Republic of Lithuania as well as the constitutionally relevant aims, thirdly, the restrictions do not deny the nature and the essence of the rights and freedoms, and fourthly, the principle of constitutional proportionality is complied with.³⁰ In this regard, the Competition Council said that the soundness, necessity and the proportionality of the suggested draft amendments were doubtful, since they were discriminatory based merely on the ownership of healthcare institutions.³¹

²⁵ Project of the Law amending Articles 2, 26 and 27 of the Law on Health Insurance No. I-1343, 24 May 2018, No. XIII P-2226 (available at: <https://e-seimas.lrs.lt/portal/legalAct/lt/TAP/1a192b905f3611e896f6c1bcca8cd3a8?jfwid=-n7cyhzc5n> (in Lithuanian)).

²⁶ The opinion of the Competition Council of the Republic of Lithuania, 13 June 2018, No. (2.30E-35)6V-1493 (available at: <https://e-seimas.lrs.lt/portal/legalAct/lt/TAK/2ebb9ab17e8f11e89188e16a6495e98c?jfwid=-n7cyhzc5n> (in Lithuanian)).

²⁷ *Ibid.*, para. 4.

²⁸ *Ibid.*, para. 5.

²⁹ Ruling of the Constitutional Court of the Republic of Lithuania, 31 May 2006, No. 42/03.

³⁰ *Ibid.*, Part II of the legal findings of the Court, para. 2.2.

³¹ The opinion of the Competition Council of the Republic of Lithuania, 13 June 2018, No. (2.30E-35)6V-1493 (available at: <https://e-seimas.lrs.lt/portal/legalAct/lt/TAK/2ebb9ab17e8f11e89188e16a6495e98c?jfwid=-n7cyhzc5n> (in Lithuanian)), para. 7.

12. It is noteworthy that, although the Parliament of the Republic of Lithuania passed the Law amending the Law on Health Insurance on 30 June 2018,³² the President of the Republic of Lithuania did not sign it into law (vetoed it).³³ This law has been considered as not passed.³⁴

³² Law on the amendment of Articles 2, 26 and 27 of the Law on Health Insurance No. I-1343, 30 June 2018, No. XIII-1424 (available at: <https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/6908f7127f9511e89188e16a6495e98c?jfwid=-n7cyhzc5n> (in Lithuanian)).

³³ The Decree of the President of the Republic of Lithuania as of 10 July 2018, No. 1K-1349 (available at: <https://e-seimas.lrs.lt/portal/legalAct/lt/TAD/72f263f0847811e89188e16a6495e98c?positionInSearchResults=11&searchModelUUID=ae5e9f05-bc9d-4a29-93f8-c22f38236843> (in Lithuanian)).

³⁴ Available at: <https://e-seimas.lrs.lt/portal/legalAct/lt/TAP/ba39cf70844911e89188e16a6495e98c?positionInSearchResults=10&searchModelUUID=ae5e9f05-bc9d-4a29-93f8-c22f38236843> (in Lithuanian).