

Roadmap for Improving Access to Medicines in Latvia

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Executive summary

The level of out-of-pocket (OOP) spending on health in Latvia, mainly driven by outpatient medicines, is the third highest in the EU; and medicines are almost exclusively responsible for catastrophic spending in all quintiles of the population. This report, developed in cooperation with the Latvian Ministry of Health, aims to identify and review issues affecting access to medicines for patients in Latvia. It focuses on coverage, pricing and distribution of medicines and provides a set of recommendations on reducing private out-of-pocket expenditure.

In Latvia, total spending on medicines (both per capita and as percentage of GDP) is slightly higher than in other Baltic countries; primarily due to high OOP spending on over the counter (OTC) medicines. The Latvian Positive Drug List (PDL) provides poorer access to publicly covered, in particular “recently authorised”, prescribed medicines compared to other Baltic countries. For the most common groups of drugs, Latvia consumes slightly less DDDs per capita. OOP expenditure on medicines has been growing rapidly in recent years and was in 2018 roughly equally split between prescribed and OTC medicines.

Latvia uses international price comparisons to regulate ex-factory prices of medicines if they are (co)financed by its National Health Service, while medicines that are paid by patients in full can be freely priced by marketing authorization holders. A comparison of prices between the Baltic countries undertaken in 2019 reveals that manufacturers mainly set lower ex-factory prices in Latvia than they do in Estonia and Lithuania, but that this does not result in better accessibility as most of the observed medicines end up, in major part due to larger mark-ups, being sold at higher prices in Latvian pharmacies than in the other two countries. Wholesaler and pharmacy revenues are further supplemented through unregulated discounts, not subject to limitations or rebates, that are passed down the supply chain, occasionally reaching as much as 50% of the regulated prices. Latvia’s comparatively high rate of VAT on medicines (both prescribed and OTC) is also a contributing factor towards large OOPs for patients and functions as a highly regressive form of tax targeting people with health care needs.

Latvia operates progressive (in absolute amounts) wholesale and retail mark-ups for non-covered medicines; the more expensive the product, the greater the wholesaler and pharmacy revenues. But for the cheapest medicines, wholesale mark-ups are smaller both in Estonia where they reach between 3% and 57% and in Lithuania where they reach between 7% and 50% of Latvian retail mark-ups. Retail mark-ups for non-covered medicines are also highest in Latvia (but for the cheapest products); in Estonia they reach between 2% and 63% and in Lithuania between 8% and 75% of Latvian retail mark-ups.

Regulated mark-ups for covered products are sizeably more modest than they are for the non-reimbursed ones; wholesale mark-ups are progressive (in absolute amounts), while retail mark-ups are progressive (in absolute amounts) up until the product ex-factory price reaches EUR 100, at which point they are capped. The differences between wholesale and retail mark-ups for covered medicines in Latvia and the other two countries are much less pronounced than they are for non-reimbursed medicines.

As a result, in Estonia, for given ex-factory prices, retail prices of non-reimbursed medicines reach between 80% and 86% of Latvian prices (but for the cheapest medicines priced at around EUR 1 which are slightly more expensive), while in Lithuania they reach between 78% and 88% of Latvian prices. Retail prices of covered medicines priced over EUR 3 in Estonia and EUR 5 in Lithuania (for given ex-factory prices) are also smaller than they are in Latvia, but the differences are smaller than they are for the non-reimbursed medicines; and the cheapest covered medicines are least expensive in Latvia of all three countries, however at very small differences in absolute terms.

Large numbers of retail (community) pharmacies and wholesalers relative to the population indicate that the supply chain in Latvia may have not been as exposed to financial incentives promoting economies

of scale as it was in the other countries, where wholesaling and retailing have become more concentrated. Vertical integration trends in supply and the growth of pharmacy chains could be negatively affecting competition in the market.

Options to decrease OOPs for medicines in Latvia include:

1. Increasing public funding for coverage of medicines to:
 - a. include more cost-effective medicines in the Positive Drug List (PDL), and
 - b. improve coverage levels for medicines listed in the PDL.
2. Reforming regulation on OOPs for medicines by:
 - a. setting limits on maximal monthly OOPs or co-payments,
 - b. widening population group-based exemptions, and
 - c. by making sure administrative hurdles do not prevent individuals subject to benefits from exercising their rights.
3. Mandating INN prescribing of non-reimbursed medicines as has been already done for covered medicines.
4. Reforming pricing regulation to:
 - a. use International Price Comparisons to determine wholesale or retail prices rather than ex-factory prices of covered medicines,
 - b. expand pricing regulation to include maximal allowed prices of non-reimbursed prescribed medicines,
 - c. expand pricing regulation to include maximal allowed prices of OTC medicines,
 - d. tighten the rules on maximal allowed co-payments for reimbursed medicines, and to
 - e. make sure patients who need to buy medicines that are reimbursed for other indications (but not the one they are using the product for) are not overcharged.
5. Reforming regulation determining and influencing wholesale mark-ups to:
 - a. reduce distributor fees for non-covered medicines by adopting a single mark-up schedule for all medicines,
 - b. tighten mark-ups for both non-reimbursed and reimbursed medicines,
 - c. tender a part of off-patent medicines,
 - d. review regulation and market conditions that are influencing how wholesaling is undertaken to stimulate a more efficient mix of full-line, direct to pharmacy and reduced wholesaler model schemes wholesaling, bearing in mind both positive and negative aspects of the models with the ultimate goal of making medicines more affordable,
 - e. claw-back a part of the wholesaler revenues if these are judged to be inappropriately high, and
 - f. review regulation that allows wholesalers to own pharmacies if these vertically integrated chains are using their dominant position in the market to generate excessive profits.
6. Reforming regulation on retail mark-ups to:
 - a. reduce pharmacy fees by adopting a single mark-up schedule for all medicines,
 - b. tighten mark-ups for both non-reimbursed and reimbursed medicines, and
 - c. adopt low fixed co-payments instead of mark-ups.
7. Decreasing the VAT rate on all or prescribed medicines only.
8. Further regulation of the OTC market to make sure these products are used rationally.

Short introduction - Pharmaceutical Policy in Latvia

Pricing and reimbursement of medicines

Latvia uses international price comparisons to regulate ex-factory¹ prices of medicines if they are (co)financed by its National Health Service (NHS), while medicines that are paid by patients in full can be freely priced by pharmaceutical companies. The maximal allowed regulated ex-factory price can't be higher than the second lowest ex-factory price of the product (brand, prices of other brands of the same INN are not considered) in the Czech Republic, Denmark, Poland, Romania, Slovakia and Hungary, and can't exceed its ex-factory price in Estonia and Lithuania. Marketing authorization holders (MAHs) are free to set prices of non-covered medicines as they please. Nevertheless, they need to report these to the State Agency of Medicines (SAM) that maintains Latvia's Register of Human Medicines. Products that can be prescribed for different indications are subject to dual pricing in case any of the registered indications are not publicly reimbursed. In this case, pricing regulation is not applied and patients are generally subject to greater prices than those determined for the publicly covered indications².

Publicly covered medicines are subject to copayments determined by reimbursement levels, and those that are interchangeable, to copayments defined through internal reference pricing as well. Medicines included in the Latvian Positive Drug List (PDL) are classified into one of three reimbursement categories (100%, 75% and 50%), depending on the duration (chronicity) and severity of illnesses for which they have been covered. Medicines covered at 100% are subject to low (EUR 0,71) fixed co-payments. In addition, the PDL consists of three parts: A) interchangeable products subject to internal reference pricing³, b) noninterchangeable products and c) high-cost medicines that can only be prescribed if approved by the NHS, with annual treatment costs exceeding EUR 4,300, for which a mandatory rebate is applied. In special situations, the NHS may also approve the reimbursement of medicines that are not included in the PDL, subject to approval issued by a council of specialists.

Mark-ups and discounts

Latvia operates progressive (in absolute amounts) wholesale and retail mark-ups for non-covered medicines⁴; the more expensive the product, the greater the wholesaler and pharmacy revenues. The maximal allowed wholesaler price⁵ (WP) is formed as follows: $WP = MP \text{ (manufacturer price)} * k \text{ (correction coefficient)} + X \text{ (correction amount)} + \text{value added tax (VAT)}$. The maximal allowed pharmacy price (PhP) is formed as follows: $PhP = PP \text{ (purchase price)} * c \text{ (correction coefficient)} + Y \text{ (correction amount)} + \text{VAT}$. See table 1 for a detailed overview of coefficients and amounts. As the manufacturer price increases from EUR 1 to EUR 2,000, the wholesale mark-up increases from EUR 0,18 to 200,94 EUR (decreasing as a share of the retail price, including VAT, from 10% to 7%) and the

¹ The price at which the manufacturer sells the product to the wholesaler.

² Competition Council. Price formation of medicinal products and possible restrictions of competition that affect the financial availability of medicinal products. Riga, 2019.

³ Groups consist of either products with the same active ingredient or products within one pharmacotherapeutic group that have similar efficacy and side effects, the same route of administration and the same patient target groups

⁴ Including both prescribed and over-the-counter (OTC) medicines

⁵ The price at which the wholesaler sells the product to the pharmacy.

retail mark-up increases from EUR 0,47 to EUR 223 (decreasing as a share of the retail price, including VAT, from 26% to 8%) per dispensed pack of medicines.

Table 1 - Correction coefficients and correction amounts used for the calculation of maximal allowed wholesale and retail prices⁶ for non-covered medicines

Maximal wholesaler prices

Manufacturer price in EUR (MP)	Correction coefficient (k)	Correction amount (X)
Up to 4,26	1,18	0
4,27-14,22	1,15	0,13
14,23 and more	1,1	0,84

Maximal pharmacy prices

Purchase price in EUR (PP)	Correction coefficient (c)	Correction amount (Y)
Up to 1,41	1,4	0
1,42-2,84	1,35	0,07
2,85-4,26	1,3	0,21
4,27-7,10	1,25	0,43
7,11-14,22	1,2	0,78
14,23-28,45	1,15	1,49
28,46 and more	1,1	2,92

Source: Competition Council. Price formation of medicinal products and possible restrictions of competition that affect the financial availability of medicinal products. Riga, 2019

Regulated mark-ups for covered products are sizeably more modest than they are for the non-reimbursed ones; wholesale mark-ups are progressive (in absolute amounts), while retail mark-ups are progressive (in absolute amounts) up until the product ex-factory price reaches EUR 100, at which point they are capped at EUR 6.05 per pack. The maximal allowed wholesale price (BRP) is formed as follows: $BRP = RMP$ (manufacturer price) + WhM (wholesale mark-up). The maximal allowed pharmacy price (RPP) is formed as follows: $RPP = BRP$ (wholesale price) * k (correction coefficient) + X (correction amount) + VAT. See table 2 for a detailed overview of coefficients and amounts. As the manufacturer price increases from EUR 1 to EUR 2,000, the wholesale mark-up increases from EUR 0,1 to EUR 20 (decreasing as a share of the retail price, including VAT, from 6,25% to 0,88%) and the retail mark-up increases from EUR 0,33 to EUR 6,05 (decreasing as a share of the retail price, including VAT, from 20% to 0,27%) per pack of dispensed medicines.

Table 2 - Correction coefficients and correction amounts used for the calculation of maximal allowed wholesale and retail prices for covered medicines

Maximal wholesaler prices

Manufacturer price in EUR (RMP)	Wholesaler mark-up (WhM)
0,01-2,83	10%
2,84-5,68	9%
5,69-11,37	7%
11,38-21,33	6%
21,34-28,44	5%
28,45-142,27	4%

⁶ The price at which pharmacies sell products to patients. Also referred to as the pharmacy price.

142,28-711,42	3%
711,43-1422,86	2%
1422,87 and more	1%

Maximal pharmacy prices

BRP in EUR (PP)	Correction coefficient (k)	Correction amount (X)
Up to 1,41	1,3	0
1,42-2,83	1,25	0,07
2,84-4,25	1,20	0,21
4,26-7,10	1,17	0,43
7,11-14,21	1,15	0,57
14,22-21,33	1,10	1,28
21,34-28,44	1,07	1,92
28,45-71,13	1,05	2,49
71,14 and more	1,00	6,05

Competition Council. Price formation of medicinal products and possible restrictions of competition that affect the financial availability of medicinal products. Riga, 2019

Wholesaler and pharmacy revenues are further supplemented through unregulated discounts, not subject to any claw-backs, that are passed down the supply chain, occasionally reaching as much as 50% of the regulated prices⁷. Manufacturers grant volume and early payment discounts to wholesalers or provide payments or price reductions for marketing activities. Wholesalers mostly provide volume discounts to pharmacies, but discounts based on general payment discipline, early payment, ordered baskets of products, etc. are also common. These savings are habitually not passed down to patients through reductions of retail prices, but are kept by the wholesalers and pharmacists.

OOPs for health and medicines

Due to weak protective mechanisms, in Latvia the level of OOP spending on health, mainly driven by outpatient medicines, is the third highest in the EU; and medicines are almost exclusively responsible for catastrophic spending in all quintiles of the population⁸. Copayment exemptions (including for medicines) are in place only for children under 18 years of age and the very poorest households with monthly income of less than 50% of the minimum wage per family member under the Social Safety Net. Furthermore, earlier reports analysing utilisation of this program have noted that a substantial part of the eligible population had not used these benefits, and it remains unclear whether this has changed for the better⁹. In addition, children up to 2 years of age are eligible for 50% reimbursement and pregnant women (the period extends until 70 days after childbirth) for 25% reimbursement of all registered prescription medicines that are not listed on the PDL. Finally, Latvia operates a cap on health co-payments equal to one and a half month's minimum wage which is not

⁷ Competition Council. Price formation of medicinal products and possible restrictions of competition that affect the financial availability of medicinal products. Riga, 2019.

⁸ WHO Regional Office for Europe. Medicines Reimbursement Policies in Europe. Copenhagen, 2018.

⁹ A World Bank report (Griffin CC, Mozhaeva I. Distribution of health subsidies under the emergency social safety net and their impact on unemployed. Washington DC, 2013), reveals that about half the eligible people of retirement age did not take advantage of the Social Safety Net's extended exemptions and co-payment reductions when they were in place in 2010 and 2011. It is not clear whether this was because of inadequate information or outreach, bureaucratic hurdles or stigma associated with using the programme.

sufficiently protective for poorer households, and it does not take into account copayments for outpatient medicines at all¹⁰.

Private OOP expenditure on medicines has been growing rapidly in recent years and was in 2018 roughly equally split between prescribed and over the counter (OTC) medicines. From 2013 to 2018, private OOP expenditure on OTCs almost doubled (it grew from EUR 39 to EUR 75 per capita). Private OOP expenditure on prescribed medicines increased from 56 EUR to 70 EUR per capita in the period. The private share of expenditure on prescribed medicines was on the rise from 2013 to 2015, and later decreased to a still very considerable 43 % of the total¹¹. See table 3 for more detail.

Table 3 – Per capita out of pocket (OOP) expenditure on medicines in Latvia in EUR

	2013	2014	2015	2016	2017	2018
OTCs	38,9	45,9	51,4	68,6	70,1	75,4
Prescribed medicines	56,3	61,7	71,8	72,5	68,6	70,1
Share of OOP expenditure on prescribed medicines	49%	50%	52%	48%	46%	43%

Source: OECD.stat, 2021.

Latvia has in 2020 taken a successful step towards reducing OOPs for a segment of covered medicines; copayments generated by prescribing of reimbursed brands of INNs that have cheaper generic alternatives have in the period from April to November been reduced by almost a half¹². In 2016, copayments for covered medicines (not including OTCs and non-reimbursed medicines) stood at 21% of their total cost, but around 59% of this private OOP expenditure was spent as patients were prescribed with brands priced over the reference product of the same INN. This amounted to EUR 23,6 million¹³. According to the MoH, the amount has from April to November 2020 been reduced by 48%, corresponding to an annual estimated per capita impact of around 6,25 EUR or around 6% of the total OOP expenditure on all medicines. A price ceiling for medicines subject to internal reference pricing was introduced and the most expensive alternatives now need to be less than double the price of the cheapest ones. Prescription by international non-proprietary name (INN) has been made mandatory for at least 70% of doctors' yearly prescriptions and pharmacies have been mandated to keep in stock and dispense the cheapest brands with no or lowest copayments when medicines are prescribed by INN.

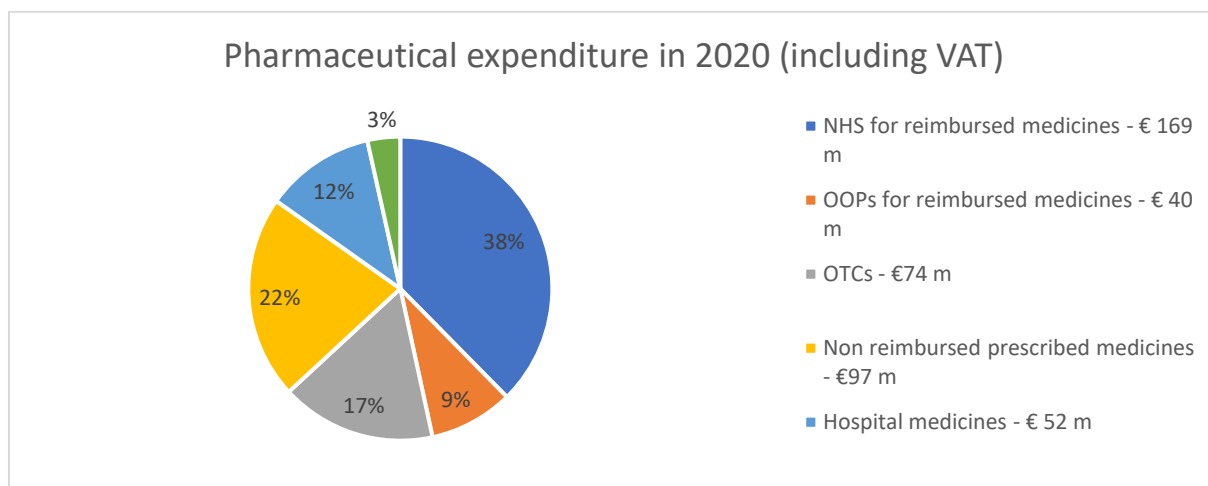
¹⁰ WHO Regional Office for Europe. Can people afford to pay for healthcare? New evidence on financial protection in Latvia. Copenhagen, 2018.

¹¹ Source: OECD.stat, 2021.

¹² Source: MoH estimates.

¹³ Svens Henkuzens/ The State Agency of Medicines (SAM) of Latvia/ presentation "Kasvisbūtiskāk ietekmē zāļu cenuLatvijā?"/ 2017.

Figure 1 – Latvian pharmaceutical market by products and funding agents in 2020



Source: MoH data

Most recent MoH data indicate that, regardless the success of the 2020 reform, private OOP expenditure on prescribed medicines actually further increased slightly from 2018 to 2020 to around EUR 72 per capita, with 63% of this amount being accounted for by expenditure on non-reimbursed medicines and the remaining 37% by co-payments for covered medicines. Further (moderate) savings generated by the reform should however be accrued in 2021 as the reform was implemented in April of 2020. The same data indicate that per capita expenditure on OTCs declined substantially in the period to EUR 39 (including VAT) per capita, almost halving, but comparisons with OECD reported data for earlier years should be taken with caution due to potential methodological issues including different data sources, definitions of OTC products, etc.

Apart from prescribing and dispensing rules introduced in 2020, Latvia uses several other mechanisms to promote rational prescribing (with limited success) and/or control public expenditure. There are few policies to control costs of widely used non-reimbursed prescribed medicines. The NHS has since 2010 developed a number of clinical guidelines, however mainly focusing on very expensive treatments and not common illness. Physician prescribing is monitored quarterly and reports are sent to the Health Inspectorate on physicians if their prescriptions are on average 30% or more expensive for a group of diagnoses than the average in the country. Nevertheless, in the absence of strong penalties, there is a feeling that the system is not particularly effective at discouraging inappropriate prescriptions. Finally, the NHS implements a pay-back system where pharmaceutical companies (depending on their market share) have to compensate the NHS to a certain degree if the annual drug budget is exceeded¹⁴. Prescribing and dispensing of non-reimbursed medicines is not regulated to promote their rational use.

¹⁴ European Observatory on Health Systems and Policies. The health system and policy monitor: regulation – Latvia. 2017.

Comparative assessment focusing on Latvia, Lithuania & Estonia, with additional insight from Croatia and Denmark

Spending on health and medicines

Compared to other Baltic countries, Latvia invests less in health and its citizens need to cover a larger share of health care costs out of pocket. Estonia and Lithuania spend more on health per capita, as percentage of Gross Domestic Product (GDP) and cover a greater part of expenditure from public sources. Denmark, chosen as a Western European comparator, spends in total over 5 times more per capita, and the private share of expenditure reaches only about a third of its share in Latvia. Croatia, chosen as a slightly less developed South-Eastern European comparator, spends around 13% less on health (per capita) in total, but covers an almost four times larger share of this amount from public sources, providing better protection from health care costs to its citizens. Both countries spend more as percentage of GDP as well. See table 4 for more detail on all health and pharmaceutical financing indicators.

Table 4 - Health and medicines financing indicators, 2019 or last available year

	Latvia	Lithuania	Estonia	Croatia	Denmark
THE (per capita) current prices	€ 993	€1.179	€1.436	€ 861	€5.367
THE (% of GDP)	6,3%	6,8%	6,8%	6,8%	10%
OOP THE (% of total)	39,2%	31,6%	24%	10,5%	13,8%
TPE (per capita) current prices	€ 248	€ 234	€228	€ 178	€ 336
TPE (% of GDP)	1,6%	1,4%	1,2%	1,4%	0,6%
TPE (% of THE)	26,5%	22,1%	17,4%	20,7%	6,4%
EPM (per capita) current prices	€ 163,9	N/A	€ 169,8	€ 126,3	€ 217
OOP EPM (% of total)	42,8%	N/A	37%	23,6%	29,8%
EOTC (per capita) current prices	€75,4	N/A	€46,3	€ 30,8	€61,7

Source: OECD.stat 2021. Danish Krone converted to EUR using the yearly average conversion rate. Eurostat for Croatia

Note: THE=total health expenditure, TPE=total expenditure on pharmaceuticals and other medical non-durable goods, EPM=expenditure on prescribed medicines, EOTC= expenditure on OTC medicines

Latvia spends slightly more on all medicines in total (both per capita and as percentage of GDP) than the other Baltic countries; this disbalance between pharmaceutical financing and other health care expenditures results in medicines consuming the greatest share of total health care spending of all three countries. Denmark spends only around 35% more and Croatia around 28% less on medicines per capita, and expenditure on medicines in both countries (in Denmark in particular) accounts for a smaller share of total health expenditure. Expenditure on medicines as percentage of GDP is in Croatia 0,2 and in Denmark an entire percentage point lower than it is in Latvia.

Latvia's comparatively (to the Baltics) larger pharmaceutical expenditure is due to its outsized private spending on OTC medicines, as the country actually spends slightly less (per capita) on prescribed medicines than Estonia (data for Lithuania is not available). While Denmark spends

33% more and Croatia 22% per capita on prescribed medicines, both countries spend substantially less on OTCs per capita, of which Croatia less than half.

Latvians pay a substantially greater share of prescribed medicines out-of-pocket compared to all other countries. The public share of expenditure on outpatient prescribed medicines in Estonia outstrips that of Latvia by 15%, in Croatia it is almost double and in Denmark it is 1,6 times larger. Data for Lithuania is not available.

Access to medicines

Compared to all other countries (but Denmark), the volume of consumption of medicines in Latvia (in DDDs per 1.000 inhabitants) does not correspond to its high pharmaceutical expenditure; for the most common groups of medicines, Latvia consumes slightly less DDDs per capita than Lithuania and Estonia and much less than Croatia. The mismatch between volumes and expenditure to other countries may be a consequence of higher retail prices for prescribed medicines, higher retail prices for OTCs and wider use of OTC medicines as well as food supplements and other products that do not have ATC codes assigned, but may (for some countries) be counted in OTC expenditure by the OECD nevertheless. Methodological issues elaborated in Table 5 may also play a role. Eurostat data (even though outdated as they are reported for 2014, from which time per capita OTC expenditure in Latvia increased by 50% as reported by the OECD) point to widespread use of OTCs in Latvia and higher OTC prices compared to Estonia, Croatia and Denmark as the volume differences do not fully account for the differences in expenditure. See tables 5 and 6 for more detail.

Table 5 - Pharmaceutical consumption for most common groups of medicines, measured in defined daily dosage per 1.000 inhabitants per day in 2019 (or last year available)

	Latvia	Lithuania	Estonia	Croatia	Denmark
Cardiovascular system (C)	313,3 (401,2)	457,1 (457,1)	429,9 (431,2)	502,3	551,5
Alimentary tract and metabolism (A)	309,7 (124,13)	138,2 (138,17)	176,6 (149,8)	218,7	183,6
Nervous system (N)	105,5	153,6	134,2	195,5	267,7
Blood and blood forming organs (B)	90,9	89,9	107,8	99,72	14,1
Respiratory system (R)	51,1 (57,6)	73,8 (73,1)	93,9 (94,1)	78,29	142,8
Musculo-skeletal system (M)	77,9	76,3	84,1	77,8	61,4
Genito-urinary system (G)	15,1 (26,2)	31,6 (31,2)	56,6 (55,4)	36,3	98,6
Anti-infectives for systemic use (J)	16 (17,3)	21,9 (21,9)	19,2 (19,58)	22,9	20,6

Sources: OECD, stat 2021, Baltic Medicines Agencies - Sales Statistics 2018 for Latvia, Lithuania and Estonia in (brackets) where large differences were observed to OECD data, Croatian Agency for Medicines and Medical Devices (HALMED) for Croatia

Note*: The second source (Sales Statistics 2018) has been introduced to the table where OECD figures for Latvia drastically diverge from other Baltic countries. The Sales Statistics data have a minor methodological difference to the OECD source. The

classification of medicinal products may vary between countries. Consequently, data on drug use in different countries may not be directly comparable in all of the drug classes. For example, some products may be classified as food supplements or natural remedies in one country and as a medicine in another country. For this reason, in the Baltic Sales Statistics ATC groups A11 (vitamins) and A12 (mineral supplements) have been excluded from the count.

Table 6 - Self reported use of non-prescribed medicines in the past 2 weeks, percentage of population, reporting country (2014!)

Country	% of population
Latvia	53,7%
Lithuania	56,8%
Estonia	46,9%
Croatia	31%
Denmark	56%
EU (27)	33,9%

Source: Eurostat

While discussions on comparative effectiveness and cost-effectiveness as well as the definition of “innovative” medicines fall outside the scope of this report, access to publicly covered (in particular “recently authorised”) medicines in Latvia appears to be worse than it is in other Baltic countries¹⁵, and possibly Croatia. An industry press release published in 2020 has noted that both Estonia and Lithuania publicly reimburse a much larger number of “innovative medicines” in total and specifically those registered for cancer treatment than Latvia does¹⁶. The number of covered prescriptions per capita¹⁷ in 2018 appears to indicate that overall accessibility of medicines is worse in comparison to Estonia, but not to Lithuania. Croatia records a far larger number of prescriptions than Latvia; the size of the difference and the miss match in pharmaceutical expenditures between the countries may merit further looking into to establish to what extent access to medicines really differs and, if it indeed does, how was Croatia able to accomplish it at more favourable financial circumstances.

Table 7 – Number of covered prescriptions in 2018 and access to “innovative” medicines in 2020 in Baltic countries

	Estonia	Latvia	Lithuania	Croatia (2017)
Number of covered prescriptions per capita in 2018	6,5	3,5	3,3	15,2
Number of “innovative”, “younger generation” medicines (co)financed by the state in September 2020	80	67	99	N/A
Number of “innovative” “younger generation” medicines for cancer (co)financed by the state in September 2020	49	34	60	N/A

¹⁵ <https://www.world-today-news.com/in-latvia-the-availability-of-medicines-for-cancer-treatment-lags-behind-even-in-the-baltics/>

¹⁶ This information should however be interpreted with caution as the press release does not reveal the methodology behind the reported figures. In addition, value for money should play a critical role in deciding on reimbursement of “innovative” medicines so it would be wrong to assume that greater access is always better from a societal perspective.

¹⁷ This indicator is also difficult to interpret as medicines used in hospitals are not subject to prescriptions and as regulation on prescribing (chronic prescriptions that allow for dispensing of therapies over several months, number of packs that can be dispensed against a prescription, etc.) may differ between the countries.

Sources: Number of covered prescriptions in Baltic countries: Baltic Medicines Agencies - Sales Statistics 2018; Number of reimburses prescriptions in Croatia: https://www.dzs.hr/Hrv_Eng/CroInFig/croinfig_2018.pdf; Numbers of “innovative” medicines: <https://www.world-today-news.com/in-latvia-the-availability-of-medicines-for-cancer-treatment-lags-behind-even-in-the-baltics/>

Prices, VAT and supply chain

A comparison of real prices (excluding VAT) between the Baltic countries undertaken in 2019¹⁸ reveals that manufacturers mainly set lower ex-factory prices in Latvia than they do in Estonia and Lithuania, but that this does not result in better accessibility as most of the observed medicines end up, due to larger mark-ups and VAT, being sold at higher prices in Latvian pharmacies than in the other two countries. The comparison with Lithuania focused on 18 and the comparison with Estonia on 19 “most popular” medicines sold in Latvian pharmacies under € 50 (including VAT), and it encompassed OTCs, as well as reimbursed and non-reimbursed prescribed medicines. Out of 18 medicines compared with Lithuania, the ex-factory price was lower in Latvia for 10 and five had the same price. 9 of these had a higher retail price in Latvia. Out of 19 medicines compared with Estonia, the ex-factory price was lower in Latvia for 13 and 3 had the same price. 10 of these were sold at higher retail prices in Latvia. As the analysis only reports joint results and does not specify which products were compared, an evaluation of prices between the drug categories or individual products could not have been undertaken.

Large numbers of retail (community) pharmacies and wholesalers relative to the population also indicate that the supply chain in Latvia may have not been as exposed to financial incentives promoting economies of scale as it was in the other countries, where wholesaling and retailing have become more concentrated. Whereas in Latvia (population 1,92 million) as many as 8 wholesalers hold around 95% of the market, in Croatia (population of 4,1 million) there are 4 major wholesalers, in Lithuania (population 2,9 million) there are 6, in Estonia (population 1,3 million) there are 3 and in Denmark (population 5,8 million) only 2. The situation is similar with retailers; Denmark, Croatia and Estonia have far fewer community pharmacies per 100,000 population than Latvia as well.

Table 8 – Numbers of wholesalers and pharmacists in 2019

Country	Retail pharmacies per 100.000 inhabitants	Number of wholesalers (human medicines) total and per 1 million population
Latvia	45	84 (44 per 1 million population), 8 hold over 94% of the market
Lithuania	47	125 (45 per 1 million population), 6 hold 94% of the market
Estonia	37	61 (46 per 1 million population), 3 hold 75% of the market
Croatia	32	42 (10 per 1 million population), 4 hold 95% of the market
Denmark	5,5 pharmacies and pharmacy branches that can dispense prescribed drugs and OTCs and 13	204 registered (43 per 1 million population), but only are 2 are large scale full line distributors

¹⁸ Competition Council. Price formation of medicinal products and possible restrictions of competition that affect the financial availability of medicinal products. Riga, 2019

	pharmacy shops and OTC sales outlets that can dispense OTCs (2011)	
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Source: For Baltic countries: calculated based on Baltic Medicines Agencies – Sales Statistics 2018; for Croatia: Croatian Health Insurance Fund and Croatian Agency for Medicines and Medical Devices (HALMED) data, for Denmark: PPRI Pharma Profile 2011 and Danish Medicines Agency (wholesalers)

Growing vertical integration of pharmacies and wholesalers may be impeding market competition in both segments of the supply chain, particularly as large pharmacy chains owned by wholesalers tend to occupy the most attractive retail locations. For instance, according to the Latvian Ministry of the Economy¹⁹, the largest pharmacy chain, *AS Sentor Farm* pharmacies that accounts for around a third of the retail market, is owned by the same owner as the *AS Recipe plus* wholesaler that accounts for between 40% and 50% of the wholesale market. Individual pharmacies or wholesalers that do not own so many pharmacies can hardly compete against such large players which may lead to additional takeovers by vertically integrated chains, further increasing their market dominance.

Latvia's high rate of VAT on medicines is a further contributing factor towards large OOPs for patients and functions as a highly regressive form of tax targeting people with health care needs. Out of the comparator countries, the VAT rate is higher only in Denmark, but this fact should be interpreted understanding that prescribed medicines in Denmark are subject to far greater public subsidies than they are in Latvia and that Danish health authorities operate under over 5 times larger budgets per capita.

Table 9 – VAT rates for medicines

Country	VAT rate for medicines
Latvia	12%
Lithuania	5%
Estonia	9%
Croatia	5%
Denmark	25%

Source: European Commission, VAT rates in the member states as of January 1, 2020. Available from: https://ec.europa.eu/taxation_customs/sites/taxation/files/resources/documents/taxation/vat/how_vat_works/rates/vat_rates_en.pdf (Accessed in January 2021)

Wholesale and retail mark-ups for non-covered medicines

While, as Latvia, Estonia and Lithuania also do not regulate ex-factory prices of non-covered medicines, their retail prices (for given ex-factory prices) are in both countries sizeably smaller due to less relaxed regulation determining wholesale and retail mark-ups, as well as lower rates of VAT. In Estonia, retail prices of non-reimbursed medicines reach between 80% and 86% of Latvian prices (but for the cheapest medicines priced at around EUR 1 which are slightly more expensive), while in Lithuania they reach between 78% and 88% of Latvian prices. See table 10 for a detailed overview

¹⁹ https://www.em.gov.lv/sites/em/files/medikamenti_zinojums_28.111_0.pdf and <https://www.em.gov.lv/lv/jaunums/nemiro-darba-grupas-ietvaros-rasti-risinajumi-medikamentu-cenu-samazinasai>

of retail prices for given ex-factory prices, and tables 11, 12 and 13 that provide a comparative overview of wholesale and retail mark-ups and VAT rates in the Baltic states.

Table 10 - Non reimbursed medicines- retail prices with VAT in EUR in the Baltics for given ex-factory prices

Ex-factory price	Latvia	Estonia	Lithuania	Est as % of Latv	Lith as % of Latv
1	1,85	2,25	1,61	121%	87%
3	5,39	4,32	4,22	80%	78%
5	8,71	7,19	6,98	83%	80%
11	18,05	14,48	14,46	80%	80%
20	31,09	25,82	25,80	83%	83%
50	72,06	61,70	63,39	86%	88%
200	275,34	230,11	238,75	84%	87%
500	681,9	557,54	558,45	82%	82%
2000	2713,84	2192,54	2133,45	81%	79%

Source: author calculations

But for the cheapest medicines (ex-factory priced below EUR 3, e.g. medicines priced at EUR 1 are subject to a 2 Eurocent higher mark-up in Estonia than they are in Latvia), wholesale mark-ups for non-covered medicines in Estonia reach between 3% and 57% and in Lithuania between 7% and 50% of Latvian retail mark-ups. Apart from overall lower allowed rates (but for the cheapest of medicines), the major difference both in Lithuania and Estonia is that medicines priced over a certain amount no longer have percentage defined mark-ups, but that they are subject to capped wholesaling fees. In Estonia, the highest allowed wholesale mark-up is EUR 6,39 (affecting medicines priced over EUR 210) and in Lithuania EUR 14,48 (affecting medicines priced over EUR 263,30). To illustrate, Latvian wholesalers are allowed to charge an EUR 200 mark-up for a product (ex-factory) priced at EUR 2.000, while their Estonian counterparts are allowed to charge EUR 6,39 and the Lithuanian ones EUR 14,48.

Table 11 - Non reimbursed medicines – wholesale mark-ups in EUR in the Baltics

Ex-factory price	Latvia NR	Estonia	Lithuania NR	Est as % of Latv	Lith as % of Latv
1	0,18	0,20	0,18	111%	100%
3	0,54	0,30	0,27	56%	50%
5	0,88	0,50	0,45	57%	51%
11	1,78	0,55	0,77	31%	43%
20	2,84	0,60	1,00	21%	35%
50	5,84	1,50	2,50	26%	43%
200	20,84	6,00	10,00	29%	48%
500	50,84	6,39	14,48	13%	28%
2.000	200,84	6,39	14,48	3%	7%

Source: author calculations

Retail mark-ups for non-covered medicines are also highest in Latvia (but for the cheapest products ex-factory priced around 1 EUR in Estonia); in Estonia they reach between 2% and 63% and in Lithuania between 8% and 75% of Latvian retail mark-ups. As with wholesale mark-ups, the differences grow with ex-factory prices, so that for a product ex-factory priced at EUR 2.000, Latvian pharmacies charge EUR 223 for dispensing, while Estonian pharmacies charge EUR 5,11 and Lithuanian ones EUR 17,38. In addition to overall lower rates, capped dispensing fees post 144,82 ex-factory price (at EUR 17,38) in Lithuania and post EUR 44,74 ex-factory price (at EUR 5,11) in Estonia both contribute to the large differences.

Table 12 - Non covered medicines – retail mark-ups in EUR in the Baltics

Ex-factory price	Latvia NR	Estonia	Lithuania NR	Est as % of Latv	Lith as % of Latv
1	0,47	0,86	0,35	183%	75%
3	1,27	0,66	0,75	52%	59%
5	1,9	1,10	1,20	58%	63%
11	3,34	1,73	2,00	52%	60%
20	4,92	3,09	3,57	63%	73%
50	8,5	5,11	7,88	60%	93%
200	25	5,11	17,38	20%	70%
500	58	5,11	17,38	9%	30%
2.000	223	5,11	17,38	2%	8%

Source: author calculations

The impact of Latvia’s larger VAT rate on generating OOP expenditure should also not be overlooked. VAT charges for non-reimbursed medicines in Estonia reach between 61% and 93% and in Lithuania between 35% and 38% of Latvian VAT charges. For a product ex-factory priced at EUR 2.000, the Estonian Ministry of Finance charges VAT at EUR 181,04, the Lithuanian one VAT at EUR 101,59 and the Latvian one charges VAT at EUR 290.

Table 13 - Non-covered medicines – VAT in EUR in the Baltics

Ex-factory price	Latvia NR	Estonia	Lithuania NR	Est as % of Latv	Lith as % of Latv
1	0,2	0,19	0,08	93%	38%
3	0,58	0,36	0,20	61%	35%
5	0,93	0,59	0,33	64%	36%
11	1,93	1,20	0,69	62%	36%
20	3,33	2,13	1,23	64%	37%
50	7,72	5,09	3,02	66%	39%
200	29,5	19,00	11,37	64%	39%
500	73,06	46,04	26,59	63%	36%
2000	290	181,04	101,59	62%	35%

Source: author calculations

Wholesale and retail mark-ups for covered medicines

Retail prices of covered medicines priced over EUR 3 in Estonia and EUR 5 in Lithuania (for given ex-factory prices) are also smaller than they are in Latvia, but the differences are smaller than they are for the non-reimbursed medicines; and the cheapest medicines are least expensive in Latvia of all three countries (however at very small differences in absolute terms). These differences are also generated by less relaxed regulation determining wholesale and retail mark-ups, as well as lower rates of VAT. In Estonia, retail prices of reimbursed medicines ex-factory priced over EUR 3 reach between 92% and 97% of Latvian prices, while in Lithuania non-reimbursed medicines priced over EUR 5 reach between 82% and 96% of Latvian prices. See table 14 for a detailed comparative overview of retail prices for given ex-factory prices.

Table 14 - Reimbursed medicines – retail price with VAT in EUR in the Baltics

Ex-factory price	Latvia R	Estonia	Lithuania R	Est as % of Latv	Lith as % of Latv
1	1,60	2,25	2,64	140%	165%
3	4,63	4,32	4,74	93%	102%
5	7,63	7,19	6,84	94%	90%
11	15,80	14,48	13,14	92%	83%
20	27,55	25,82	22,59	94%	82%
50	63,94	61,70	60,43	97%	95%
200	237,50	230,11	227,78	97%	96%
500	583,58	557,54	546,28	96%	94%
2000	2269,18	2192,54	2121,28	97%	93%

Source: author calculations

The differences between wholesale and retail mark-ups for covered medicines in Lithuania and the other two countries are much less pronounced than they are for non-reimbursed medicines. This is to a large extent due to less relaxed rates than those for non-reimbursed medicines as defined by Latvian regulation. Estonia uses the same regulation on wholesale and retail mark-ups for reimbursed and non-reimbursed medicines; while Lithuania uses 3 wholesaling and 3 dispensing fees for reimbursed medicines that depend on their purchase prices, and these are generally higher for less expensive medicines and lower for the more expensive ones than they are for non-reimbursed medicines. It should be noted, however, that patients in Estonia need to pay an additional dispensing fee of EUR 2,5 per prescription, and that pharmacies keep this money as revenue. See tables 15 and 16 for a detailed comparison.

Table 15 - Reimbursed medicines – wholesale mark-ups in EUR in the Baltics

Ex-factory price	Latvia R	Estonia	Lithuania R	Est as % of Latv	Lith as % of Latv
1	0,10	0,20	0,51	200%	510%
3	0,27	0,30	0,51	111%	189%
5	0,45	0,50	0,51	111%	113%
11	0,77	0,55	0,51	71%	66%
20	1,20	0,60	0,51	50%	43%

50	2,00	1,50	2,45	75%	123%
200	6,00	6,00	2,45	100%	41%
500	15,00	6,39	5,79	43%	39%
2000	20,00	6,39	5,79	32%	29%

Source: author calculations

Table 16 - Reimbursed medicines – retail mark-ups in EUR in the Baltics

Ex-factory price	Latvia R	Estonia	Lithuania R	Est as % of Latv	Lith as % of Latv
1	0,33	0,86	1,00	261%	303%
3	0,86	0,66	1,00	77%	116%
5	1,36	1,10	1,00	81%	74%
11	2,34	1,73	1,00	74%	43%
20	3,40	3,09	1,00	91%	29%
50	5,09	5,11	5,10	100%	100%
200	6,05	5,11	14,48	84%	239%
500	6,05	5,11	14,48	84%	239%
2000	6,05	5,11	14,48	84%	239%

Source: author calculations

The impact of Latvia's larger VAT rate on burdening public health expenditure and generating OOP expenditure for covered medicines should also not be overlooked. VAT charges for reimbursed medicines in Estonia reach between 71% and 75% (but for the cheapest medicines priced at around EUR 1) and in Lithuania between 36% and 74% of Latvian VAT charges. For a product ex-factory priced at EUR 2.000, the Estonian Ministry of Finance charges VAT at EUR 181,04, the Lithuanian one VAT at EUR 101,01 and the Latvian one charges VAT at EUR 243,3. See table 17 for a detailed comparative overview of VAT rates.

Table 17 - Reimbursed medicines – VAT in EUR in the Baltics

Ex-factory price	Latvia R	Estonia	Lithuania R	Est as % of Latv	Lith as % of Latv
1	0,17	0,19	0,13	109%	74%
3	0,50	0,36	0,23	71%	45%
5	0,82	0,59	0,33	72%	40%
11	1,69	1,20	0,63	71%	37%
20	2,95	2,13	1,08	72%	36%
50	6,85	5,09	2,88	74%	42%
200	25,45	19,00	10,85	75%	43%
500	62,53	46,04	26,01	74%	42%
2000	243,13	181,04	101,01	74%	42%

Source: author calculations

Croatia uses a different logic to regulate prices of medicines, it sets maximal allowed wholesale (and not ex-factory) prices for both covered and non-reimbursed prescribed medicines using

international price comparisons, leaving only dispensing costs to be added to these in line with national rules. Wholesale prices are annually set at the average INN level (so including all brands of an INN) of wholesale prices in neighbouring Slovenia and Italy and the Czech Republic. If prices are not publicly available in any of these countries, then French and Spanish prices are consulted. Reimbursed medicines are also subject to further annual internal reference pricing at ATC levels 4 and 5 as well as mandatory discount rules for generics, biosimilars and me-too medicines requesting reimbursement. Wholesale mark-ups can account for up to 8,5% of these regulated prices. Pharmacists are prohibited from charging retail mark-ups for covered medicines and are paid flat dispensing fees by the Health Insurance Fund for their services at € 0,93 per prescription (a maximum of 2 packs of the same product can be prescribed on a single prescription). Retail mark-ups ranging between 10% and 35% of the wholesale price can be charged on top of regulated wholesale prices for non-covered prescribed medicines (these account for a miniscule proportion of pharmacy revenues) and for OTCs for which wholesale prices can be determined by distributors freely as they do not undergo international or therapeutic price referencing.

Table 18 – retail mark-ups for non-reimbursed and OTC medicines in Croatia

Wholesale price	Retail mark-up
0-13,3	35%
13,34- 26,67	30%
26,68-40	25%
40,01-66.67	20%
66,68 – 133,33	15%
133,34 and above	10%

Source: Croatian Chamber of Pharmacists, 2021

Detected issues and options to decrease OOPs for medicines

Options to decrease OOPs for medicines include measures that can impact:

1. OOPs for non-covered medicines estimated at € 97 million annually in 2020,
2. OOPs for partially covered medicines estimated at € 30 million annually in 2020,
3. OOPs for OTCs estimated at EUR 74 million annually in 2020.

Increase public funding for coverage of medicines	
Increasing public funding for coverage of medicines would positively impact OOPs as citizens now have to pay for these products themselves.	
Increase NHS funding for outpatient medicines to include more cost-effective medicines in the PDL	<p>To maximise impact on OOPs for the society and for affected individuals, additional investments in reimbursed medicines could primarily target widespread cost-effective therapies (particularly for chronic conditions) that are currently financed out of pocket. A thorough review of the PDL should be undertaken to this purpose.</p> <p>This would also positively impact the prices of these drugs (assuming no changes in price regulation), further increasing their cost-effectiveness, as they are currently not regulated.</p>
Increase NHS funding for outpatient medicines to improve coverage levels for medicines that are listed on the PDL	An alternative approach, primarily targeting OOPs for medicines that are already partially funded by the state would be to revisit current modest coverage levels (50% and 75%).

Reform regulation on OOPs for medicines	
OOPs in Latvia account for a larger share of total expenditure on prescribed medicines than they do in other countries; 13% more compared to Estonia and 44% more compared to Croatia. The level of OOP spending on health, mainly driven by outpatient medicines, is the third highest in the EU and medicines are almost exclusively responsible for catastrophic spending in all quintiles of the population.	
Set limits for maximal monthly OOPs or co-payments on medicines	Latvia could include all private OOP pharmaceutical expenditure on prescribed medicines in the monthly cap on health co-payments or co-payments only if that is not feasible. Ideally, the cap should not be uniform across the population, but should be means tested

	(lower for less affluent households and higher for the better-off ones).
Widen population group-based exemptions for co-payments on medicines	Currently, only children and the very poorest households with monthly income of less than 50% of the minimum wage per family member are exempt from health co-payments. Latvia could consider widening the definition of poor households exempted from co-payments on medicines.
Make sure that administrative hurdles (or other reasons) do not prevent individuals subject to benefits from exercising their rights	Earlier reports have noted that a substantial part of the eligible population had not used benefits to which they were entitled. The MoH should investigate whether this is still the case and take steps to make sure any barriers both for current benefits and those that will be introduced are resolved.

Regulate prescribing rules for non-covered medicines

The 2020 reform that mandated prescribers to prescribe over 70% of prescriptions for covered medicines by INN (among other measures) has been very successful in reducing OOPs for these products. However, the reform did not target OOPs for non-reimbursed prescribed medicines that account for a staggering EUR 97 million of expenditure annually.

Mandate INN prescribing of non-reimbursed medicines	<p>Equally as for reimbursed medicines, Latvia could consider mandating prescribing of non-reimbursed medicines by INN as well.</p> <p>Initially, prescribing of non-reimbursed medicines could be made subject to the same above-mentioned administrative rule requiring at least 70% of all prescriptions to be done by INN. As a second step, Latvia could, in time, opt to develop a list of interchangeable products to specify which medicines can and which can't be prescribed by brand name.</p> <p>An effective mechanism could be put in place to enforce prescribing regulation.</p>
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Reform pricing regulation

Latvia currently regulates ex-factory prices of covered prescribed medicines through international price comparisons and these are generally lower than they are in other Baltic countries. However, due to comparatively larger wholesale and retail mark-ups, retail prices of medicines (in particular those that are not reimbursed) are not correspondingly more affordable.

As of 2020, a permanent price ceiling for medicines subject to internal reference pricing (part A of the PDL) was introduced (companies were asked to decrease prices of these products in the same way in 2018 and 2019) and the most expensive alternatives now need to be less than double the price of the cheapest ones.

Use International Price Comparisons to determine wholesale or retail prices rather than ex-factory prices of covered medicines	Latvia could adopt a different logic to price setting so that it shifts the focus of international price comparisons to wholesale or retail prices. This would “internalise” well performing regulation from other countries (primarily from the Baltics) and ensure that medicines are not overcharged in total. Mark-ups should still be regulated to ensure the financial sustainability of pharmacies and provide the right incentives for dispensing that would promote rational drug use.
Expand pricing regulation to include maximal allowed prices of non-reimbursed prescribed medicines	Latvia could expand pricing regulation conducted through international price comparisons to include non-reimbursed prescribed medicines as well. This is not uncommon in Europe, e.g. Croatia, Bulgaria, the Netherlands, Norway, Portugal and Romania do it ²⁰ . While most European countries, as Latvia, regulate only prices of reimbursed products, expenditure on non-reimbursed drugs is in these countries a much smaller concern due to substantially more generous PDLs.
Expand pricing regulation to include maximal allowed prices of OTC medicines	Very few European countries regulate prices of OTC medicines (Cyprus, Belgium, Greece and Luxembourg ¹⁴). Most countries rely on competition to determine market prices. However, this is also an option given high expenditure on these medicines in Latvia.
Tighten the rules on maximal allowed co-payments for reimbursed medicines	Latvia could further tighten its rules on maximal allowed co-payments for medicines listed in the part A of its PDL. For instance, in Hungary,

²⁰ Vogler S and Martikainen JE. Chapter 19: Pharmaceutical Pricing in Europe. In Z.-U.-D. Babar (ed.), *Pharmaceutical Prices in the 21st Century*. Springer International Publishing Switzerland 2015. DOI 10.1007/978-3-319-12169-7_19

	products subject to internal reference pricing with more than 50% (ATC level 5 groups) or 60% (ATC level 4 groups) price differential compared to the cheapest product are excluded from reimbursement ²¹ .
Make sure patients who need to buy medicines that are reimbursed for other indications (but not the one they are using the product for) are not overcharged	Latvia could apply international price comparisons to set maximal prices of medicines for non-reimbursed indications as well as the reimbursed-ones.

Reform regulation determining and influencing wholesale mark-ups

Wholesaler mark-ups in Latvia are higher than they are in other Baltic countries, in particular for non-reimbursed and expensive reimbursed medicines. The relatively high number of wholesalers, the emergence of large vertically integrated pharmacy chains owned by large wholesalers and the extent of discounts provided to pharmacies (even though these are present in other countries as well) could be pointing towards overly favourable market conditions (in terms of wholesaler profitability) and opportunities to rationalise both public and private expenditure on medicines by reducing wholesaling fees.

Several issues should be carefully assessed when planning changes to wholesale mark-ups or other regulation influencing wholesaling:

- 1) decreasing mark-ups for lower priced medicines will result in greatest total savings given the fact that they account for the vast majority of dispensed packs. For example, medicines priced under EUR 10 account for almost 80% of all packs of dispensed medicines in Latvia. See table 18 for more detail.
- 2) However, a substantial part of these costs per patient may not be substantial. For instance, total wholesaler charges for 12 packs of a medicine (hypothetical annual consumption) ex-factory priced at EUR 5 should not exceed EUR 10,56. The most excessive costs for individual patients are generated by high mark-ups on high-priced medicines. For instance, a pack of non-reimbursed medicines ex-factory priced at EUR 2.000 is subject to a further EUR 200 wholesale mark-up.
- 3) Any reduction in wholesaler revenues will be (in part) passed on to pharmacies through decreased discounts. This may in particular compromise the profitability of small independent pharmacies.
- 4) Some of the smaller wholesalers will likely not be able to operate under decreased revenues, their role (and business) will be taken over by others, leading to further market concentration. Wholesalers that own large pharmacy chains may especially be in a better position to compensate decreasing revenues, which could further increase their dominance in the market.
- 5) If any part of the market is not regulated or if maximal allowed wholesaler mark-ups are currently not charged on any products where they can be (due to competition), wholesalers will likely respond to new regulation by increasing charges on these products.

Reduce distributor fees for non-covered medicines	As Estonia, Latvia could adopt a single mark-up schedule for all medicines. Its
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²¹ Inotai A et al. Drug Policy in Hungary. Value in Health Regional Issues 13c(2017)16-22

	<p>mark-up schedule for covered medicines could be used for non-reimbursed medicines as well.</p>
<p>Tighten regulation for both non-reimbursed and reimbursed medicines</p>	<p>As in Estonia and Lithuania, wholesaling fees could be capped at a certain level of ex-factory prices.</p> <p>Alternatively, Latvia could adopt either the Lithuanian or the Estonian mark-up schedule in full as they work well in these countries and as wholesaling costs do not differ markedly between the Baltic countries²². This fact could be used to argue the reform.</p>
<p>Tender a part of off-patent medicines</p>	<p>A part of off-patent medicines could be tendered out directly to marketing authorization holders. This would significantly drive down both ex-factory prices and wholesale revenues for these products and could be implemented so that it reduces OOPs as well.</p> <p>This reform should be very carefully assessed as it may have major consequences for the entire pharmaceutical market. Practice (and consequences) in Germany and the Netherlands should be consulted as these two countries have the greatest experience with tenders for off-patent medicines in Europe. The differences in size and pharmaceutical expenditure between Latvia and the two countries should also be kept in mind.</p>
<p>Review regulation and market conditions that are influencing how wholesaling is undertaken to stimulate a more efficient mix of full-line, DTP and RWM wholesaling, bearing in mind both positive and negative aspects of the models with the ultimate goal of making medicines more affordable</p>	<p>The pharmaceutical distribution landscape in Europe has changed in the last decade, but full-line wholesalers that operate at national or regional levels still occupy a central position in the supply chain as they distribute nearly three quarters²³ of all medicinal products sold in Europe.</p> <p>Some of the most significant changes were the increase of direct sales (also known as DTP-direct to pharmacy) and the development of new pharmaceutical</p>

²² Competition Council. Price formation of medicinal products and possible restrictions of competition that affect the financial availability of medicinal products. Riga, 2019

²³ <https://girp.eu/files/GIRP-IPF%20Study%202016.pdf>

distribution models. In direct sales, the pharmaceutical manufacturer sells its medicinal products directly to the pharmacist. Distribution is usually contracted (at reduced rates) with one or several third-party logistic providers (that may be full line wholesalers) that do not take ownership of the product or the company does this on its own. In Reduced Wholesaler Model Schemes (RWM), a pharmaceutical company will use specific distribution partners and will withhold its products from other wholesalers. Apart from the restriction on the number of wholesalers used, the RWM model is based on the traditional wholesale business model as the wholesaler/s owns the stock and can offer discounts in the usual way, but mark-ups are squeezed due to economies of scale and reduced competition in distribution. These models may improve the affordability of medicines.

Traditional pharmaceutical full-line wholesalers pre-finance nearly the entire medicinal product market and secure the cash flow in the healthcare system. While this is on its own not necessarily an issue, it may also give them excessive market power (in particular in countries that are experiencing payment delays) towards governments, pharmaceutical companies and pharmacies that can be used to generate market share and revenue to the detriment of affordability for the patients and health care systems. For instance, pharmacies depend on this financing function for their economic sustainability; without it they are not able to afford to stock their shelves with all necessary medicines and medicinal products. On the other side, through their bundling function, pharmaceutical full-line wholesalers create significant efficiencies in the medicines supply chain. Furthermore, due to their supply capacity they play a central role in ensuring timely delivery of medicines to pharmacies with daily or even twice daily deliveries.

In the EU, mixed interpretation of Public Service Obligations (outlined by Directive 2001/83/EC) to guarantee permanently an adequate range of medicinal products to

	<p>meet the requirements of a specific geographical area in defined time limits²⁴ as well as mixed implementation of regulation limiting manufacturer rights to choose wholesalers²⁵, requiring them to provide products on equal terms to all parties in the distribution chain, further complicate the matter.</p> <p>In some countries, full-line wholesalers have to handle all medicinal products, whereas pharmaceutical short-liners and direct sales distributors can decide to predominantly distribute specialty, high volume and high margin products.</p> <p>To conclude, the establishment of new relationships with select wholesalers has increasingly been leading to a new type of distributor in Europe, formed through the consolidation of bigger wholesalers with DTP deals with major pharma companies, instead of lots of smaller wholesalers²⁶. Market regulations implemented in the countries have significantly impacted the extent to which this has happened.</p> <p>The Latvian MoH could openly discuss the status of wholesaling in the country with associations of pharmaceutical companies, wholesalers and pharmacies to establish ways in which to improve its efficiency while maintaining its quality. The central topic of this conversation could be which regulation could be improved to ensure market power works towards making medicines more affordable.</p>
<p>Claw-back a part of the wholesaler revenues</p>	<p>A number of European countries have legislation that enables clawing back a part of wholesalers' revenues. According to WHO EURO, these include Austria, Denmark, Finland, France, Italy (if the retail budget for pharmacies is surpassed), Poland, Portugal, Spain, Sweden and the UK²⁷.</p> <p>Germany had in 2011 introduced a temporary wholesaler rebate at 0,85% of</p>

²⁴ https://ec.europa.eu/health/sites/health/files/files/committee/ev_20180525_summary_en.pdf

²⁵ http://eprints.lse.ac.uk/51051/1/Kanavos_pharmaceutical_distribution_chain_2007.pdf

²⁶ <https://www.pharmtech.com/view/pharma-takes-control-distribution-chains>

²⁷ https://www.euro.who.int/__data/assets/pdf_file/0019/322444/HiT-pharmaceutical-regulation-15-European-countries.pdf?ua=1

	<p>manufacturer price²⁸ In Austria, ‘<i>Rahmen-Pharmavertrag</i>’ contracts regulate ex-post rebates to the Austrian sickness funds. Pharmaceutical companies and wholesalers paid € 125 million in 2016, and € 160 million in 2017 and 2018 (€ 10 million per percentage point increase in pharmaceutical expenditure per year). In Spain, rebates are designed to be shared by all actors (pharmaceutical companies, wholesalers, pharmacies) in the pharmaceutical supply chain. In France, wholesalers must pay a tax of 1.2% of sales to social security²⁹.</p> <p>Similar solutions could be considered in Latvia as well, however noting that these would (on their own) not affect out of pocket payments.</p>
<p>Review regulation that allows wholesalers to own pharmacies if these vertically integrated chains are using their dominant position in the market to generate excessive profits</p>	<p>A number of European countries mandates that only pharmacists can own pharmacies or requires that they have a certain stake in ownership. These include Germany, Spain, France, Poland, etc.</p> <p>In 2009, the European Court of Justice confirmed that each and every EU member state can take its own measures to guarantee a high level of consumer protection. In this context, Germany’s ownership requirement were ruled to be perfectly in line with EU law and considered effective measures of consumer protection.</p> <p>Furthermore, Hungary, Estonia and Poland, have moved from a liberalized system to restriction of community pharmacy ownership in 2009, 2015 and 2017, respectively. In Hungary the transition of ownership was gradual: pharmacists needed to own at least 25% of the shares of the pharmacy by 2014 and 50% by 2017. In Estonia, the new ownership regulations were to be implemented gradually until 2020. In Poland, the new legislation only came into effect for new community pharmacies, but the provisions also apply in case of a</p>

²⁸ http://eprints.lse.ac.uk/68290/7/Wouters_Pharmaceutical_regulation.pdf

²⁹ <http://plg-group.com/wp-content/uploads/2014/03/France-Pharmaceutical-Pricing-and-Reimbursement-Corinne-BI.pdf>

	<p>transfer of existing licences (in the case of company mergers other than partnerships between pharmacists)³⁰.</p> <p>Latvia could also consider reforming its regulation on pharmacy ownership to address trends in vertical integration and the growth of pharmacy chains that lead to market dominance. Measures could be put in place to target newly founded pharmacies only, or as in Hungary established pharmacies as well.</p>
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Table 18 – Number of packs sold in Latvian pharmacies by price categories

Ex-factory price	No of packs sold in 2020
0,01 - 1	438.892
1,01 - 2	1.932.900
2,01 - 3	1.733.093
3,01 - 5	2.319.612
5,01 – 7	1.449.500
7,01 -10	871.250
10,01 - 15	756.095
15,01 - 25	574.187
25,01 – 50	677.347
50.01 -100	151.826
100,01 and more	137.239

Source: MoH data

³⁰ <https://www.pgeu.eu/wp-content/uploads/2019/10/WHO-Europe-Report-Regulatory-framework-for-community-pharmacies-October-2019.pdf>

Reform regulation on retail mark-ups

Latvia has substantially more pharmacies (relative to the population) than Estonia, Croatia and Denmark and marginally less than Lithuania. This large number of pharmacies has two important consequences – total revenues per pharmacy are smaller and medicines are much more available to the population. The latter is not, per se, negative if products are consumed rationally. This is in particular relevant for OTC medicines that do not require prescriptions.

Retail mark-ups in Latvia are higher for non-reimbursed medicines than they are in Estonia and Lithuania, while the difference is much less pronounced for reimbursed medicines. Nevertheless, as in other countries, the profitability of pharmacies (apart from their distance from other pharmacies) depends primarily on their location. Pharmacies in well frequented, highly urbanised areas, usually do better than those in scarcely populated suburbs or rural areas. In addition, large pharmacy chains and vertically integrated operations may be in a position to negotiate better commercial conditions than small individual pharmacies. So, it is fair to assume that some pharmacies in Latvia do very well, while others may struggle to remain in business.

Recent proposals by the association of pharmacies to raise (rather than reduce) retail mark-ups by as much as 50% (on average) and to reform regulation so that wholesalers earn less and pharmacies earn more further indicate that some pharmacies may indeed be in financial problems. However, given that neighbouring Lithuania has a very similar number of pharmacies per capita, slightly smaller total expenditure on medicines per capita as well as smaller retail mark-ups, it is not entirely clear to what extent issues in pharmacy profitability are realistically widespread. It is highly likely that they are concentrated in small individual pharmacies that do not operate in economically attractive locations.

In any case, public funding and household budgets should not be used to provide for irrationally high retail mark-ups to generate pharmacy income where the lack of profitability is due to a too high density of pharmacies. Availability of medicines to the population achieved through lower prices should be prioritized as a public goal. Nevertheless, when planning reforms, attention should also be paid to understand how they will impact competition in the sector. Reductions of pharmacy revenues will have the highest impact on small individual pharmacies that are already facing issues with profitability, potentially further contributing to the dominance of the large players. As discussed earlier, measures to prevent that from happening should be planned in parallel.

Finally, a review could be undertaken to inform the development of a demographically/geographically determined network as it is in a number of EU countries. If needed, less demanding regulatory conditions or financial subsidies should be provided to pharmacies in scarcely populated (e.g. rural) areas to ensure profitability and steady supply of medicines.

Focus on non-covered medicines	As Estonia, Latvia could adopt a single mark-up schedule for all medicines. Its mark-up schedule for covered medicines could be used for non-reimbursed medicines as well. Detailed calculations estimating the financial consequences of these options, that are outside the scope of this report, should be undertaken before a final decision is made.

<p>Tighten regulation for both non-reimbursed and covered medicines</p>	<p>Latvia could adopt either the Lithuanian or the Estonian mark-up schedule in full as they work well in these countries and as pharmacy costs do not differ markedly between the Baltic countries³¹. This fact could be used to argue the reform. Detailed calculations estimating the financial consequences of these options, that are outside the scope of this report, should be undertaken before a final decision is made in particular noting the EUR 2,5 dispensing fee (per prescription) that exists in Estonia. These calculations should consider that vulnerable population groups could be relieved of the dispensing fee.</p>
<p>Adopt linear dispensing fees instead of mark-ups</p>	<p>Latvia could adopt low fixed co-payments (dispensing fees) instead of pharmacy mark-ups. For reimbursed medicines, these could be part financed by the NHS and part by patients (if needed). Dispensing fees should be set to ensure sufficient revenues for pharmacies to cover operating costs and modest profits. As mentioned, additional subsidies or less demanding regulatory conditions could be targeted towards pharmacies located in scarcely populated areas to ensure access.</p>

<p>Decrease the VAT rate on medicines</p> <p>Latvia's 12% VAT rate for medicines is far higher than the rate used in Lithuania (5%), Estonia (9%) and Croatia (5%).</p>	
<p>Decrease the VAT rate on medicines</p>	<p>WHO recommends that countries consider exempting essential medicines and active pharmaceutical ingredients from taxation or, alternatively, that countries consider any tax reductions or exemptions, with measures to ensure that the policy results in lower prices of medicines to patients and purchasers³².</p> <p>Latvia could decrease its VAT rate on medicines. The decreased rate should ideally apply to all medicines. Alternatively, if this is not feasible, the decreased rate could apply to</p>

³¹ Competition Council. Price formation of medicinal products and possible restrictions of competition that affect the financial availability of medicinal products. Riga, 2019

³² WHO guideline on country pharmaceutical pricing policies, second edition. Geneva: World Health Organization; 2020.

	prescribed medicines only to alleviate their financial burden on the population.
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Further regulate the OTC market

According to the OECD, Latvia's expenditure on OTCs per capita appears to be far above all other analysed countries. It is currently not entirely clear to why this is occurring; for example it could be a consequence of high prices (indicating low competition in the market or even collusion) or irrational consumption. This should be further explored to target policy interventions.

Review drivers of high OTCs consumption

Before engaging in action, it will be of vital importance to develop a better understanding of what is driving Latvia's heavy OTC usage (e.g., poor accessibility of prescribed medicines, issues in access to primary care, aggressive marketing, etc.).

Latvia could toughen marketing regulation for OTC products to ensure their rational use. The MoH could implement media campaigns educating the public on rational use of OTC medicines.

The MoH could also consider supporting the development of a lasting non-commercial source of information on the rational usage of OTC medicines for the public (e.g., a website), as it appears such information is not readily available in the country³³.

³³ Dobelniece, Signe & Kulikovska, Ieva & Mezinska, Signe & Rungule, Ritma. (2011). Information sources regarding common cold medicines in Latvia. *Filosofija Sociologija*. 22. 198-206.

The political economy of pharmaceutical reforms in Latvia

Pharmaceutical reforms can be tough to implement due to vested financial interests in keeping the status quo. However, it is clear from the evidence reviewed that these financial interests are leading to excessive out of pocket spending by patients. This report outlines a wide array of measures that could be implemented to reduce high out-of-pocket payments for medicines in Latvia. They range from increasing public funding for medicines, over tightening regulation on prices and mark-ups to ensuring more rational use of OTCs.

In order to facilitate the implementation of this reform, it will be critical to clearly communicate about the public health and political need for this to happen and about its intended results to the public and to the market stakeholders. Clear messages should be used to describe the current situation, preferably comparisons with neighbouring Estonia and Lithuania as these will be easily understood. The intended results, more efficient public sector spending on medicines, lower out of pocket payments for citizens and better access to medicines, should be appropriately highlighted and understood by all. Given the high level of out-of-pocket payments for medicines in the country and their impact on the accessibility of therapies, it would be difficult to argue against the need for reform – both from the perspectives of the Government and market stakeholders. In many countries the process of reform has been informed by a stakeholder consultation process.

Finally, ensuring a mix of increased public investment and cost-saving measures should bolster adoption by all participating parties and demonstrate the state's commitment to improving access to cost-effective and fairly priced medicines for the population whilst maintaining a viable and healthy market as is seen in other similar countries

Annex 1 – Wholesale and retail prices in Lithuania

Wholesale prices

Wholesale prices of non-reimbursed medicinal products in Lithuania are calculated in accordance with the formula $WP=MP+MUC+LMA$, where WP – wholesaler price, MP – manufacturer price, LMC – mark-up coefficient and LMA – mark-up amount.

No.	Manufacturer price, EUR	Mark-up coefficient, %	Mark-up amount, EUR
1.	Up to 1,86	18	0
2.	1.87-2.99	16	0
3.	3.00-5.63	9	0
4.	5.64-7.24	8	0
5.	7.25-15.51	7	0
6.	15.52-19.74	6	0
7.	19.75-263.29	5	0
8.	263.30 and more	0	14.48

Wholesale prices of covered medicinal products in Lithuania are formed in accordance with the formula $WP=MP+WM$, where: WP – wholesaler price, MP – manufacturer price, WM – wholesaler mark-up.

No.	Manufacturer price, EUR	Wholesaler mark-up, EUR
1.	Up to 49.99	0.51
2.	50-263.29	2.45
3.	263.30 and more	5.79

Retail prices

The pharmacy prices of non-reimbursed medicinal products in Lithuania is calculated in accordance with the formula $PhP = PP + PMC + PMA + VAT$, where: PhP – pharmacy price, PP – purchase price, PMC – mark-up coefficient, PMA – mark-up amount.

No.	Purchase price, EUR	Mark-up coefficient, %	Mark-up amount, EUR
1.	Up to 2.37	30	0
2.	2.38-2.89	25	0
3.	2.90-4.42	23	0
4.	4.43-7.24	22	0
5.	7.25-7.90	19	0
6.	7.91-21.72	17	0
7.	21.73-144.81	15	0
8.	144.82 and more	0	17.38

The pharmacy prices of covered medicinal products in Lithuania is calculated in accordance with the formula $PhP = PP + PhM + VAT$, where: PhP – pharmacy price, PP – purchase price, PhM – Pharmacy mark-up.

No.	Purchase price, EUR	Pharmacy mark-up, EUR
1.	Up to 47.46	1.00
2.	47,47-144,48	5.10
3.	144.81 and more	14.48

Annex 2 – Wholesale and retail prices in Estonia

Wholesale prices for both non-reimbursed and covered medicinal products are formed according to the formula: $WP=MP+WM$, where: WP – wholesaler price, MP – manufacturer price, WM – wholesaler mark-up.

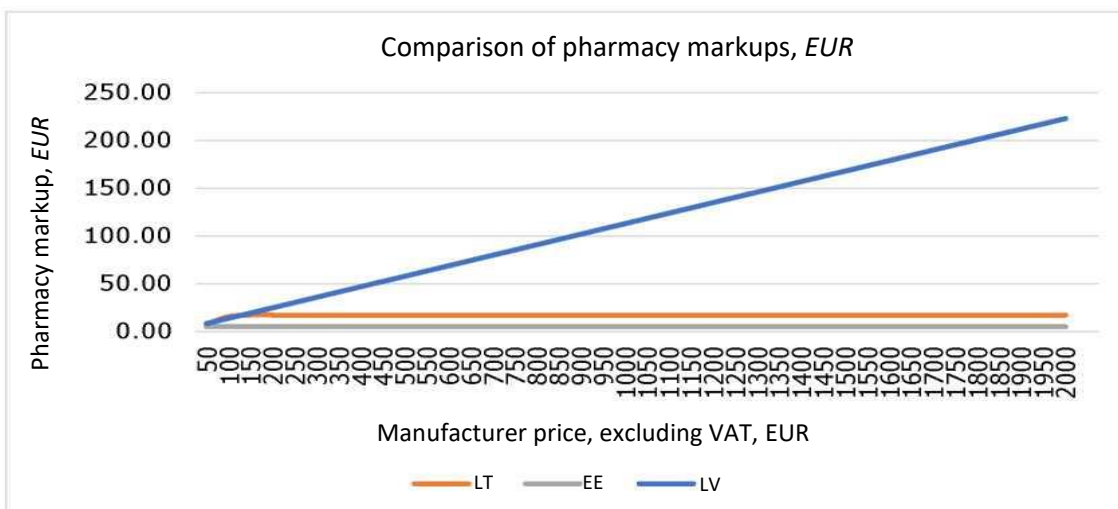
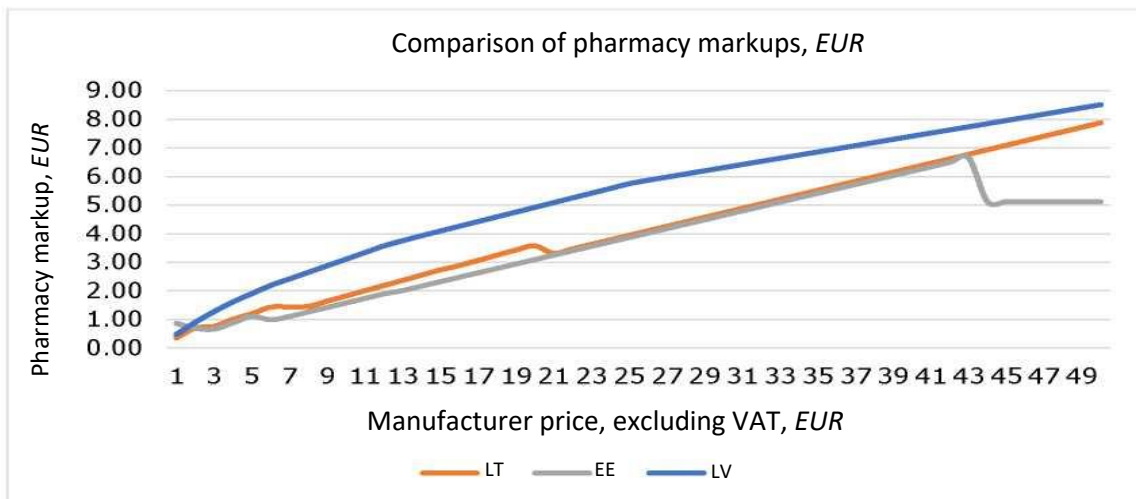
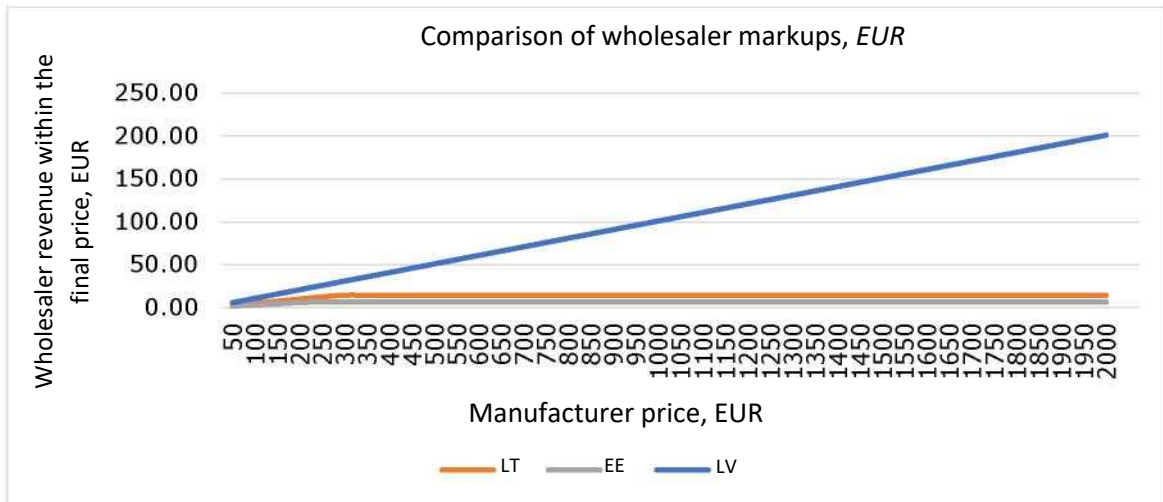
No.	Manufacturer price, EUR	Wholesaler mark-up,%
1.	Up to 1.60	20
2.	1.61-2.88	15
3.	2.89-6.39	10
4.	6.40-12.78	5
5.	12.78 and more	3 (maximum EUR 6.39)

The pharmacy prices for both non-reimbursed and covered medicinal products is formed according to the formula: $PhP = PP + PhM_{\%} + PhM_n + VAT$, where: PhP – pharmacy price, PP – purchase price, $PhM_{\%}$ – pharmacy mark-up as percentage, PhM_n – pharmacy mark-up in monetary units.

No.	Purchase price, EUR	Pharmacy mark-up, %	Pharmacy mark-up, EUR
1.	Up to 0.64	0	0,38
2.	0.65-1.28	40	0,38
3.	1.29-1.92	35	0
4.	1.93-2.56	30	0
5.	2.57-3.20	25	0
6.	3.21-6.39	20	0
7.	6.40-44.74	15	0
8.	44.74 and more	0	5.11

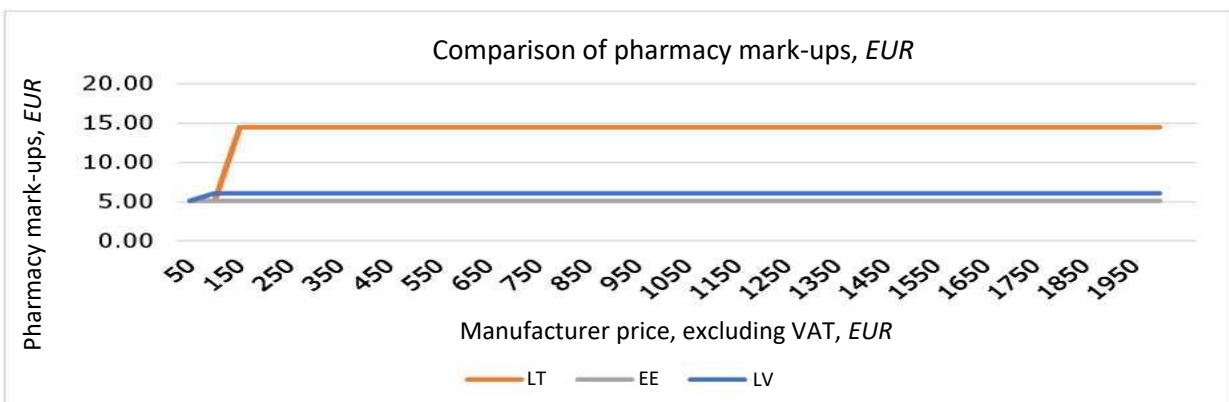
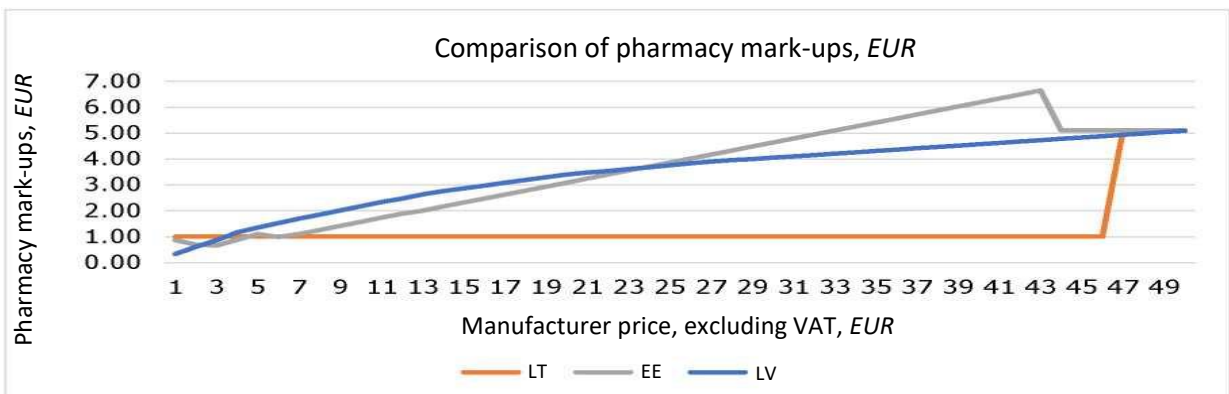
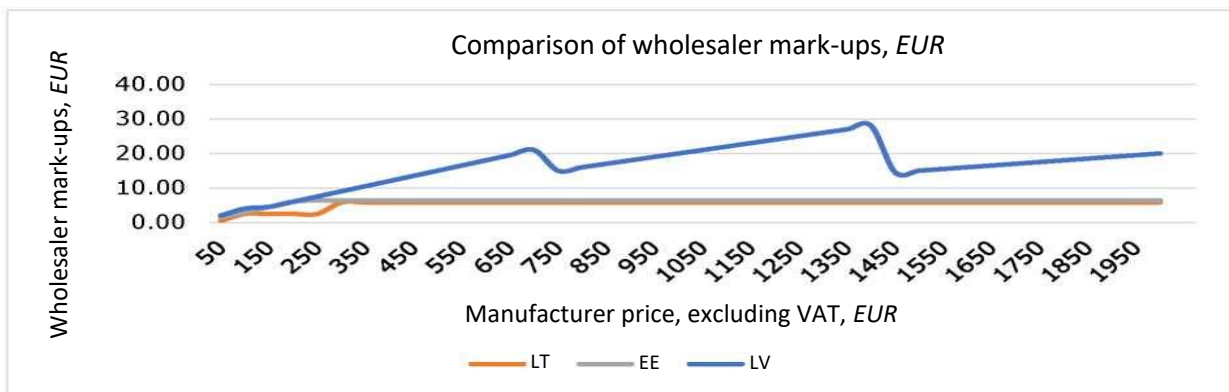
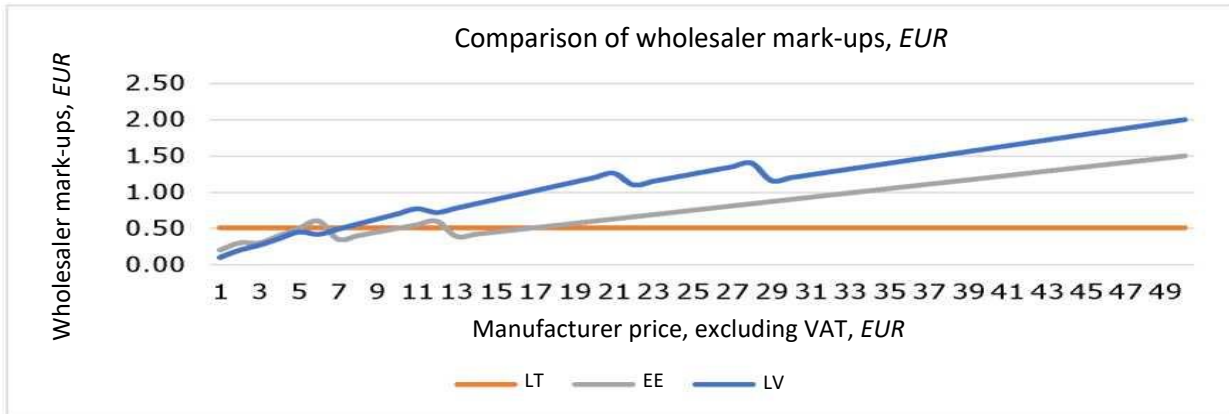
Annex 3 – Comparative charts, mark-ups in the Baltics

Non reimbursed medicines



Source: Competition Council. Price formation of medicinal products and possible restrictions of competition that affect the financial availability of medicinal products. Riga, 2019

Covered medicines



Source: Competition Council. Price formation of medicinal products and possible restrictions of competition that affect the financial availability of medicinal products. Riga, 2019