ExportReady DISCOVER | SEV Hellenic Federation of Enterprises | SECTORAL REPORT | Lithuania

Sector: Pharmaceuticals

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1. Pharmaceutical Sector Overview

1.1 General Overview

The Lithuanian pharmaceutical market is one of the smallest in the Central and Eastern European (CEE) region, primarily owing to the country's small population. On a per capita basis Lithuania is on par with the regional average, highlighting the sector's development. Lithuanian per capita pharmaceutical expenditure is even higher than that of regional peers such as Romania, Serbia and Russia, which are all much larger markets on an absolute basis. In 2020, total pharmaceutical sales in Lithuania were worth EUR686mn, equivalent to 1.4% of GDP and 20.2% of total healthcare expenditure. The majority of this total (as much as 76.6%) was spent on prescription drugs.

In the same year, Lithuania's healthcare expenditure came in at EUR3.4bn, equivalent to 6.95% of GDP. This figure is relatively high both within the CEE region and within the EU as whole. On a per capita basis, Lithuanian healthcare expenditure was a substantial USD1,4,20 Lithuania's epidemiological profile resembles that of other CEE states, with non-communicable diseases, such as heart disease, cancer and stroke, the leading causes of mortality and morbidity in the country.

The country's pharmaceutical market is home to many multinationals as well as domestic pharmaceutical companies despite its size. Multinational presence is limited to sales offices rather than direct manufacturing facilities. Key foreign players include **Pfizer, GlaxoSmithKline, Merck, Novartis, Sanofi and Roche**.

Canada-based firm **Valeant Pharmaceuticals** holds a presence in the country through its subsidiary Sanitas, which is a key generic drugmaker and manufacturer in Lithuania. There are few access to market barriers in Lithuania given its EU membership. Bureaucratic procedures are rapidly processed, enabling drugmakers to market and commercialise pharmaceuticals quickly; however, given the limited size of the pharmaceutical market and the small population, the country remains a modest prospect for large multinationals.

Table 1: Pharmaceutical Sales, Historical Data And Forecasts (Lithuania 2017-2025)

PHARMACEUTICAL SALES, HISTORICAL DATA AND FORECASTS (LITHUANIA 2017-2025)									
Indicator	**2017**	**2018**	**2019**	**2020**	**2021f**	**2022f**	**2023f**	**2024f**	**2025f**
Pharmaceutical sales, EURbn	0.639	0.623	0.655	0.686	0.719	0.749	0.778	0.807	0.836
Pharmaceutical sales, EURbn, % y-o-y	3.40	-2.62	5.19	4.73	4.78	4.18	3.87	3.69	3.61
Pharmaceutical sales, EUR per capita	224.7	222.3	237.4	252.0	267.2	281.3	295.0	308.6	322.5
Pharmaceutical sales, USDbn	0.721	0.735	0.733	0.782	0.884	0.944	0.988	1.016	1.045
Pharmaceutical sales, USDbn, % y-o-y	5.35	2.00	-0.24	6.62	13.09	6.72	4.69	2.87	2.79
Pharmaceutical sales, USD per capita	253.3	262.4	265.7	287.2	328.7	354.5	374.6	388.8	403.1
Pharmaceutical sales, % of GDP	1.51	1.37	1.34	1.41	1.42	1.39	1.36	1.34	1.31
Pharmaceutical sales, % of health expenditure	23.5	20.9	20.7	20.2	20.0	19.7	19.4	19.1	18.7

Source: VLK, VVKT, SAM, Fitch Solutions

1.2 SWOT Analysis

Strengths

- Lithuania's EU membership has stimulated regulatory harmonisation.
- The Covid-19 induced recession aside, consumer spending power is strengthened by falling oil prices and rising employment.
- Euro adoption makes transactions easier to manage in the country.
- The intellectual property environment is strong and aligned with EU norms.
- There is rapid and efficient decision making by regulatory bodies.

Weaknesses

- The absolute size of pharmaceutical market is small.
- Government reimbursement cost and price controls have had a major impact on the market.
- The domestic market receives limited foreign direct investment, while the investment environment in the sector is weaker than in other Baltic States.
- Pharmaceutical revenues remain vulnerable to economic downturns amid still relatively high out-of-pocket spending.

Opportunities

- The generic drugs sector is likely to remain strong given the constraints on government spending and limited means for out-of-pocket spending.
- There is potential for growth in spending on innovative medicines with an ageing demographic profile and growing levels of health awareness in the country.
- Falling unemployment and rising wages is to provide a boost to consumer healthcare spending on OTC medicines.
- Signs of growth of the population will support eventual increased demand for healthcare and medicines.
- Combined procurement with Estonia and Latvia presents an opportunity for larger volume, discounted purchasing.
- The introduction of a reduced rate VAT on all non-reimbursed prescription medicines will improve volumes.

Threats

- Reimbursement changes to lead to lower revenues in the generic drugs sector.
- Consolidation in the wholesale and retail sectors to lead to a sharp increase in pricing pressures on suppliers as a few strong international and domestic players control the marketplace.
- Government's support to increase generic substitution to depress overall market's value growth.
- Pan-European joint procurement initiatives to place downward pressure on market values.

2. Healthcare in Lithuania

2.1 General Overview

The structure of the country's healthcare system has changed a number of times since Lithuania gained independence. The ministries of health, labour and social welfare were amalgamated into the single ministry responsible for health and welfare in 1993. Sickness funds were established in 1994, followed by the creation of the State Compulsory Health Insurance Agency in 1998. Local governments are by and large responsible for healthcare delivery at primary and secondary levels. The state is accountable for specialised services, such as oncology. Nevertheless, private provision has increased and patients are free to choose their physicians. However, most users of private healthcare are those with higher incomes. Key areas of private sector provision include cosmetic surgery, dental procedures and gynaecological and psychotherapy services.

In 2020, Lithuania spent EUR3.39bn on healthcare, and it is expected to reach EUR3.59bn in 2021. Between 2020 and 2025, it is forecasted that health expenditure will increase at a compound annual growth rate (CAGR) of 7.6% in US dollar terms to reach EUR4.46bn. Over our extended 10-year forecast period to 2030, the market's value will grow to EUR5.75bn, posting a CAGR of 6.4% in US dollar terms.

The public sector will continue to provide the bulk of funding, though private healthcare spending will also grow on an absolute basis, on account of an increase in healthcare service quality and an increased consumer purchasing power driven by higher wages. As a percentage of GDP, healthcare expenditure, which accounted for 6.95% in 2020, is expected to edge higher for a short period before declining and reaching 6.93% by 2030. Per capita healthcare spend, which came in at a substantial USD1,420 in 2020, is forecast to increase to USD2,893 by 2030. The government contributes more than two thirds of total health spending, which it is expected to remain the dominant, but slightly eroded, source of funding in the coming decade, accounting for 64.7% of the total in 2030, a little below the 66.4% level in 2020.

Despite the focus on medicine price cuts, the allocation of funds for medicine reimbursement for the National Health Insurance Fund (VLK) was slated to rise by 6.6% y-o-y in 2020, up to EUR311mn. Lithuania's healthcare expenditure is relatively high as a percentage of GDP within the Central and Eastern European region, but it is more aligned with that of its EU peers. The switch to the euro in 2015 - alongside the structural funds injected into Lithuania - has led to a more stable economy. Lithuania's progress in stabilizing its current account means that the country will likely be able to maintain surplus. However, in August 2015, the country noted that the EU cross-border directive had not delivered the increase in medical tourism it had expected. There have also been no reports of major progress since then.

Table 2: Healthcare Expenditure Trends, Historical Data And Forecasts (Lithuania 2017-2025)

HEALTHCARE EXPENDITURE TRENDS, HISTORICAL DATA AND FORECASTS (LITHUANIA 2017-2025)									
Indicator	**2017**	**2018**	**2019**	**2020**	**2021f**	**2022f**	**2023f**	**2024f**	**2025f**
Health spending, EURbn	2.725	2.973	3.166	3.391	3.589	3.793	4.006	4.227	4.458
Health spending, EURbn, % y-o-y	5.55	9.12	6.50	7.11	5.85	5.68	5.60	5.53	5.46
Health spending, EUR per capita	957.5	1,061.3	1,147.3	1,245.7	1,334.4	1,425.2	1,519.2	1,617.4	1,720.5
Health spending, USDbn	3.071	3.509	3.544	3.865	4.415	4.780	5.087	5.327	5.573
Health spending, USDbn, % y-o-y	7.54	14.29	1.00	9.04	14.24	8.26	6.44	4.70	4.62
Health spending, USD per capita	1,079.1	1,252.7	1,284.3	1,419.6	1,641.3	1,795.7	1,929.4	2,037.9	2,150.6
Health spending, % of GDP	6.44	6.54	6.49	6.95	7.11	7.03	6.99	7.00	7.00

Source: WHO, Fitch Solutions

Table 3: Government Healthcare Expenditure Trends, Historical Data And Forecasts (Lithuania 2017-2025)

GOVERNMENT HEALTHCARE EXPENDITURE TRENDS, HISTORICAL DATA AND FORECASTS (LITHUANIA 2017-2025)									
Indicator	**2017**	**2018**	**2019**	**2020**	**2021f**	**2022f**	**2023f**	**2024f**	**2025f**
Govt. health spend, EURbn	1.812	1.993	2.111	2.251	2.372	2.495	2.625	2.761	2.903
Govt. health spend, EURbn, % y-o-y	5.39	10.01	5.93	6.59	5.40	5.21	5.19	5.18	5.16
Govt. health spend, USDbn	2.042	2.353	2.364	2.565	2.918	3.144	3.334	3.479	3.629
Govt. health spend, USDbn, % y-o-y	7.38	15.23	0.46	8.51	13.75	7.77	6.03	4.35	4.33
Govt. health spend, % total health spend	66.50	67.05	66.69	66.37	66.08	65.78	65.53	65.31	65.13

Source: WHO, Fitch Solutions

Table 4: Private Healthcare Expenditure Trends, Historical Data And Forecasts (Lithuania 2017-2025)

PRIVATE HEALTHCARE EXPENDITURE TRENDS, HISTORICAL DATA AND FORECASTS (LITHUANIA 2017-2025)									
Indicator	**2017**	**2018**	**2019**	**2020**	**2021f**	**2022f**	**2023f**	**2024f**	**2025f**
Private health spend, EURbn	0.913	0.980	1.055	1.141	1.217	1.298	1.381	1.467	1.555
Private health spend, EURbn, % y-o-y	5.86	7.33	7.66	8.14	6.75	6.61	6.39	6.20	6.01
Private health spend, USDbn	1.029	1.156	1.181	1.300	1.497	1.635	1.754	1.848	1.943
Private health spend, USDbn, % y-o-y	7.85	12.42	2.10	10.09	15.21	9.21	7.24	5.37	5.17
Private health spend, % total health expenditure	33.50	32.95	33.31	33.63	33.92	34.22	34.47	34.69	34.87

Source: WHO, Fitch Solutions

2.2 Healthcare Sector's Funding and Performance

Healthcare funds are sourced mainly from taxes. Currently, the self-employed contribute a minimum of EUR39 per month towards compulsory insurance, with other employees

contributing around EUR90. Those unable to pay (or the exempt, such as children and the elderly) are covered by the state at EUR31 per month, which is seen as insufficient. A 0.5% proportion on taxes collected on alcohol and gambling is also used to fund healthcare. The 2021 budget was approved by parliament in October 2020. The total budget for 2021 totals over EUR18bn of expenditure, of which more than EUR4.7bn is earmarked for social protection.

The economy will receive EUR3.5bn, of which EUR1.2bn is allocated for healthcare and EUR1.08mn for the management of the negative consequences of the Covid-19 pandemic. The 2019 budget for the public health insurance fund was set at EUR2.6bn, up by EUR296.0mn on the previous year, with compulsory premiums expected to cover EUR1.4mn. Around 16.5% of the 2019 budget was to be allocated to general healthcare services, 12.6% to reimbursement and 16.7% to rehabilitation services. Expenditure in 2019 was forecast at EUR1.4bn. Co-payments were finally legalised by the Lithuanian Constitutional Court in March 2014 based on patients' ability to pay.

Official figures released in April 2019 show that the compulsory healthcare insurance fund spent EUR230.0mn on reimbursement of medicines in 2018, though the government saved almost EUR0.5mn through the widening of the consolidated public drug procurement initiative, while the increased level of reimbursement also resulted in a 28.0% y-o-y drop in patient co-payments. Public procurement has at times reportedly achieved 70.0% savings. In 2018, the number of consolidated purchases rose to 34 (from just four in the previous year), with public institutions buying not only medicines but also various other medical supplies and stationery items in this manner. Additionally, the programme was extended to smaller towns' medical facilities, from only hospitals previously.

Private Expenditure On Medicines: Patients pay significant out-of-pocket costs for medicines, which has traditionally been one of the major impediments to drugmaker revenue growth. While the National Health Fund (VLK) provides comprehensive coverage of medicines through its 50.0%, 80.0% or 100.0% reimbursement tiers, patients are required to pay the difference between the manufacturer price and the retail price (made up of mark-ups and VAT), even for medicines in the 100.0% reimbursement list. This creates a significant level of inequality of access to drugs between the more and less affluent. However, in 2017, the government imposed an amendment to the country's Pharmacy Act, which established price revisions for medicines on the reimbursed list every quarter.

As a result, the average co-payment reportedly fell by EUR1 (USD1.24) between September and December 2017. In an effort to further this decline in patient contributions to medicines, the Lithuanian Cabinet of Ministers approved a new drug pricing project in January 2018. The new legislation, implemented in July 2018, introduced a ceiling for reimbursed medicine premiums, making medicines more affordable.

The co-payment for one package of the reimbursable medicines in 2019 cannot exceed EUR4.71, in cases of a 100.0% reimbursement. The ceiling is waved if the medicines can only be sourced from a single manufacturer or if it is not interchangeable. Previously, reimbursement funds from the VLK covered either 50.0%, 80.0% or 100.0% of the base price (manufacturer price), depending on the reimbursement classification of the medicine. Patients were required to cover the remainder of the base price (if not at 100.0% reimbursement) in addition to mark-ups applied by wholesalers and pharmacies.

On January 1 2018, Lithuania implemented a reduction in the VAT rate for non-reimbursed prescription medicines, down from the standard rate of 21.0% to the reduced rate of 5.0% that reimbursed medicines already benefit from. This will result in a significant reduction in patient costs and thus benefit volume sales as the changes impact pharmacy margins and reduce patient co-payments.

Healthcare Insurance: Since 1998, free basic healthcare has been covered by the State Compulsory Health Insurance Fund (CHIF/SODRA). Executed by the State Patients' Fund (SPF) of the Ministry of Health, the scheme entitles insured patients to free visits to a doctor, hospital treatment (including medicines) and rehabilitation. People who do not pay insurance contributions may only receive free emergency treatment and must cover the cost of other services themselves; the prices of such services are set by the Ministry of Health.

Payment for services also occurs to a degree among the insured population. Although privatization and health insurance has curtailed the Soviet tradition of making gratuity payments, they still continue in the hospital sector, covering the costs of pharmaceuticals and staff wages. In June 2005, Lithuania's parliament amended the health insurance law, changing eligibility for provision under the state healthcare system by extending it to foreigners living in the country.

The government introduced compulsory health insurance for all permanent residents in the country, regardless of nationality. In April 2018, compulsory contributions to the healthcare insurance fund were increased in order to bring them up to the same level as for people who are self-employed. The extra funds (EUR410mn) are needed to finance more vulnerable groups that do not contribute, including pensioners, students, children younger than 18 years old and the disabled (who jointly account for 55.0% of the population).

Only a small proportion of the population has private health insurance policies, but there is a growing network of private clinics and other services available outside of the state system. Still, out-of-pocket payments are made in the form of voluntary health insurance, which has a low uptake in Lithuania owing to the wide range of services that are available free of charge.

Table 5: Healthcare Resources (Lithuania 2015-2020)

HEALTHCARE RESOURCES (LITHUANIA 2015-2020)						
Indicator	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**
Hospitals, total	144	139	136	133	130	129
Hospitals, public	134	127	124	121	118	117
Hospitals, private	10	12	12	12	12	12
Hospitals, beds	25,385	24,755	24,552	24,078	23,842	23,708
Hospitals, beds, per '000 population	8.66	8.57	8.63	8.60	8.64	8.71

Source: Fitch Solutions

Table 6: Healthcare Personnel (Lithuania 2015-2020)

HEALTHCARE PERSONNEL (LITHUANIA 2015-2020)						
Indicator	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**
Physicians, total	13,490	13,681	13,731	13,680	13,731	14,058
Physician, per '000 population	4.60	4.73	4.83	4.88	4.98	5.16
Nurses, total	22,342	22,187	21,903	21,562	21,393	21,643
Nurses, per '000 population	7.62	7.68	7.70	7.70	7.75	7.95
Dentists, total	2,723	2,877	2,921	2,823	2,708	2,643
Dentists, per '000 population	0.93	1.00	1.03	1.01	0.98	0.97
Pharmacists, total	3,192	3,267	2,953	2,934	2,907	2,928
Pharmacists, per '000 population	1.09	1.13	1.04	1.05	1.05	1.08

Source: Fitch Solutions

Table 7: Healthcare Activity (Lithuania 2015-2020)

HEALTHCARE ACTIVITY (LITHUANIA 2015-2020)						
Indicator	**2015**	**2016**	**2017**	**2018**	**2019**	**2020**
Inpatient admissions, '000	776.57	756.04	742.39	727.26	711.57	669.05
Inpatient admissions, per '000 population	264.87	261.64	260.91	259.62	257.85	245.77
Hospitals, average length of stay, days	5.8	5.7	5.7	5.7	5.7	5.4
Surgical procedures, '000	339.78	346.82	313.86	313.00	313.00	265.00
Outpatient visits, '000	29,767.90	30,640.50	31,353.70	32,239.60	33,199.80	32,175.90
Outpatient visits, per '000 population	10,153.18	10,603.87	11,019.03	11,508.95	12,030.54	11,819.43

Source: Fitch Solutions

3. Pharmaceutical Sub-sectors

3.1 Prescription Drugs

Prescription drugs accounted for around 76.6% of total drug sales in 2020, amounting to EUR526mn (USD599mn) in value, with the figures to grow to EUR553mn in 2021. Through to 2025, sales will post a compound annual growth rate (CAGR) of 4.6% in local currency terms and 6.5% in US dollar terms to reach a value of EUR657mn.

Over the 10-year forecast period, the prescription market is expected to post a local currency CAGR of 4.3% and a US dollar CAGR of 5.2% to reach a value of EUR799mn in 2030. By this point, prescription drugs will represent 80.7% of the total drug market in value terms despite the liberalisation of the OTC market and the maturation of the consumer healthcare market. This will largely be due to rising demand for chronic disease treatments and widening access to reimbursed medicines.

The country's ageing population and underlying disease profile will continue to drive this modest prescription drug growth. A gradual increase in the consumption of more expensive, sophisticated drugs, such as biologics, should drive spending growth in the long term and consequently lead to the increased presence of foreign producers. Lithuania's disease profile - particularly the high incidence of circulatory system diseases and cancer - should stimulate the growth of those segments of the prescription market and the rising demand for new patented medicines to treat those conditions. In recent years, the market has also been shaped by VAT changes.

The government reduced the VAT imposed on non-reimbursed prescription medicines from the standard rate of 21.0% to the lower 5.0% rate from January 1 2018. As a result, the non-reimbursed prescription market, which accounted for just 24.0% of total medicine sales in 2017, lost some market share in 2018 and is expected to continue along the same trajectory in 2019.The Joint Baltic Drug Procurement Agreement poses risks to the prescription market, with patented drug sales at particular risk. Increased purchasing power will lead to reduced prices. However, this will be partially offset by larger volume sales.

Government cost-containment measures will drive the increase of generic medicines used at the expense of patented medicines sales both in value and volume terms. At the same time, pricing changes will also negatively impact the price of reimbursed prescription drugs.

Table 8: Prescription Drug Market Indicators, Historical Data and Forecasts (Lithuania 2017 – 2025)

PRESCRIPTION DRUG MARKET INDICATORS, HISTORICAL DATA AND FORECASTS (LITHUANIA 2017-2025)									
Indicator	**2017**	**2018**	**2019**	**2020**	**2021f**	**2022f**	**2023f**	**2024f**	**2025f**
Prescription drug sales, EURbn	0.488	0.472	0.501	0.526	0.553	0.579	0.605	0.631	0.657
Prescription drug sales, EURbn, % y-o-y	3.24	-3.26	6.16	4.97	5.30	4.69	4.40	4.22	4.14
Prescription drug sales, USDbn	0.549	0.557	0.561	0.599	0.681	0.730	0.768	0.794	0.821
Prescription drug sales, USDbn, % y-o-y	5.19	1.33	0.68	6.86	13.65	7.24	5.23	3.40	3.31
Prescription drug sales, % of total sales	76.3	75.8	76.4	76.6	77.0	77.4	77.8	78.2	78.6

Source: VLK, VVKT, SAM, Fitch Solutions

3.2 Patented Drugs

Lithuania's patented drug market was worth EUR316mn in 2020, accounting for around 46.1% of the total drug market (and 60.2% of the prescription segment) by value. It is expected a marginal value increase in 2021, to EUR331mn. By 2025, it is forecasted that the innovative drug market will grow to EUR381mn, at a compound annual growth rate (CAGR) of 3.8% in local currency terms and 5.7% in US dollar terms.

Over the 10-year period to 2030, patented sales are forcasted to increase to a value of EUR448mn, accounting for a smaller 45.2% of the total drug market (and 56.0% of the prescription segment) and reflecting a local currency CAGR of 3.5%, which will trail that of generic drugs and the overall market. Data from the National Health Fund (VLK) on public drug expenditure and patient co-payments on reimbursed medicines show that the market share of generic medicines has been eroded in recent years on account of strong cost-containment policies that have pushed down their prices.

On the other hand, the VAT reduction on non-reimbursed prescription medicines from the standard rate of 21.0% to the reduced 5.0% rate at the at the start of 2018 has promoted prescription (especially patented) drug sales. However, government cost-containment initiatives are expected to favour the use of generic drugs wherever possible. The collective procurement initiative between the Baltic States of Estonia, Latvia and Lithuania poses both benefits and risks to patented drug sales. An increase in high-volume orders will drive growth of sales, but larger orders will also have to be at discounted prices.

The introduction of therapeutic reference groups may actually prove beneficial for marketers of truly innovative drugs in the long run as budget savings made by using only cheap generic products can be used to fund spending on these drugs. This will largely be determined by the breadth of the therapeutic groups and whether innovative medicines are included with older products. However, given the pending health technology assessment changes and the

likely adoption of cost-sharing agreements, risks to the patented medicines sector are largely on the downside.

Table 9: Patented Drug Market Indicators, Historical Data and Forecasts (Lithuania 2017 – 2025)

PATENTED DRUG MARKET INDICATORS, HISTORICAL DATA AND FORECASTS (LITHUANIA 2017-2025)									
Indicator	**2017**	**2018**	**2019**	**2020**	**2021f**	**2022f**	**2023f**	**2024f**	**2025f**
Patented drug sales, EURbn	0.299	0.289	0.304	0.316	0.331	0.344	0.356	0.368	0.381
Patented drug sales, EURbn, % y-o-y	4.25	-3.35	5.31	3.99	4.51	3.90	3.64	3.46	3.38
Patented drug sales, USDbn	0.337	0.341	0.341	0.361	0.407	0.433	0.452	0.464	0.476
Patented drug sales, USDbn, % y-o-y	6.22	1.23	-0.13	5.86	12.80	6.43	4.46	2.65	2.56
Patented drug sales, % of total sales	46.8	46.4	46.5	46.1	46.0	45.9	45.8	45.7	45.6

Source: VLK, VVKT, SAM, Fitch Solutions

3.3 Generic Drugs

Lithuania's generic medicine market reached a value of EUR209mn in 2020, accounting for 30.5% of the total drug market by value. It is expected an increase in value in 2021, to EUR223mn. By 2025, the generic drug market will grow to EUR276mn, at a compound annual growth rate (CAGR) of 5.7% in local currency terms and 7.6% in US dollar terms.

Over the 10-year forecast period to 2030, generic sales are forecasted to increase to a value of EUR352mn, accounting for 35.5% of the total drug market and reflecting a local currency CAGR of 5.3%. Over the same 10-year period, generics would account for 44.0% of the overall prescription sales by value, from 39.8% in 2020. The government has taken a strong stance towards rational medicine prescription and notably towards generic medicines, which are reportedly priced significantly higher than in the majority of the EU member states. As a result, the market share of generic medicines has been eroded in recent years.

In 2018, the change in VAT for non-reimbursed prescription medicines and the ceiling placed on reimbursement premiums dampened the growth. Nevertheless, penetration of generic medicines by volume is high in Lithuania, given the reimbursement co-payments scheme, whereby patients are required to pay the excess of the reimbursed base price of any medicine (including any wholesaler and pharmacy mark ups). There is a significant financial benefit from consumption of low-value medicines. Generally speaking, authorities have been committed to increasing generic uptake.

Legislation mandates that prescriptions may only note down international non-proprietary names as opposed to brand or trade names. Similarly, all pharmacies are required to tell patients about the prices of medicines prior to their choosing a medicine to purchase, and pharmacies must stock enough of the cheapest generic available. The government promotes the use of lower-cost drugs whenever possible, as part of its broader cost-containment policy.

Therapeutic reference pricing was introduced in 2010 and contributed to price erosion in the generic drugs market as high-priced branded generic products were substituted in favour of higher volumes of low-priced and more comprehensively reimbursed products. Generally

speaking, the climate of cost containment is expected to continue and thus pose a drag on the value growth of all pharmaceutical market segment.

Table 10: Generic Drug Market Indicators, Historical Data and Forecasts (Lithuania 2017 – 2025)

GENERIC DRUG MARKET INDICATORS, HISTORICAL DATA AND FORECASTS (LITHUANIA 2017-2025)									
Indicator	**2017**	**2018**	**2019**	**2020**	**2021f**	**2022f**	**2023f**	**2024f**	**2025f**
Generic drug sales, EURbn	0.189	0.183	0.195	0.209	0.223	0.236	0.249	0.262	0.276
Generic drug sales, EURbn, % y-o-y	1.67	-3.11	6.63	7.37	6.50	5.86	5.52	5.31	5.20
Generic drug sales, USDbn	0.213	0.216	0.218	0.238	0.274	0.297	0.316	0.330	0.345
Generic drug sales, USDbn, % y-o-y	3.59	1.48	1.12	9.31	14.94	8.44	6.35	4.48	4.37
Generic drug sales, % of total sales	29.5	29.4	29.8	30.5	31.0	31.5	32.0	32.5	33.0

Source: VLK, VVKT, SAM, Fitch Solutions

3.4 OTC Medicines

The formal OTC market accounted for 23.4% of the total pharmaceutical market in 2020, or EUR160mn, which translated into USD67 per capita. In 2021, the value to increase is expected to EUR165mn. By 2025, it is believed that the OTC drug market will be worth EUR179mn, accounting for a declining 21.4% of the total drug market and posting a local currency compounded annual growth rate (CAGR) of 2.2%. Over our 10-year forecast period to 2030, it is calculated that the sector will post a CAGR of 1.8% in local currency and 2.7% in US dollar terms respectively, reaching a value of EUR191mn and accounting for a diminishing share of the overall market value (19.3%) as public spending initiatives and epidemiological trends boost prescription sales. On a per capita basis, spending will have risen to USD96.

Despite reduced penetration, there is likely to be a marginal increase in self-medication of minor diseases, prescription-to-OTC switching and a desire by consumers to bypass an often-inefficient primary care and hospital system - all of which should boost market growth in absolute terms. In addition, the consolidation of the retail pharmacy sector may lead to tighter margins, but the trend also increases opportunities for promoting OTC products. Consumers are also likely to welcome regulatory changes that will allow easier access to some commonly used OTCs, such as pain relievers, through non-pharmacy outlets (such as petrol stations), which were introduced at the start of 2019.

Huge marketing campaigns are also becoming a key strategy with many firms offering small gifts to pharmacists in exchange for favourable placement and recommendation of their products. Analgesics, as in most other Central and Eastern European markets, will see the least growth owing to earlier market saturation and low prices. Other segments will almost double in value and spending will be driven by income growth and likely difficulties in the reimbursement sector; however, downside risks remain posed by potential downturn in consumer spending power.

Table 11: OTC Medicine Market Indicators, Historical Data and Forecasts (Lithuania 2017 – 2025)

OTC MEDICINE MARKET INDICATORS, HISTORICAL DATA AND FORECASTS (LITHUANIA 2017-2025)									
Indicator	**2017**	**2018**	**2019**	**2020**	**2021f**	**2022f**	**2023f**	**2024f**	**2025f**
OTC medicine sales, EURbn	0.152	0.151	0.154	0.160	0.165	0.169	0.173	0.176	0.179
OTC medicine sales, EURbn, % y-o-y	3.90	-0.57	2.17	3.96	3.08	2.48	2.03	1.82	1.71
OTC medicine sales, USDbn	0.171	0.178	0.173	0.183	0.203	0.213	0.220	0.222	0.224
OTC medicine sales, USDbn, % y-o-y	5.86	4.14	-3.11	5.84	11.25	4.98	2.84	1.02	0.90
Over-the-counter (OTC) medicine sales, % of total sales	23.8	24.3	23.8	23.4	23.0	22.6	22.2	21.8	21.4

Source: VLK, VVKT, SAM, Fitch Solutions

4. Pharmaceutical Trade

Pharmaceutical imports reached EUR1.25bn in 2020, and the value is expected to grow to EUR1.29bn in 2021. It is forecasted that they will post a five-year compounded annual growth rate (CAGR) of 2.2% in local currency and 4.1% in US dollar terms to reach EUR1.39bn in 2025.

Pharmaceutical exports, worth a more modest EUR836.2mn in 2020, are forecast to grow to EUR921mn in 2021. The figures will increase by a CAGR of 10.2% in local currency and 12.3% in US dollar terms to EUR1.36bnn in 2025. This means that the negative trade balance will begin to narrow over our forecast period from a deficit of EUR410mn in 2020 to EUR32mn by 2025.

Medicine exports from Lithuania remain heavily reliant on a select group of European markets, which will leave growth highly contingent on the business environment there. According to UN Comtrade, exports to the five markets of Russia, Latvia, Estonia, Germany and the Netherlands accounted for almost 70% of the total value of pharmaceuticals exported from Lithuania in 2015. With cost-containment measures widespread in these markets, as well as the depreciation of key export markets Russia and Belarus, export growth will be subdued relative to its strong historical growth.

Additionally, an increase in domestic production in Commonwealth of Independent States countries will limit the country's export growth potential in the long term. However, owing to the limited nature of the domestic market, Lithuanian pharmaceutical firms will continue to focus their efforts on increasing their export base, especially given the recent changes to reimbursement pricing.

Key import partners include Belgium, Germany, Poland, Latvia, and Hungary, according to UN Comtrade. While Lithuania has relatively high per capita pharmaceutical spending, growth will remain volume- more than value-driven. This is in line with wider cost-containment in the region, on account of austerity pressures.

Table 12: Pharmaceutical Imports/Exports (Lithuania 2019 – 2025)

PHARMACEUTICAL TRADE DATA AND FORECASTS (LITHUANIA 2019-2025)							
Indicator	**2019**	**2020**	**2021f**	**2022f**	**2023f**	**2024f**	**2025f**
Pharmaceutical exports, USDmn	853.86	952.96	1,133.28	1,273.99	1,412.31	1,548.18	1,700.97
Pharmaceutical exports, USDmn, % y-o-y	5.14	11.61	18.92	12.42	10.86	9.62	9.87
Pharmaceutical imports, USDmn	1,332.66	1,420.88	1,592.67	1,677.46	1,725.97	1,737.60	1,740.86
Pharmaceutical imports, USDmn, % y-o-y	16.69	6.62	12.09	5.32	2.89	0.67	0.19
Pharmaceutical trade balance, USDmn	-478.80	-467.92	-459.40	-403.46	-313.66	-189.42	-39.89

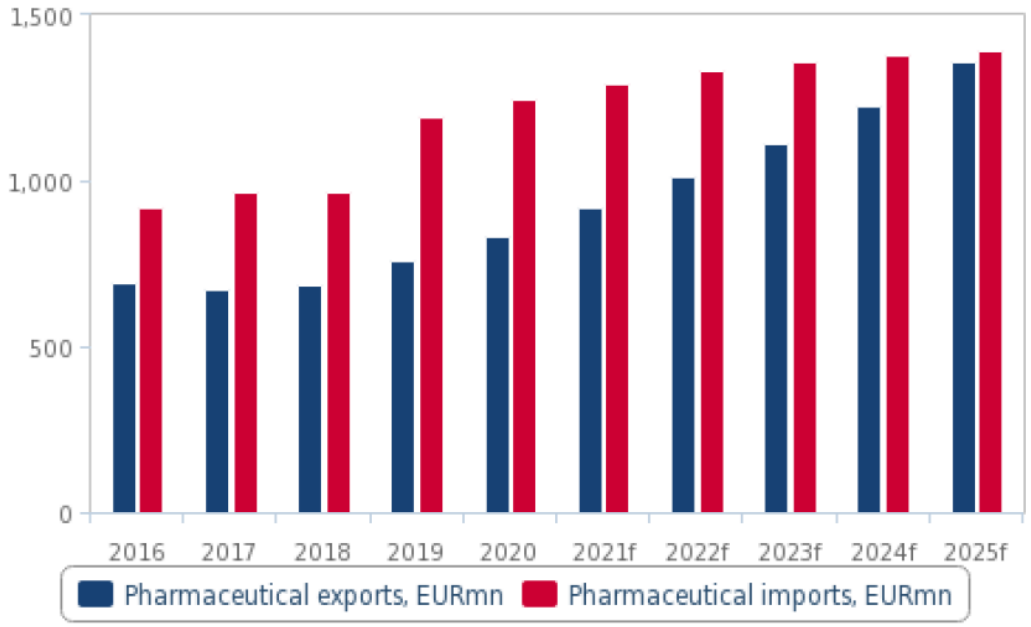
Source: United Nations Comtrade Database DESA/UNSD, Fitch Solutions

Table 13: Pharmaceutical Imports/Exports (Lithuania 2019 – 2025)

PHARMACEUTICAL TRADE DATA AND FORECASTS, LOCAL CURRENCY (LITHUANIA 2019-2025)							
Indicator	**2019**	**2020**	**2021f**	**2022f**	**2023f**	**2024f**	**2025f**
Pharmaceutical exports, EURmn	762.74	836.19	921.36	1,011.10	1,112.06	1,228.71	1,360.78
Pharmaceutical exports, EURmn, % y-o-y	10.87	9.63	10.19	9.74	9.98	10.49	10.75
Pharmaceutical imports, EURmn	1,190.45	1,246.79	1,294.86	1,331.31	1,359.03	1,379.05	1,392.69
Pharmaceutical imports, EURmn, % y-o-y	23.04	4.73	3.86	2.82	2.08	1.47	0.99
Pharmaceutical trade balance, EURmn	-427.71	-410.59	-373.49	-320.21	-246.98	-150.34	-31.91

Source: United Nations Comtrade Database DESA/UNSD, Fitch Solutions

Graph 1: Pharmaceutical Trade Forecast. 2016-2025



Source: United Nations Comtrade Database DESA, UNSD, Fitch Solutions

5. Regulatory Environment

5.1 Recent Developments

The State Medicines Control Agency (SMCA) - known locally as Valstybinė vaistų kontrolės tarnyba (VVKT) - is the main regulatory body in Lithuania. It falls under the auspices of the Ministry of Health and is responsible for issues such as marketing authorisation of pharmaceuticals, clinical trials, quality control of medicines and drug advertising.

All pharmaceutical products, both those available on the domestic market and exported elsewhere, must receive authorization from the SMCA. Lithuanian legislation protects confidential test data that is used by pharmaceutical firms as the basis for patent and trademark registration. Since late 2010, e-submissions have been accepted.

SMCA is also responsible for the compilation of the reimbursed list of medicines. A list of registered drugs is made publicly available through its website. As of July 2018, with the aim to prevent shortages, approval of medical product registrations without Lithuanian packages has been possible.

The agency additionally oversees post-marketing surveillance. The quality control of medicines, medicinal substances and substances of natural origin is carried out according to the Lithuanian pharmacopoeia, requirements of bilateral agreements of which Lithuania is a party, or requirements for quality control of medicines as established by international organizations of which Lithuania is a member.

Since the country became a member of the EU in May 2004, the basis for market regulation has been EU Directives. EU Directive 98/44 covers biological inventions. The last update of the Law on Pharmacy was carried out over the course of 2010, aligning domestic legislation fully with Directives 2004/27/EC and 2004/24/EC. The documents also contain requirements for switching to OTC drugs.

A major regulatory change since accession has been legislation on import licenses and an increase in the cost of wholesale pharmaceuticals trading permits. This obliged would-be licensees to prove that their suppliers could meet strict criteria, which has helped drive concentration in local manufacturing. The legislation generated considerable criticism from local pharmaceuticals and wholesaler groups.

5.2 Pharmaceutical Advertising

The advertising of medicinal products is governed by a number of laws, including the Law on Pharmaceutical Activities, the Law on Advertising and the supporting Rules on Advertising of Medicines, last amended in January 2006. Pharmaceutical companies and associations have also established the Code on Medicines Marketing, but the provisions of the document may not be enforced by the state. The Medicines Information and Monitoring Division of the SMCA is responsible for controlling the advertising of medicinal products. Only registered medicines may be advertised in Lithuania. Advertising to the general public is limited to non-prescription medicines and food products with certain medicinal purposes.

Advertisements for prescription medicines may be placed in special publications. Adverts should be objective, straightforward and based on scientific research. A number of advertising activities are forbidden, including the advertising of medicines which have not yet received marketing authorisation, comparative advertising, the use of hidden advertising, radio advertisements being read by famous people and the creation of websites containing the names of medicines. Free samples of the advertised product may not be distributed to the public.

Advertisements of OTCs to the general public must contain at least the following information: the name of the medicinal product, the shape and potency of the medicine, information necessary for correct use, directions to read the package leaflet before use, a warning to encourage the consultation of a doctor or pharmacist on possible side effects and a warning to consult a doctor if the pain does not stop after using analgesics.

The advertisement must not: state that a medical consultation, operation or treatment is not necessary, guarantee that the product is effective and has no side effects, state that not taking the product would be detrimental to a patient's health, be directed to children, state that the medicine is safe or effective because of the product's natural status, provide case history which could lead to incorrect self-diagnosis, or announce that the product is authorised in the Republic of Lithuania.

Advertisements to health professionals must include: essential information compatible with the summary of product characteristics, the type of medicine, the name of the product, the name and potency of all active substances, the pharmaceutical form, the quantity in the package, indications for use, contraindications and name of the manufacturer and its representative in Lithuania.

In July 2018, advertising regulations were further tightened to protect safety and promote transparency. The changes distinguish medicines from food and nutritional supplements and restrict visits by medical representatives to promotional events at medical facilities. According to the International Federation of Pharmaceutical Manufacturers & Associations (IFPA), EUR11.2mn was spent in Lithuania on 2017 medical promotion.

5.3 Intellectual Property Issues

As per EU regulation 1768/92, Supplementary Protection Certificates (SPCs) can extend existing patents to around 15 years from the date of the first marketing authorisation granted in the EU for products placed on the market after the regulation entered into force. An SPC can be granted whenever a drug application takes more than five years, but the maximum extension it can give is five years.

Data exclusivity (DE) for pharmaceuticals is implemented at EU level. At up to 11 years, it is one of the longest DE protection periods in the world. It is applied under an 8+2+1 formula. This breaks into eight years of data exclusivity followed by two years where generic manufacturers may prepare dossiers for filing. They may not, however, launch during this period. The final year is added if the original manufacturer is able to demonstrate an additional indication for the product.

Directive 2011/62/EU, which amended directive 2001/83/EC, has been implemented by all EU member states. The directive prevents falsified medicines from entering the supply chain, with measures that aim to increase safety measures across Europe, including the following:

- Labels on the outer packaging of medicines indicating authenticity.
- Strengthened requirements for the inspection of pharmaceutical manufacturers.
- Enforcing an obligation for manufacturers and distributors to report any suspicion of counterfeit medicines.
- A logo appearing on the websites of online pharmacies with a link to official national registers.

5.4 Regional Harmonization

The Common Baltic Package Guidance agreement was signed between the three Baltic States - Estonia, Latvia and Lithuania - in May 2005. The agreement simplifies the work of marketing authorisation for marketers wishing to use common packaging in the region. The agreement complies with local and EU laws and helps manufacturers keep production costs down.

The Baltic States have considered the creation of a combined drug approval agency, with the primary aim of eliminating the duplication of efforts. However, this appears to have been abandoned. The original aim was to establish a Baltic FDA, which would integrate the activities of Estonia's state agency of medicines Ravimiamet, Latvia's State Agency of Medicines and the SMCA. The three markets instead formed a joint procurement system in 2012 that aims to reduce costs by improving bargaining power in relation to both medicines and medical equipment.

In February 2011, Estonia, Latvia and Lithuania decided to follow a centralised procedure for granting approvals for drug labelling. The centralised procedure is expected to help companies save resources and make the approvals simpler, faster and clearer. Estonia's Ravimiamet is responsible for the coordination and maintenance of the database of approved packages. According to the procedure, the companies are required to file similar applications with the drug agencies in three countries in English and national languages in an electronic format. A reference country is then selected and a verdict issued. The marketing authorisation holder submits labelling samples to all drug agencies following the approval.

More recently, in March 2018, Lithuania, Poland, Slovakia, Croatia and Hungary signed a memorandum of understanding in the field of the affordable medicines. The countries will aim to increase patient access to innovative products in particular therapeutic areas through joint procurement initiatives; details of selection and further processes will be worked out in a pilot project.

5.5 Pricing Regime

The Department of Pharmacy within the Ministry of Health is responsible for developing pricing policy for pharmaceuticals. The Pharmaceuticals Cost Management Division of the Department of Pharmacy sets fixed retail and maximum wholesale prices of reimbursed pharmaceuticals. The Ministry of Health approves the prices by issuing an order.

Cost-containment measures are widespread across Europe given the ageing demographic profiles of populations and the resultant rising prevalence of chronic diseases. In Lithuania, the prices of innovative medicines are among the lowest in Europe. Although joint purchasing initiatives, such as the Joint Baltic Agreement, enable larger volume orders and consequently a greater ability to apply pressure on prices, in general the Lithuanian population's size will continue to limit demand and therefore reduce the ability to demand discounts. As joint purchasing agreements between Central European countries become more common, commercial potential will remain depressed.

By contrast, there is significant room for price reductions on the generic medicine market. Across European markets, once a patented medicine loses its exclusivity rights, the price of the medicine is progressively reduced by approximately 40% of the original price. This allows patients access to these off-patent medicines while also enabling healthcare providers to channel funds to the newest medicines.

In mid-2018, Lithuania introduced new pricing methodology. Previously, the cost of medicines manufactured by one producer in Lithuania was calculated as the average price from the basket of reference markets (Bulgaria, Czech Republic, Estonia, Hungary, Latvia, Poland, Romania and Slovakia). The new regulations state that the price will be calculated from the average price of the lowest three EU markets.

Non-reimbursed products are subject to similar price controls as those subsidised by the state. Reference pricing uses 14 EU states to determine prescription products and six for OTC medicines. Manufacturers are then required to declare clean-in-place processes (CIPs). Digressive maximum wholesale and retail mark-ups are in line with those for reimbursed medicines. Worryingly for drugmakers, the legislation states that prices must not exceed those declared by parallel importers, thus placing considerable pressures on prices.

The government's tax reform reduced the VAT on non-reimbursed prescription medicines from the start of 2017. Previously, only reimbursed medicines benefited from a reduced-rate 5.0% VAT, while non-reimbursed medicines attracted the standard-rate 21.0% VAT. The move has been praised as a positive step towards increasing patient access to medicines, and - unlike the reimbursement changes - will not affect manufacturer prices.

5.6 Reimbursement Regime

The reimbursement system was introduced in mid-1997 and was based on therapeutic reference pricing. This followed financial difficulties experienced by the state insurance agency SODRA (CHIF) - which covers medical costs for children, pensioners, invalids and patients suffering from serious diseases. Since 1991, the healthcare system has been financed directly from the state budget and SODRA payroll contributions. Pharmaceuticals

may be added to a reimbursement list if their addition leads to the exclusion of other drugs from the lists. Pharmaceuticals that are likely to have an adverse effect on state health insurance expenditure may be included on a list if they have been designed for the treatment of severe diseases, are recommended for use in children or will reduce other costs borne by hospitals in treating the disease. OTC products tend not to be added to the positive lists. Reimbursed drugs must carry the purchase cost, compensation rate and retail prices approved by the Ministry of Health. The Ministry of Health revokes the reimbursement status of a drug if a cheaper alternative is found, if health insurance spending to reimburse the drug is unjustifiably high or if the SMCA prohibits its use due to inadequate levels of safety, efficacy or quality. The government regulates the price of reimbursed drugs, as well as the cost of drug production in pharmacies and these rates are uniform throughout the country.

A stronger enforcement of generic substitution has been in place from April 2018. Prescription by an international non-proprietary name is mandatory, but the choice of which medicine to be consumed remains up to the patient in pharmacies.

A new regulation that came into force in early-2019 obliges pharmacists to sell the cheapest medicine to those patients that bring a reimbursable drug prescription after a break of longer than six months. The changes aim to increase competition in the pharmaceutical supply, as they will impact commonly used medicines manufactured at high volumes and generally boost the use of generics.

There are around 3,800 non-reimbursable and 1,800 reimbursable medicines in Lithuania. Drugs that have been awarded reimbursement status are assigned to one of the positive lists:

- List A contains drugs that are designed to treat specific diseases and were previously reimbursed at rates of 50.0%, 80.0% or 100.0% (based on manufacturers' price), depending on the level set for the disease. As of April 2019, all medicines in List A are reimbursed at 100.0%.
- List B contains drugs that may be reimbursed at 50.0%. Children up to three years receive 100.0% reimbursement and children between three and 16 years, pensioners and disabled patients are eligible for 80.0% reimbursement.

Authorities continue to widen access to reimbursed medicines. For example, from the start of April 2019, diabetes treatments are 100% reimbursable, having previously been reimbursed at 50%. Other medicines that have full reimbursement coverage include osteoporosis, gout, migraine and cluster headaches.

Moreover, new legislation, implemented in July 2018, sets a ceiling for reimbursed medicine premiums, with the Ministry of Health expecting to save EUR10.0mn per year:

- For cheap medicines, namely those costing less than EUR20, the maximum premium is set at 20% the base price of the drug.
- For expensive medicines (costing more than EUR20), the maximum premium is set at 20% the average base price of all reimbursed medicines. This average reimbursed medicine base price is recalculated annually.

Preliminary data from the Ministry of Health (July 22 2017) indicated that the reimbursement mechanism, in place since the start of July 2017, had significant impact. Patient co-payments in July fell on average by 9.6% y-o-y to EUR4.7. This resulted in total patient co-payments falling significantly compared with July 2016, as co-payments fell by 11.7% to EUR3.8mn.

In October 2018, a new price list for reimbursed medicines came into effect which lowers patient co-payments and covers a few new products, including antihistamines and medicines for the treatment of chronic obstructive pulmonary disease. Reimbursement prices in Lithuania are reviewed every four months.

6. Research and Development

6.1 General Overview

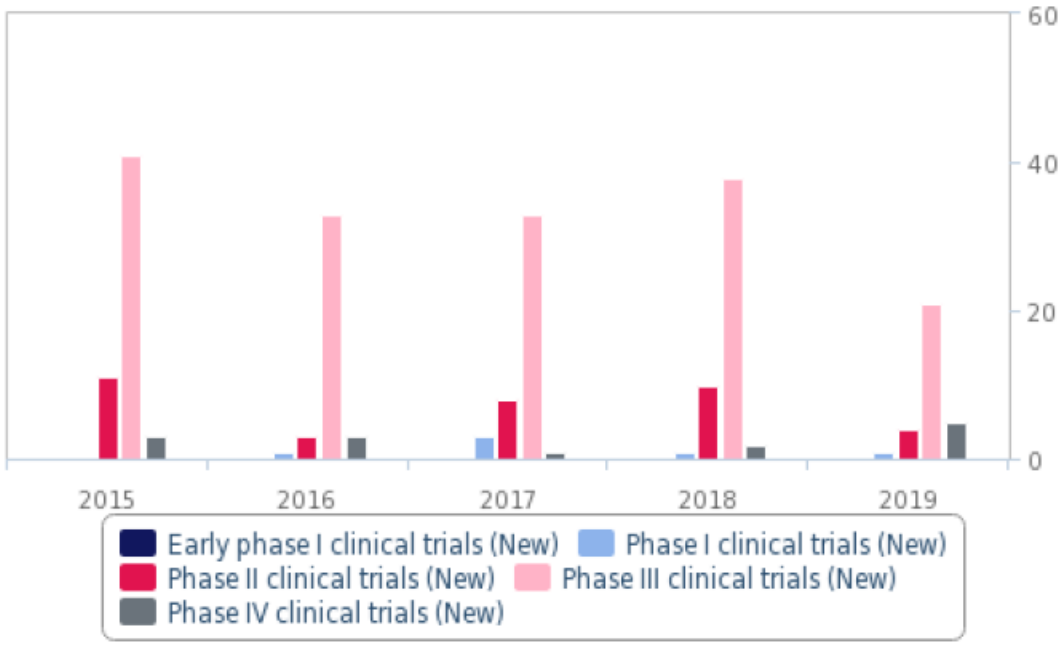
According to the International Federation of Pharmaceutical Manufacturers & Associations (IFPA), in 2017 some EUR4.7mn was spent on R&D in Lithuania. The country has one of the most significant biotechnology industries in CEE, which was born out of the establishment of the Institute of Applied Enzymology in 1975. The government has made the development of high-tech industry a priority through strategies, such as the Programme on the Development of Industrial Biotechnology. An increasing number of companies are the result of the spin-off from the well-established local universities. Successful local companies caught the attention of several global leaders in the area of biotechnology. As a result, successful Lithuanian biotechnology companies were acquired by foreign leaders of the market, such as Thermo Fisher Scientific, Moog and Teva. The Lithuanian biotechnology sector is especially strong in the field of red biotechnology, where research is conducted in the area of reagents and enzymes for molecular biology and recombinant pharmaceutical proteins. Lithuania's green biotechnology is also rapidly developing. Another spin-off from the Institute of Biotechnology is Biocentras, which has developed into a regional leader. Other leading companies are Canada-owned Fermentas andSicor, both of which evolved from former scientific institutes. The latter is a member of the Teva group, which acquired Lithuanian Biotechna in 2001. In addition to the commercial enterprises, 15 Lithuanian biotechnology research centres have been successful in their chemical and biochemical research of protein, enzymes and nucleic acid for pharmaceutical application.

6.2 Clinical Trials

Multinational pharmaceutical firms actively conducting trials include Novartis. The latter is conducting a study to examine how well the combination of two medicines, solifenacin succinate and mirabegron, work compared with each alone in the treatment of bladder problems and their safety. Since May 2004, the State Medicine Control Agency's Division of Preclinical and Clinical Trials has operated according to the provisions of Directive 2001/20/EC, which has been transposed into national law. The evolution and growth in the global clinical trials sector has seen contract research organizations (CROs) widen their

gaze in recent years. The search for new patient populations, low cost bases and improving healthcare standards is leading to a rapid expansion in operations in Asian countries, such as India and China. With often superior regulations, along with more developed facilities, there is a belief that the CEE region is still an attractive proposition for clinical trials. The region has grown in significance over the past decade, as drugmakers and CROs shifted their attention away from higher cost Western European markets. The Baltic States have a particularly large number of clinical trials in proportion to the population, which is most likely explained by their relatively developed healthcare systems, sound business environments and high burdens of disease.

Graph 2: New Clinical Trial Registrations 2015-2019



Source: ClinicalTrials.gov, Fitch Solutions

7. Epidemiology

7.1 General Overview

Non-communicable diseases dominate the epidemiological profile of Lithuania and are the leading causes of mortality and morbidity in the country. Where Lithuania differs from its regional neighbours in the CEE region is in the comparatively lower diabetes prevalence and disease burden and the higher burden of cardiovascular diseases on the overall epidemiological profile of the country. The three risk factors that account for the most disease burden in Lithuania are poor diets, high blood pressure and tobacco consumption. Alcohol consumption is also another contributor to the disease burden in Lithuania, mirroring

the situation across the region. Communicable diseases also place a burden on the healthcare system. According to the Centre for Communicable Diseases and Aids, Lithuania continues to have a major problem with tuberculosis (TB), with the number of children transmitting the disease having risen between 2014 and 2017. However, data from the WHO show the number of cases declined between 2017 and 2019, from 1,378 confirmed TB cases in 2017 to 1,145 in 2018 and 1,058 in 2019.

Cancer: Cancers accounted for almost 20.6% of deaths in Lithuania in 2015. The number of new cases of cancer per annum in Lithuania was expected to decline from 14,520 cases in 2012 to 14,217 cases in 2035, according to data from Globocan. This decline would result primarily from demographic changes as Lithuania's population is expected to decline over the next twenty years. In 2020, data from Globocan show that prostate cancer is the most prevalent, affecting 13.1% of cancer sufferers in the country. Colorectum, breast, lung and stomach cancer are the next most common among the 17,073 cases of cancer in 2020.

Cardiovascular Diseases: The mortality rate for cardiovascular disease in Lithuania (13.7 deaths per 1,000 people) is among the highest globally. This is because of the prevalence of risk factors among the Lithuanian population. In 2015, according to WHO data, around 35.0% of Lithuanians of all ages were overweight and around 20.0% were classified as obese. Smoking, which is also a strong risk factor in cardiovascular disease development, is commonplace among the adult population at 26.5%

Diabetes: Diabetes is becoming a growing concern in Lithuania given the levels of obesity, prevalence of smoking and the poor diets of Lithuanians. Whereas diabetes prevalence throughout Europe according to IDF data is 9.1%, in Lithuania the prevalence is much lower at 5.5% of the population. Given the risk factors, it is expected this prevalence to rise over the long term.

HIV/AIDS: The number of HIV cases has been steadily increasing in Lithuania since the first case was reported in 1988. According to the UNAIDS, in 2014 there were 141 new cases of HIV (4.8 per 100,000) and 37 newly registered AIDS cases. By the end of 2014, there had been 2,378 HIV cases and 415 diagnoses of AIDS reported in the country. Over the past five years, the annual number of new HIV cases has remained relatively stable but with a slight decrease (in 2010 there were 153 new cases). HIV testing was mandatory for blood donors, pregnant women, STD patients, intravenous drug users and prisoners until 1993 when testing became voluntary. It has remained mandatory for blood donors and STD patients, who are tested with consent.

8. Competition

8.1 Research-Based Industry

Innovative multinational drug companies are present in Lithuania but only through imports, rather than direct manufacturing facilities. Key players include Pfizer, GlaxoSmithKline, Merck & Co, Novartis, Sanofi and AstraZeneca. Israeli Teva entered the country through direct acquisition of Sicor Biotech UAB, as did Canadian Valeant, thus significantly reducing straight-out purchasing options of developed local pharmaceutical players.

There are over 18,000 R&D researchers and specialists working within the pharmaceutical industry sector in Lithuania. 15 research institutions carry out chemical and biochemical research for pharmaceutical purposes. 16 educational institutions, including five major universities, train high-calibre biotechnology and business specialists in cooperation with both domestic and foreign biotechnology companies. The Lithuanian biotech sector is well-developed considering the size of the country and the economy's capacity to spend on R&D. The biotech industry in the country is one of the most sophisticated in Central and Eastern Europe. Companies (CEE) within the biotech sector employ over 500 people, including about 160 R&D experts, while the entire sector's total annual revenues are estimated to exceed EUR70mn.

Table 15: Members of the IFPA.

MEMBERS OF THE IFPA APRIL 2021		
Abbvie	**Ipsen Pharma**	**Pfizer**
Astrazeneca	Janssen	Roche
Bayer AG	Eli Lily	Sanofi
Berlin Chemie Menarini	MSD	Servier
Boehringer Ingelheim	Novartis	Takeda
GSK	Novo Nordisk	

Source: ARPIM, Fitch Solutions

Table 16: Multinational Pharmaceuticals.

MULTINATIONAL MARKET ACTIVITY	
Company	**Operations**
AbbVie	The company does not have a manufacturing plant in the country but has a representative office in Vilnius. Products are imported.
AstraZeneca	The company has a representative office in Vilnius. Products are imported.
GlaxoSmithKline	GlaxoSmithKline has a representative office in Vilnius. Products are imported.
Johnson & Johnson	The company has a representative office in Vilnius. Products are imported.
Merck & Co	Merck Serono, the company's biopharmaceutical arm, has a representative office in Vilnius. Products are imported.
Novartis	The company does not have a manufacturing plant in the country but Novartis's generics subsidiary, Sandoz, its eye-care subsidiary, Alcon, and its pharmaceutical arm have representative offices in Vilnius. Products are imported.
Pfizer	Pfizer has a representative office in Vilnius. Products are imported.
Roche	The company has a representative office in Vilnius. Products are imported.
Sanofi	The company has a representative office in Vilnius. Products are imported.
Takeda	Takeda does not have a manufacturing plant in the country but it has a representative office in Vilnius. Products are imported.

Source: ARPIM, Fitch Solutions

8.2 Generic Drugmakers

Generic Drugmakers Before independence there were five main drug producers, mainly producing generic drugs: Sanitas, Endokrininiai Preparatai, Bakteriniai Preparatai, the State Plant of Pharmaceuticals and the Švenčionys state enterprise of herbal pharmacy. Since independence an increasing number of new, but small, generic companies have appeared. Sanitas remains the country's largest manufacturer. In more recent times, UAB Santonika has emerged as an increasingly prominent contract manufacturer of pharmaceutical preparations. The latest multinational generic drugmaker with a presence on the Lithuanian market is Canada-based firm Valeant, which achieved this through the purchase of Sanitas in a USD441mn, two-stage deal in May 2011. Large CEE generic drugs players are also prominently featured in Lithuania with main companies including Hungary-based Gedeon Richter, Slovenia-based Krka and Lek (owned by Novartis through its Sandoz generic drugs division) and Croatia-based Pliva (part of Israel-based generic drugs specialist Teva). Since January 1 2004, the Lithuanian pharmaceutical industry has had to upgrade production facilities in order to meet the EU requirements of Good Manufacturing Practice (GMP). Lithuania's GMP-certified pharmaceutical companies include Sanitas, Valentis, Svencioniu Vaistazoles and Sicor Biotech UAB. Sanitas has acquired a number of local companies, while Valentis has offered to develop contract production for smaller firms at its GMP-compliant facilities. In recent years, Sanitas under its new ownership of Valeant, acquired its rival Endokrininai Preaparatai and purchased Altisana from Endokrininai Preaparatai.

Altisana was developed as a joint Lithuanian-Norwegian production venture, enabling Sanitas to augment its international profile.

8.3 Pharmaceutical Distribution

There are currently around 70 active pharmaceutical wholesalers in the country (up to 170 are registered in total), supplying around 1,400 community pharmacies and 60 hospitals. While this is almost double the number in neighbouring Latvia, it is actually a relatively normal concentration for the market's size. Consolidation in the sector has led to it being dominated by a few large players, the leading five being Finland-based Tamro (which took over the management of Lithuania-based wholesaler Farmacija in 1999), Limedika Medicina (which deals in over 4,000 pharmaceutical brand names), Armila and Mauda. It is understood that these five hold upwards of 75% of the total market.

Other more prominent private distributors include Asotra which deals in medicines, healthcare and hygiene articles, as well as veterinary preparations, delivering them to hospitals, drugstores and wholesale pharmacists. Also, Entafarma, which has around 700 domestic customers, including pharmacies, hospitals, schools and other distributors. K Backevicius Personal Enterprise (Korys), which also deals in pharmaceutical waste management is also among these. Three distributors - namely Siauliu Vaistu Sandelis, Panevezio Vaistu Sandelis and the Universiteto Vaistine state enterprise in Vilnius - remain state enterprises. Strong growth in Lithuania's drug market and consolidation in the supply chain has also previously attracted investment from one of Germany's largest wholesalers. For example, in mid-2008, Andreae-Noris Zahn acquired 92.0% of Armila.

Vertical integration has been a hallmark of the supply chain recently, with many wholesalers establishing retail divisions and vice versa. For example, Armedika operates a network of pharmacies within Lithuania called 36.6 Vaistine that are involved in the retail distribution of pharmaceuticals, hygiene products and cosmetics manufactured by the companies that Armedika represents (including GlaxoSmithKline, Bristol-Myers Squibb, Boehringer Ingelheim, Apotex, Torrent, Viltechmeda and Novo Nordisk). While this provides better economies of scale for those who have combined operations, it significantly limits channels of distribution for wholesalers without it. We believe that operating pharmacy chains in the country could be a key factor for success in future.

8.4 Pharmaceutical Retail Sector

Prior to the start of 2019, medicines - including prescription and OTC products as well as homoeopathic preparations - could only be sold in pharmacies. By January 1 2019, when OTC sales were liberalised, some 100 retail outlets and petrol stations had been given marketing authorisation by the State Medicines Control Services (IWT) to sell commonly used OTCs for use by adults and children over the age of 12. Products covered by the liberalisation include anti-allergy, topical and anti-inflammatory medicines, which must also only contain one active substance. First aid kits for use in cars had already been permitted to be sold in petrol stations and similar outlets. In small rural areas, which lack pharmacies, authorised primary care institutions could have, in some cases, also dispensed medicines.

Distance selling is also allowed by pharmacies for OTCs, albeit with professional advice by pharmacists. In March 2019, proposals put forward by the cabinet to authorise hospital pharmacies to dispense medicines to outpatients were supported by the Ministry of Health, considering the move would improve access to treatment, especially after normal pharmacy working hours or during holidays. The market is fairly consolidated and new chain store openings has slowed down. Although chains are likely to continue gaining market share, it will be at a slower rate, thus minimising risks for wholesalers.

Additionally, proposals to establish stricter demographic criteria for the opening of pharmacies have been mooted. Nevertheless, e-prescriptions would have been rolled out at the end of 2019 (except for psychotropics and narcotics), allowing patients to get them filled via the pharmacy channel or to order medicines online. There are approximately 1,340 pharmacies operating in Lithuania. The Corporation of European Pharmaceutical Distributors (CEPD) sells medicines in Lithuania through a chain of nearly 470 pharmacies, including about 300 operating under two brands, Gintarine Vaistine and Norfos Vaistine, as well as about 150 partner pharmacies. With a 34.0% share in the number of pharmacies in the country, the CEPD is the primary medicine retailer. Gintarine Vaistine (Amber Pharmacy), part of the international Netherlands-based pharmacy enterprise Central European Pharmaceutical Distribution, is the second largest chain operator, with around 290 pharmacies, after Eurofarmacijos Vaistines (Eurovaistine). CEPD, through the National Pharmacy Group, reportedly accounts for 23.0% of the wholesale market and for around one-fifth of the retail pharmacy market by value. Eurovaistine, part of the Vilniaus Prekyba holding company, has around 300 pharmacies in Lithuania as well as smaller chains in Latvia, Estonia and Slovakia under the Euroapteka brand. It reportedly holds around one-third of the market. Camelia is the country's third largest chain.

The company operates approximately 260 stores, which cover all of Lithuania. Tamro, the country's largest wholesaler, has around 125 retail pharmacy stores under the Seimos Vaistines fascia, which was established in 2003. In 2004, it entered the pharmacy market with the purchase of Farmacijos Projektai, which owned 46 stores. In 2005, the company purchased the Ramuciu Vaistine chain, the Saurimeda chain (with 11 stores in Kaunas) and Vogne (with its 13 stores). Tamro has also acquired all shares of the UAB Farma Vaistines and UAB Herbarijos Vaistines chains, taking control of an additional 44 pharmacies. The acquisition of these pharmacies increased the market share of the Seimos Vaistine group..

8.5 Company Profiles

VALENTIS

SWOT ANALYSIS:

Strengths

- Valentis is among the leading local drug companies in Lithuania, with a focus on research.

- Its market position was strengthened through the 2003 acquisition of local rivals Vilniaus Farmacijos Fabrikas and Bakteriniai Preparatai.
- Good Manufacturing Practice (GMP) certification was achieved in July 2004, enabling exports to the EU and continued long-term presence on the local market.

Weaknesses

- The company has a relatively basic product portfolio, mostly consisting of herbal and natural supplements and remedies.
- EU membership is substantially increasing local competition as major regional generic drugs-based producers and multinationals target the market.

Opportunities

- It has few large domestic rivals.
- The company is in a strong position to successfully manage market consolidation.
- Consolidation of retail and wholesale is seen as a positive trend for the company, provided it ensures continuation of contracts.

Threats

- There is growing competition from regional generic drugs-based producers.
- Valentis's relatively basic portfolio opens it to multinational competition.
- Legislation affecting import licences is to increase company expenses in the case of any new in-licensing agreements.
- Regional harmonization of drug and medical devices purchasing offers potential risk.
- Pricing controls exerted on non-reimbursable prescription and OTCs will further hamper development of the local market.

Company Overview: Founded in 2002, Valentis UAB is the second largest pharmaceutical company in Lithuania with a controlling interest held by a group of private individuals. It received GMP certification in July 2004, one of only a small number of local producers to do so. Valentis, which employs around 150 people, also holds a wholesale licence in Lithuania. The company actually consists of two parts for the purposes of marketing authorisation, namely UAB Valentis and AB Bakteriniai Preparatai.

Strategy: Valentis has stated that its aim is to become the largest producer of drugs, additives and vitamins in Lithuania. It plans to establish and consolidate its market position in neighbouring countries such as Estonia, Latvia, Poland and Belarus. The firm has representative offices, but no manufacturing facilities, in Poland, Czech Republic, Latvia, Lithuania and some Commonwealth of Independent States.

Antibiotice recorded a sales revenue increase of 6.9% y-o-y in Q118, increasing from RON55.42mn (USD13.99mn) to RON59.22mn (USD14.95mn). The company's product portfolio, which focuses on natural ingredient manufacturing, includes vitamins, herbal and

natural supplements, herbal medicines and OTCs. Valentis also offers products that treat cardiovascular conditions, respiratory diseases and gastrointestinal conditions. It additionally provides contract manufacturing, is estimated to have an annual turnover of EUR20mn and invests substantial sums in research.

Sanitas (Bausch Health)

SWOT ANALYSIS:

Strengths

- Sanitas enjoys the resources and support of Canada-based owner Bausch Health (formerly Valeant).
- It is the leading local drug company in Lithuania with a growing Central and Eastern European (CEE) profile.
- Its dominant position in the Baltics was strengthened through the acquisition of one of its main rivals, Endokrininiai Preparatai, in 2004.
- It offers contract manufacturing facilities.
- Acquisitions of major Slovakian manufacturer Hoechst-Biotika and Poland's Jelfa are part of its aggressive moves into large CEE markets.

Weaknesses

- There is a government focus on cost containment.
- Its domestic market remains constrained by falling population numbers.
- The pharmaceuticals markets in the Baltic States are small and fragmented.

Opportunities

- Valeant's acquisition of Sanitas was to utilise synergies, thus potentially driving costs lower, while building on the Lithuanian firm's existing portfolio and expanding exports.
- Given the country's EU status and Sanitas's Good Manufacturing Practice (GMP) certification, its current licensing agreements with a number of foreign manufacturers will potentially expand.
- The company has high exposure to Russia, which has very promising long-term commercial potential.

Threats

- Rapid expansion could potentially lead to difficulties integrating businesses and adjusting sales and marketing strategy to operate in more developed and competitive markets.

- Pricing controls exerted on non-reimbursable prescription and OTC drugs pose threats.
- Regional harmonization of drug and medical device purchasing is also a downside.

Company Overview: Established in 1922 and privatized in 1994, Sanitas is by far Lithuania's largest pharmaceuticals manufacturer. The group's main activities are the manufacture and sale of generic medicines, the development of new products and contract manufacturing. In 2005, Sanitas gained GMP certification for the manufacture of injection preparations, the manufacture of hard capsules and the packaging of capsules and tablets. In 2008, Sanitas bought the Polish firm Homeofarm.

The acquisition, actioned through Sanitas's subsidiary Jelfa, added an ointment range to its portfolio. Sanitas's products are marketed in nine CEE countries. Its main markets are its Baltic neighbours and the ex-Soviet region, predominantly Russia, Kazakhstan and Uzbekistan.

In mid-2013, Canada-based generic drugmaker Bausch Health (formerly Valeant Pharmaceuticals International) completed a full takeover of Sanitas, having acquired an 87.0% share in it two years prior. Given that not all minority shareholders originally showed interest in selling their stake in the company, Valeant was forced to turn to court to find and force those shareholders into the mandatory squeeze-out.

Strategy: The company produces its own medicines, as well as undertakes manufacturing under contract for foreign producers. Its therapeutic focus is on dermatology, ophthalmology, gastroenterology and urology. The company offers both prescription and OTC drugs, and deals in wholesale

Sanitas's own product range comprises generic drugs, and also produces 15 products under licence. The company has approximately 80 products registered in Lithuania. It manufactures a range of formulations, including tablets and capsules, ampoules, ointments and eye drops. Sanitas ended production of tinctures during 2005, instead looking for a partner in this field. The company also expanded its production and warehousing capacities in Kaunas.

The company has a major supply agreement with leading Latvian drug producer Grindeks. Exports are made directly and through exporting Lithuanian wholesale pharmaceuticals distributors. Some 80% of Sanitas's products are for medicines that are not reimbursed, positioning the company more favourably regarding public sector cost-containment measures. However, this leaves the company vulnerable to consumer sentiment and exposed to cyclical dynamics within the Lithuanian economy.

Sicor Biotech (Teva)

SWOT ANALYSIS:

Strengths

- Sicor Biotech is the leading biotechnology company in Lithuania, with a growing global profile.
- t is backed by one of the most prominent global pharmaceuticals and biotechnology players - Israeli Teva.
- It offers contract manufacturing facilities.
- The company enjoys a strong export portfolio.

Weaknesses

- There is strong competition from larger players on the global scale.
- The pharmaceuticals markets in the Baltic States are small and fragmented.
- There are strict pricing and reimbursement regimes in the country.

Opportunities

- The rising demand for biotechnology products, locally and internationally, provides opportunity.
- There is government support for biotechnology in Lithuania.
- The company's export reach is strengthened through Sicor's ownership by Teva.

Threats

- Rapid expansion will potentially lead to difficulties integrating businesses and to adjusting sales and the marketing strategy to operate in more developed and competitive markets.
- New legislation affecting import licences will increase company expenses in the case of any new in-licensing agreements.
- Pricing controls exerted on non-reimbursable prescription and OTC drugs to further hamper development of the local market.

Company Overview: Sicor Biotech UAB was established in 1994 through the privatisation of the Institute of Biotechnology (previously the Institute of Applied Enzymology). In 1999, the company (previously Biotechna UAB) acquired the production facilities and technologies of Biofa Biopharmaceuticals and employed its staff.

In 2001, Sicor Biotech was incorporated into the US-based Sicor group, which subsequently merged with Israeli Teva Pharmaceutical. In 2007, Teva's Lithuanian Sicor operations merged into Teva Baltics with the latter's Latvian and Estonian groups. The company employs over 300 people, including more than 150 in its operations division, of which more

than 80% are university graduates with either a bachelor's or master's degree in Life Sciences. Sicor's manufacturing facility, which cost around USD40mn, is one of the largest greenfield investments ever in Lithuania. Teva Baltics reports that it is the top pharmaceutical company in the Baltic region, both by value and volume, and also in terms of generics alone.

It is the key provider of MS treatments across Lithuania, Latvia and Estonia, where it fields a total of 278 products across multiple therapeutic categories. Teva is also the only biosimilars manufacturer in the region

Strategy: The company offers a portfolio of 183 products, ranging from biosimilar medicines, specialty products (oncology, CNS and pain), generic medicines and consumer health products. It is one of the leading pharmaceutical companies in the Baltic region by value, and is ranked in the top three generic drugmakers in the region (by value and volume). The company produces 120 generic medicines in major therapeutic areas, including cardiovascular, oncology, psychiatry and neurology among others.

Its products are distributed to 52 countries, accounting for an export value of more than EUR100mn. Among its leading products are its multiple sclerosis treatments, with Sicor being the primary manufacturer of such medicines in the Baltic region. As well as producing its own medicines, the company manufactures under contract for foreign drugmakers. Teva's strategy for Sicor includes the expansion of its biopharmaceuticals output.

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