

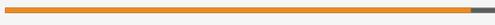
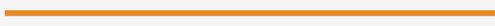
# Legislative Landscape Review: Legislative Approaches to Immunization across the European Region

December 2018

## The Baltic States:

A comparison of legislative approaches across three countries with similar historical, geographic and health contexts

### European Region Matrix: Immunization Legislation

COUNTRY	Is the right to health in this country's constitution?	Is it mandatory for the government to provide immunization?	Is it mandatory for the people to be immunized?	Does the government verify that the individual has been immunized?	Is immunization required for attending an educational institution?	Are there penalties in cases of noncompliance?	Has the judiciary of the country ruled on mandatory immunization?	Does the government finance immunization?
<b>Estonia</b> 	YES	YES	NO	YES	NO	NO	NO	YES
COVERAGE INDICATORS	DTP3  93% IPV ..... N/A					MEASLES (cases, 7/2017–6/2018) 10		
<b>Latvia</b> 	YES	YES	YES	YES	NO	NO	NO	YES
COVERAGE INDICATORS	DTP3  98% IPV ..... N/A					MEASLES (cases, 7/2017–6/2018) 20		
<b>Lithuania</b> 	YES	NO	NO	YES	NO	NO	YES	YES
COVERAGE INDICATORS	DTP3  94% IPV ..... N/A					MEASLES (cases, 7/2017–6/2018) 0		

 Answer Verified by Authoritative Secondary Sources
  Answer Verified by Survey

## Introduction

As highlighted in the full report, *Legislative Approaches to Immunization Across the European Region*, a variety of contexts, policies, systems and capacities (organizational, managerial, financial, human resources) influence the effectiveness of immunization approaches. This case study is a comparative examination across the Baltic States of Estonia, Latvia and Lithuania, which share similarities including geographic proximity, common recent history (including independence from the Soviet Union in 1991) and high coverage rates but differ in their legislative approaches. Using the “[Likert Scale: Assessing Levels of Immunization Legislation](#)” developed by the Sabin Vaccine Institute (Sabin) for this study, the Baltic States fall under the following classifications:

- Estonia: *recommended with robust monitoring and follow-up*
- Latvia: *mandatory immunization with monitoring and follow-up*
- Lithuania: *recommended*

The Baltic States have similar traits that are useful for comparison. These include:

- **High immunization coverage:** 90-99 percent depending on vaccine and year of reference
- **Limited vaccine hesitancy:** Although immunization refusal has increased, vaccine hesitancy does not affect these countries to the same extent as many European neighbors
- **Government provision of vaccines:** In all three countries, the government is legally required to provide vaccines and vaccines are financed either by the state or through insurance schemes and are free for the target population
- **Joint Procurement:** Facing high vaccine prices due to a small market share, the Baltic States have initiated a joint procurement mechanism for purchasing vaccines

The purpose of this case study is to examine how Estonia, Latvia and Lithuania implement their immunization programs and how legislation is used to support these efforts. The analysis may be useful to policy makers to understand the legislative, financial and monitoring systems in place for successful immunization programs, each stemming from a different framework for immunization legislation.

## Methodology

This study was carried out by Sabin in partnership with the O'Neill Institute for National and Global Health Law, Georgetown University. The research presented in this document was conducted using qualitative methods, surveying 53 participating countries from the European Region, as well as complementary desk research. Additional information was collected from authoritative secondary sources and from insights provided by national experts and members of the project steering committee. A comprehensive overview of legislation, supporting documents, national constitutions, public regulations, decrees and other relevant information on country immunization programs examined are now publicly available on Sabin's [European Immunization Policy Database](#) (Database).

## Context and findings

Political and economic challenges following the collapse of the Soviet Union at the beginning of 1990s had a significant impact on the health systems, and specifically immunization programs in the “communist bloc.” The Baltic States faced a challenge given the dependency of their immunization systems on vaccines produced in the Russian Soviet Republic. Immunization programs were interrupted temporarily,

vaccine shortages were common and outbreaks occurred. Diphtheria outbreaks<sup>1</sup> and tuberculosis morbidity increased<sup>2</sup> significantly in all three Baltic States. The decrease in financing and deterioration in healthcare systems exacerbated the problems in tuberculosis control and treatment.<sup>3</sup>

Over the span of the next 10 years, Estonia, Latvia and Lithuania each introduced political and legislative changes. As a result, immunization programs began to improve, immunization rates increased and outbreaks became rare. High immunization coverage rates persisted despite the 2008-2009 financial crisis and the subsequent contraction of national economies. The Baltic States, each at its own pace, have prioritized immunization and introduced comprehensive legislative provisions to help regulate national immunization programs (NIPs). Yet, since 2010, each country has faced challenges related to vaccine hesitancy. Relative to other European countries, vaccine hesitancy and refusal rates have been low<sup>4,5</sup>; however, the trend is increasing and has affected immunization rates. Each country has worked to address the issue in its own way, and from a research perspective, this presents an opportunity for comparative study.

## Estonia

### Background and legislative landscape

In Estonia, the legislative framework for immunization is set under the Communicable Diseases Prevention and Control Act (2003) ([See Database](#)).<sup>6</sup> The national immunization scheme is defined by regulation of the Minister of Social Affairs, organized by the Health Board and financed by the independent Estonian Health Insurance Fund (EHIF) and the state budget.<sup>7</sup> Immunization of children is the responsibility of family doctors and school nurses. A committee advises which vaccines to include in the national immunization scheme.

The Ministry of Social Affairs and its agencies oversee Estonia's health system. The e-Health Foundation operates the national e-Health system, which is an information exchange platform that connects all providers and allows data exchange with various other databases. The platform enables patient access to health data.

Estonia is a strong performer in immunization, with coverage remaining high (93-99 percent) across the different vaccines over the past decade.<sup>8</sup> Recently immunization coverage has decreased slightly, falling below the recommended 95 percent, while simultaneously, vaccine refusals among parents have increased. In 2017, diphtheria-tetanus-pertussis (DTP3) coverage was at 93 percent. Parental refusal levels are a mere 3-3.9 percent, depending on the vaccine,<sup>9</sup> but like the rest of the world, vaccine hesitancy and refusal are trending upwards.

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<sup>1</sup> Dittman S, Wharton M, Vitek C, Ciotti M, Galazka A, Guichard S, et al. Successful Control of Epidemic Diphtheria in the States of the Former Union of Soviet Socialist Republics: Lessons Learned. *The Journal of Infectious Diseases*. 2000 Feb; 181(1); S10-S22.

<sup>2</sup> Anon. The rise and spread of drug-resistant tuberculosis. *The Lancet*. 2008;371(9614):698

<sup>3</sup> National Institute for Health Development (Estonia). Health in the Baltic Countries 2015 [Internet]. Estonia: NIHD; 2015. 68 p. Report No. 24.

<sup>4</sup> Vaccination Programmes and Health Systems in the European Union [Internet]. Luxembourg: Expert Panel on effective ways of investing in Health (EXPH). European Commission; 2018 [cited December 2018]. Available from: [https://ec.europa.eu/health/expert\\_panel/sites/expertpanel/files/020\\_vaccinationpgms\\_en.pdf](https://ec.europa.eu/health/expert_panel/sites/expertpanel/files/020_vaccinationpgms_en.pdf)

<sup>5</sup> Larson H, Figueiredo A, Karafillakis E, Rawal M. State of Vaccine Confidence in the EU 2018 [Internet]. Luxembourg: European Commission; 2018 [cited December 2018]. Available from: [https://ec.europa.eu/health/sites/health/files/vaccination/docs/2018\\_vaccine\\_confidence\\_en.pdf](https://ec.europa.eu/health/sites/health/files/vaccination/docs/2018_vaccine_confidence_en.pdf)

<sup>6</sup> Estonia Communicable Diseases Prevention and Control Act (2003)

<sup>7</sup> Banhard P. The Estonia Health Insurance System. Estonia: Estonian Health Insurance Fund; 2017 March 31. 16 p. Available from: [https://www.haigekassa.ee/sites/default/files/pressile/presentation\\_riga\\_parliament\\_31032017\\_kodukale.pdf](https://www.haigekassa.ee/sites/default/files/pressile/presentation_riga_parliament_31032017_kodukale.pdf)

<sup>8</sup> Anon. Estonia: WHO and UNICEF estimates of national immunization coverage (WUENIC) [Internet]. World Health Organization, 2017 [cited 4 July 2018]. Available from: [https://data.unicef.org/wp-content/uploads/country\\_profiles/Estonia/immunization\\_country\\_profiles/immunization\\_est.pdf](https://data.unicef.org/wp-content/uploads/country_profiles/Estonia/immunization_country_profiles/immunization_est.pdf)

<sup>9</sup> Filippova, I. Immunization in Estonia. Tallinn: VENICE; 2017 Jan 24. 40 p. Available from: [https://intra.tai.ee/images/Immunization\\_in\\_Estonia\\_TAI\\_23.01.2017.pdf](https://intra.tai.ee/images/Immunization_in_Estonia_TAI_23.01.2017.pdf)

In Estonia, vaccination is recommended ([see Database](#))<sup>10</sup> with a Likert Scale classification as *recommended with robust monitoring and follow-up*. All vaccines included in the NIP are financed by the government and free of charge for all Estonian children ([see Database](#)).<sup>11</sup> Parents, guardians or legal representatives are empowered to make immunization decisions for their children and wards. However, if a parent refuses to vaccinate a child under the NIP, a written application is required.<sup>12</sup> Immunization issues are regulated by the Law on the Prevention and Control of Infectious Diseases and legal norms approved on its basis ([see Database](#)).<sup>13</sup> The Law on Occupational Health and Safety regulates immunization in the field of occupational health.

## Financing

Estonia has been an early adopter of innovation in health, which has led to significant gains in efficiency and higher performance across the health sector, including immunization. Its health financing structure is one reason behind Estonia's robust immunization performance. Reforms in the early 1990s introduced the principles of a purchaser and provider split,<sup>14</sup> strengthening primary care by allowing free choice of provider and a significant level of provider autonomy in the Estonian health care system. In 1991, Parliament passed the Health Insurance Act ([see Database](#)),<sup>15</sup> which set the basis for a new financing source for healthcare. As a result, nearly all health services, including immunization,<sup>16</sup> are financed through a social health insurance system funded primarily by an earmarked payroll tax (similar to the system in Moldova, see [Moldova case study](#) for more information).<sup>17</sup> The Health Services Organization Act of 1994 laid the foundation for the organizational structure. After fundamental reforms in the mid-1990s, the focus shifted to incremental improvement of the health system. In 2001, the EHIF was established as the core independent public purchaser of health services.<sup>18</sup> The EHIF administers Estonia's health insurance system and covers the costs related to immunization (for vaccines included in the immunization schedule). A Health Services Organization Act and a new Health Insurance Act were adopted in 2001 and 2002 ([see Database](#)),<sup>19</sup> further improving the financing mechanism.

Estonia's social health insurance system combines per capita payment for primary healthcare with a pay-for-performance (P4P) program and additional financial incentives for achieving immunization coverage targets. P4P, also called the quality system (QS), was launched in 2006 as a voluntary quality-based financial incentive system. In the first year, 60 percent of family practices joined the program and by the end of 2008 enrollment rose to 78 percent.<sup>20</sup> One indicator for the program's achievement is the childhood immunization coverage rate.<sup>21</sup>

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<sup>10</sup> [Estonia Communicable Diseases Prevention and Control Act \(2003\)](#)

<sup>11</sup> Public Health Act and Communicable Disease Prevention and Control Act (2003). The financing comes from the National Insurance Fund

<sup>12</sup> Ministry of Social Affairs Regulation No 116 (2003) (Постановление Министра социальных дел No 116 от 31 октября 2003 г. «Требования организации иммунизации») and Guidelines on the Organization of Immunization Services (27 October 2009): Available from: [https://www.haigekassa.ee/uploads/userfiles/immkava\\_rakendusjuhis\\_vene\\_k.pdf](https://www.haigekassa.ee/uploads/userfiles/immkava_rakendusjuhis_vene_k.pdf)

<sup>13</sup> Estonia Public Health Act and Communicable Disease Prevention and Control Act (2003) [statute on the Internet] c2018 [cited 2018 Aug 1].

<sup>14</sup> The purchaser-provider split (PPS) is a service delivery model in which third-party payers (purchasers of health care) are kept organizationally separate from service providers (e.g. hospitals). The operations of the providers are managed by contracts. One of the main aims of PPS is to create competition between providers leading to more efficiency and cost-saving.

<https://abetternhs.net/2011/01/18/commissioning-and-the-purchaser-provider-split/>

<sup>15</sup> Health Insurance Act (Estonia) 2002 [statute on the Internet] c2018 [cited 2018 July]. Available from:

<https://www.riigiteataja.ee/en/eli/529122016002/consolide>

<sup>16</sup> All vaccines included in the national immunization calendar are free for children (and DT vaccine for adults).

<sup>17</sup> Employers are obligated to pay social tax for employees of which includes 13 percent of gross wages for health insurance.

<sup>18</sup> Legislative documents regulating the establishment, financing and organization of the EHIF include: the Health Insurance Act (1991) and the Social Tax Act ([see Database](#))

<sup>19</sup> Health Services Organization Act (2001) and Health Insurance Act (2002) ([see Database](#))

<sup>20</sup> Eesti Haigekassa. Estonian Health Insurance Fund Annual Report 2008 [Internet]. Tallinn: Estonian Health Insurance Fund; 2008 [cited 2018 Aug]. 92 p. Available from: [https://www.haigekassa.ee/uploads/userfiles/Majandusaasta%20aruanne%202008\\_ENG.pdf](https://www.haigekassa.ee/uploads/userfiles/Majandusaasta%20aruanne%202008_ENG.pdf)

<sup>21</sup> Merilind E, Salupere R, Vastra K, Kalda R. Pay for performance of Estonian family doctors and impact of different practice- and patient-related characteristics on a good outcome: A quantitative assessment. *Medicina*. 2016; 52(3): 192-198.

A study assessing the influence of P4P mechanisms on childhood immunization coverage<sup>22</sup> compared childhood immunization coverage rates of all Estonian family physicians in two groups, connected and not connected, to the QS during the observation period of 2006-2012.<sup>23</sup> It showed a significant difference between the two groups; doctors connected to the quality system met the 90 percent vaccination criterion more frequently compared to doctors not connected. And more importantly, “doctors not joined to the quality system were below the 90 percent vaccination criterion in all vaccinations listed in the Estonian State Immunization Schedule.”<sup>24</sup> The study supports the argument that P4P mechanisms as a financial incentive encourages higher levels of childhood immunizations. Another study, assessing 11 P4P programs in Organisation for Economic Co-operation and Development (OECD) countries found that the P4P program in Estonia resulted in a modest increase in coverage rates for childhood immunization.<sup>25, 26</sup> Estonia has embraced P4P as a mechanism to encourage childhood immunization and help overcome vaccine hesitancy/refusal by incentivizing doctors.<sup>27</sup>

### Political will and scientific support

In Estonia’s case, political stability in the years following independence was a crucial factor for the success of the healthcare system reform, and in particular, the NIP. System reform benefited from the consensus and commitment of political parties, and there was minimal opposition to the introduction of healthcare and immunization reforms.<sup>28</sup> The Estonian Medical Association (EMA) also played a significant role in the successful initiation and implementation of health insurance reform.

## Latvia

### Background and legislative landscape

Latvia also has strong immunization program performance, with coverage rates ranging between 90-99 percent, depending on the vaccine, for the last decade.<sup>29</sup> The NIP expanded the number of antigens from 11 in 2008 to 14 in 2015. Like Estonia and Lithuania, Latvia experienced a decline in coverage beginning in 2012, but later rebounded. In 2017, DTP3 coverage was at 98 percent, up from 95 percent in 2012-2015.<sup>30</sup> Although the rates among the three countries are similar, Latvia has the highest coverage rates among the three Baltic States and is the only one with coverage at or above 95 percent between 2015 and 2017.

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<sup>22</sup> Merilind E, Salupere R, Västra K, Kalda R. The influence of performance-based payment on childhood immunisation coverage. [Internet]. Current neurology and neuroscience reports. U.S. National Library of Medicine; 2015. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/25686796>.

<sup>23</sup> Note: Immunisation coverage was calculated as the percentage of persons in the target age group who received a vaccine dose by a given age. From: Merilind E, Salupere R, Västra K, Kalda R. The influence of performance-based payment on childhood immunisation coverage. [Internet]. Current neurology and neuroscience reports. U.S. National Library of Medicine; 2015. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/25686796>

<sup>24</sup> Merilind E, Salupere R, Västra K, Kalda R. The influence of performance-based payment on childhood immunisation coverage. [Internet]. Current neurology and neuroscience reports. U.S. National Library of Medicine; 2015. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/25686796>

<sup>25</sup> How Provider Payment Approaches Affect Immunization Services [Internet]. Immunization Financing. Available from: <https://www.immunizationfinancing.org/en/strategic-purchasing-and-procurement/how-provider-payment-approaches-affect-immunization-services#>

<sup>26</sup> Paying for performance in health care. Implications for health system performance and accountability (2014) [Internet]. World Health Organization. World Health Organization; 2017. Available from: [http://www.euro.who.int/\\_\\_data/assets/pdf\\_file/0020/271073/Paying-for-Performance-in-Health-Care.pdf?ua=1](http://www.euro.who.int/__data/assets/pdf_file/0020/271073/Paying-for-Performance-in-Health-Care.pdf?ua=1)

<sup>27</sup> Ministry not in favor of vaccination coercion measures [Internet]. Eesti Rahvusringhääling | ERR; 2017. Available from: <https://news.err.ee/592617/ministry-not-in-favor-of-vaccination-coercion-measures>

<sup>28</sup> Atun RA, Menabde N, Saluvere K, Jesse M, Habicht J. Introducing a complex health innovation--primary health care reforms in Estonia (multimethods evaluation). [Internet]. Current neurology and neuroscience reports. U.S. National Library of Medicine; 2006. Available from: <https://www.ncbi.nlm.nih.gov/pubmed/16406131>

<sup>29</sup> Anon. Immunization country profiles 2017 [Internet]. UNICEF DATA. 2018. Available from: [https://data.unicef.org/wp-content/uploads/country\\_profiles/Latvia/immunization\\_country\\_profiles/immunization\\_lva.pdf](https://data.unicef.org/wp-content/uploads/country_profiles/Latvia/immunization_country_profiles/immunization_lva.pdf)

<sup>30</sup> Anon. Estonia: WHO and UNICEF estimates of national immunization coverage (WUENIC) [Internet]. World Health Organization, 2017 [cited 4 July 2018]. Available from: [https://data.unicef.org/wp-content/uploads/country\\_profiles/Estonia/immunization\\_country\\_profiles/immunization\\_est.pdf](https://data.unicef.org/wp-content/uploads/country_profiles/Estonia/immunization_country_profiles/immunization_est.pdf)

Latvia's NIP includes both recommended and mandatory vaccines resulting in a classification of *mandatory immunization with monitoring and follow-up*. While Section 30 of the Epidemiological Safety Law (1997)<sup>31</sup> states that the Cabinet of Ministers determine which groups receive mandatory immunization and against which diseases,<sup>32</sup> "Vaccine Regulation" No. 330 (2000)<sup>33</sup> further clarifies this provision and states that "[w]ithin the framework of the State Immunisation Programme vaccination shall be mandatory for (3.1.) children..." and then enumerates for which diseases.

Under the legislation, physicians must explain the advantages and disadvantages of immunization and obtain written refusal of services for those patients who decline. Section 32 of the Epidemiological Safety Law stipulates that health practitioners need to report complications observed as a result of the administration of a vaccine; however, there is no provision on compensation for potential damages. Paragraph 32 of the Vaccine Regulation states that "heads of educational institutions and social care institutions have a duty to request that a person to be educated or socially cared for, upon entering an educational or social care institution, submits a statement certified by a medical practitioner which shall specify which vaccines the person has received in conformity with the vaccination calendar of the State Immunisation Programme." In addition to the monitoring system, this is a verification mechanism to help ensure that children have been immunized. No provision is noted to prevent unvaccinated children from attending school.

## Financing

The Law (1997) and Regulations (2000) guarantee that costs associated with mandatory vaccines, as well as complications arising from immunization, will be covered by state funds;<sup>34</sup> however, costs for recommended vaccines are not covered by the state budget. The Epidemiological Law (1997) reserves funding not only for vaccine purchase, but also for monitoring activities and routine program costs.

The Compulsory Health Insurance Agency is responsible for purchasing vaccines used in the official immunization program in Latvia. Mandatory health insurance is the basic level of medical assistance provided by the state, as laid out in Regulation No. 1046 "Health Care Organization and Financing Procedure," issued by the Cabinet of Ministers on December 19, 2006.<sup>35</sup> The state is obligated to insure basic healthcare services. State mandatory health insurance resources, in accordance with the Regulations, are financed by a state budget subsidy as outlined in the annual law, "On the State Budget," for healthcare. These resources guarantee the provision of healthcare services within fixed parameters. Latvia does not have a specific budget line for immunization, but the government can invoke the law, supported by the legal framework described above (see Database), to help justify funding requests and "costs associated with vaccination."<sup>36</sup> In practice, this can mean a delay or shortage of funds.

<sup>31</sup> Epidemiological Safety Law (1997). Latvia [Internet]. VENICE III. Available from: [http://venice.cineca.org/documents/latvia\\_ip.pdf](http://venice.cineca.org/documents/latvia_ip.pdf)

<sup>32</sup> Within the framework of the State Immunisation Programme vaccination shall be mandatory for:

3.1. children – against tuberculosis, diphtheria, tetanus, whooping cough, poliomyelitis, measles, rubella, epidemic parotitis, b-type infection caused by Pfeiffer's bacilli (influenza bacteria), virus hepatitis type B;

3.2. adults – against diphtheria, tetanus; and

3.3. children and adults – against rabies after contact with animals or humans who are ill or are suspected of being ill with rabies.

<sup>33</sup> Vaccination Regulations [Internet]. Cabinet Regulation No. 330. Adopted 26 September 2000. Available from:

[www.vvc.gov.lv/export/sites/default/docs/LRTA/Citi/Cab\\_Reg\\_No\\_330\\_-\\_Vaccination\\_Regulations.doc](http://www.vvc.gov.lv/export/sites/default/docs/LRTA/Citi/Cab_Reg_No_330_-_Vaccination_Regulations.doc)

<sup>34</sup> Regulation No 330, Section I, par 6: "All expenditures related to the State Immunisation Programme and the vaccinations referred to in Paragraph 3 of these Regulations, their organisation, supervision and control, also to the acquisition of vaccines, drawing up of medical documentation, vaccine injection, as well as to the treatment of complications (side-effects) caused by vaccination which treatment has been included in the minimum of medical services to be provided for inhabitants specified in regulatory enactments, shall be financed from the State basic budget and the State special health care budget." Latvia's Epidemiological Law (1997) reserves funding not only for vaccine purchases but for monitoring activities and routine program costs, Chapter VI, Section 30: "Costs associated with vaccination against the referred to diseases shall be covered from the resources provided for such purpose in the annual State budget."

<sup>35</sup> State mandatory health insurance is the basic level of medical assistance provided by the state, as laid out in Regulations No. 1046 "Health Care Organization and Financing Procedure," issued by the Cabinet of Ministers on 19 December, in 2006.

<sup>36</sup> Republic of Latvia Vaccine Regulations No. 330 adopted 26 September 2000 [statute on the Internet].

As noted earlier, the Baltic States have been exposed to higher medical prices, including for vaccines, given the size of the small market they represent. To improve their negotiating position, reduce costs and guarantee access to the vaccines included in their national schedules, all three countries entered into a joint procurement agreement in 2012. It took some time to work out the process, however the end result was a 25 percent savings on price.<sup>41</sup>

### **Joint immunization procurement under the Baltic Partnership Agreement**

On May 2, 2012 the three Baltic countries entered into an agreement (Baltic Partnership Agreement) to carry out joint tenders for purchasing medications and medical equipment as well as lending medications and medical equipment.<sup>37</sup> Since 2012, in times of need, the countries have used the Agreement to loan medications to each other and this has helped to alleviate serious shortages.

The joint procurement efforts, on the other hand, took more time to negotiate and implement. Collaboration around procurement began at the end of 2014, and to date, has focused solely on vaccines. All three countries have similar vaccine schedules and use the same preparations/dosages (given the size of the population, geographic distribution, etc.). The price range is also similar for all three given their purchase volumes, delivery schedules and development status. Pooled procurement would ideally result in a reduction in prices due to increased volumes and predictability of purchases/planning.

The first joint tender for the BCG vaccine, or bacille Calmette-Guerin, a vaccine for tuberculosis, was announced in 2015. It was organized in accordance with Latvia's Public Procurement Law, as Latvia was the lead partner. The tender was unsuccessful, with no submissions, since the only manufacturer who would have qualified under the technical specifications of the tender did not apply because the required doses could not be produced within the specified timeframe. It also became evident that several producers were not interested in participating in joint tenders for such a small market, so the three countries worked to refocus their procurement strategy.<sup>38</sup>

As a next step, Estonia and Latvia identified a rotavirus vaccine as the next most promising candidate for joint procurement (Lithuania's immunization program does not include the rotavirus vaccine in its schedule) and signed a two-year partnership agreement. Estonia became the lead partner for this round and the process was undertaken in accordance with its procurement provisions. The joint procurement for the rotavirus vaccine was announced on October 2016 and in February 2017, the Estonian Social Ministry and Latvian Health Ministry announced that it was successful, and as a result, both countries saved money. Estonia and Latvia purchased 61,000 doses of vaccine, of which 24,710 went to Estonia and 36,290 to Latvia. According to the Social Ministry, Estonia purchased the vaccines for a price 25 percent lower than it would have without the joint tender.<sup>39</sup> Latvia also entered a two-year partnership agreement with Lithuania for procurement of pneumococcal vaccines. Although further plans for procurement remain unclear, the governments have expressed interest to continue and increase the scope of joint procurement.<sup>40</sup>

<sup>37</sup> Partnership Agreement between the Ministry of Health of the Republic of Latvia, the Ministry of Social Affairs of the Republic of Estonia and the Ministry of Health of the Republic of Lithuania on Joint Procurements of Medicinal Products and Medical Devices and Lending of Medicinal Products and Medical Devices Procurable Centrally [Internet]. LIKUMI.LV. Available from: <https://likumi.lv/doc.php?id=248008>

<sup>38</sup> Espin J, Rovira J, Calleja A et al., authors; Richardson E, Palm W, editors. How can voluntary cross-border collaboration in public procurement improve access to health technologies in Europe? [Internet] Copenhagen (Denmark): European Observatory on Health Systems and Policies; 2016. (Policy Brief, No. 21.) Policy brief. Available from: <https://www.eu2017.mt/Documents/Programmes/PB21.pdf>

<sup>39</sup> Estonia and Latvia jointly purchase rotavirus vaccine [Internet]. The Baltic Course | Baltic States news analytics. Available from: [http://www.baltic-course.com/eng/baltic\\_states/?doc=127652](http://www.baltic-course.com/eng/baltic_states/?doc=127652)

<sup>40</sup> Latvia to purchase vaccines jointly with Baltic neighbors [Internet]. The Baltic Times. Available from: [https://www.baltictimes.com/latvia\\_to\\_purchase\\_vaccines\\_jointly\\_with\\_baltic\\_neighbors/](https://www.baltictimes.com/latvia_to_purchase_vaccines_jointly_with_baltic_neighbors/)

<sup>41</sup> Espin J, Rovira J, Calleja A et al., authors; Richardson E, Palm W, editors. How can voluntary cross-border collaboration in public procurement improve access to health technologies in Europe? [Internet] Copenhagen (Denmark): European Observatory on Health Systems and Policies; 2016. (Policy Brief, No. 21.) Policy brief. Available from: <https://www.eu2017.mt/Documents/Programmes/PB21.pdf>

# Lithuania

## Background and legislative landscape

Like Estonia and Latvia, Lithuania went through a difficult period after the breakup of the Soviet Union and implemented new legislation and policies to establish a robust and efficient immunization program. The right to health is enshrined in the Constitution of Lithuania<sup>42</sup> and the government is required to provide immunization under the Health Systems Law, Art. 34, and the Law on Human Communicable Disease Prevention and Control.<sup>43</sup>

According to the NIP<sup>44</sup> and WHO/UNICEF coverage estimates,<sup>45</sup> immunization coverage under the Lithuanian program quickly improved and was between 94-99 percent for a number of vaccines until 2009. In a similar pattern to the other Baltic countries, this was followed by several years of growing hesitancy and a slight decrease in rates. Since 2012, immunization coverage improved, but it has not yet reached former high rates. In 2016-2017, coverage was at 94 percent, up from 93 percent in 2012-2015.

During the transition years, Lithuania introduced new legislation to help reorganize its health system and immunization program. The principal guidelines for public health services, including immunization, were outlined in the Health System Law (1994), the Lithuanian Health Program (1998-2010), with an updated version for 2014-2025,<sup>46</sup> and the National Public Health Strategy (2006-2013). In 2002, Parliament adopted the Public Health Care Law and the Public Health Monitoring Law.<sup>47</sup> The NIP has been largely regulated by the Health Systems Law<sup>48</sup> and the Law on Human Communicable Disease Prevention and Control,<sup>49</sup> as well as Ministerial decrees, orders and regulations based on this legislation.<sup>50</sup>

Immunization is *recommended* in Lithuania and all vaccines included in the national schedule are administered upon receiving consent.<sup>51</sup> Immunization policy is regulated by an official Immunization Calendar.<sup>52</sup> Health institutions report immunization data to public health centers.<sup>53</sup> Public health centers in turn report the aggregate data to the Center for Communicable Diseases Prevention and Control,<sup>54</sup> who is responsible for preparing recommendations for immunization, surveillance of vaccine-preventable

<sup>42</sup> The Constitution of Lithuania of 1992 with Amendments through 2016 [statute on the Internet]. C2018 [cited 18 August 2018]. Available from: [https://www.constituteproject.org/constitution/Lithuania\\_2006.pdf?lang=en](https://www.constituteproject.org/constitution/Lithuania_2006.pdf?lang=en)

<sup>43</sup> Lithuania Law on Human Communicable Disease Prevention and Control of July 1991 [statute on the Internet]. C2018 [cited 2 December 2018]. Available from: <http://www.vaspvt.gov.lt/files/EN/LAW%20ON%20HEALTH%20SYSTEM.pdf>

<sup>44</sup> Čaplinskienė I. Lithuanian Immunization Program – Vaccination Coverage Evaluation by the Effectiveness Criteria [Internet]. Health Policy and Management (Vol 1, No 6); 2014. Available from: <https://www3.mruni.eu/ojs/health-policy-and-management/article/view/1712>

<sup>45</sup> Anon. Immunization Country Profiles Lithuania 2017 [Internet]. UNICEF DATA. 2018. Available from: [https://data.unicef.org/wp-content/uploads/country\\_profiles/Lithuania/immunization\\_country\\_profiles/immunization\\_ltu.pdf](https://data.unicef.org/wp-content/uploads/country_profiles/Lithuania/immunization_country_profiles/immunization_ltu.pdf)

<sup>46</sup> Lietuvos Respublikos Konstitucija. Resolution for Lithuanian Health Program Approval 2014-2025 (Legislation, 2014, No. 2014-09403). C2018 [cited July 2018]. Available from: [http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc\\_l?p\\_id=476512](http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=476512)

<sup>47</sup> Lithuania Public Health Care Law and the Public Health Monitoring Law of 3 July 2002 [statute on the Internet]. C2018 [cited 7 August 2018]. Available from: <https://e-seimas.lrs.lt/portal/legalActPrint/lt?jfwid=191fum7z7o&documentId=914533008c8111e6a0f68fd135e6f40c&category=TAD>

<sup>48</sup> Republic of Lithuania Law of the Health System of 1994.

<sup>49</sup> Republic of Lithuania Law on Human Communicable Disease Prevention and Control 25 September 1996 No. I-1553 [statute on the Internet]. C2018 [cited 18 August 2018]. Available from: <https://e-seimas.lrs.lt/portal/legalActPrint/lt?jfwid=g0zrzend5&documentId=TAIS.373789&category=TAD>

<sup>50</sup> Ministerial Order: Action plan approval for reducing health inequalities in Lithuania 2014-2023 (Legislation, 2014, No. 2014-10332) [http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc\\_l?p\\_id=478355&p\\_tr2=2](http://www3.lrs.lt/pls/inter3/dokpaieska.showdoc_l?p_id=478355&p_tr2=2)

<sup>51</sup> Law on Human Communicable Disease Prevention and Control. Article 11. Immuno-prophylaxis: “1. Immuno-prophylaxis may only be applied to persons with their consent, except for instances stipulated in other legal acts, and when they are incapable, upon obtaining the consent of their representatives according to the law. “. Law on Health System, Part 1, Chapter 2, Section 1, Art 38: <http://www.litlex.lt/litlex/eng/frames/laws/Documents/164.HTM>

<sup>52</sup> Latvia [Internet]. VENICE III. Available from: [http://venice.cineca.org/documents/latvia\\_ip.pdf](http://venice.cineca.org/documents/latvia_ip.pdf)

<sup>53</sup> The Law on Public Health Monitoring of Republic of Lithuania (3 July 2002, No. IX-1023); The Law on Human Communicable Prevention and Control of Republic of Lithuania (25 September 1996, No. I-1553); Decision of Government of Republic of Lithuania on approval of the list of statistical indicators on children health (8 June 2004, No. 695). [https://osp.stat.gov.lt/documents/10180/0/vaiku+profilaktiniai+skiepijimai\\_metainfo-EN](https://osp.stat.gov.lt/documents/10180/0/vaiku+profilaktiniai+skiepijimai_metainfo-EN)

<sup>54</sup> Law on Human Communicable Disease Prevention and Control 25 September 1996, Chapter 2, Section 1.

diseases, surveillance of Adverse Effects Following Immunization (AEFI) incidence, and monitoring and evaluation of immunization coverage at the national level.<sup>55</sup> With the rollout of the e-Health system, data collection may become even more accessible and efficient.

## Financing

The Lithuanian Health Care System is based on mandatory health insurance (CHI) which is regulated by the Law on Health Insurance.<sup>56</sup> The state health insurance scheme is implemented by the National Health Insurance Fund (NHIF).<sup>57</sup> Those who are insured get their services covered by the Territorial Patient Funds from the NHIF.

Vaccines and other NIP costs are covered by the State budget.<sup>58</sup> Vaccines provided at no cost include: tuberculosis, Hepatitis B, pertussis, tetanus, diphtheria, Influenzae type b, poliomyelitis, measles, mumps and rubella. Vaccines are given to children within the first 24 hours after birth, at two, four and six months, six-seven years old, 12 years old and 15-16 years old.<sup>59</sup>

## Analysis

The Baltic States have similarities in immunization systems — albeit with some differences in the degree of implementation — but the main difference is an immunization requirement. Estonia has *recommended with robust monitoring and follow-up*, in comparison to Latvia with *mandatory immunization with monitoring and follow-up*. Lithuania has a *recommended* approach.

In a comparison across the Baltic States, Estonia is positioned as an innovator and early adopter, based on the successful introduction of several new approaches to health and immunization. Estonia's innovation is exemplified by the electronic health information system (e-Health),<sup>60</sup> which facilitates immunization coverage monitoring and AEFI surveillance, collection and analysis of data, as well as access to immunization records for patients, doctors and officials. This innovation has resulted in positive impact to Estonia's NIP, including better data for evidence-based decision making and the ability respond faster to crises and outbreaks.<sup>61, 62</sup>

Another monitoring mechanism used by both Latvia and Estonia is the requirement for a physician-signed official refusal by individuals declining immunization. This mechanism provides an opportunity for healthcare professionals to follow up with those refusing, supply more information and create another opportunity to vaccinate. In Estonia, where immunization is voluntary, this mechanism reinforces strong implementation and monitoring efforts and supports the country's classification as *recommended with robust monitoring and follow-up*. Latvia also has this mechanism in place, however, it is coupled with an

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<sup>55</sup> Latvia [Internet]. VENICE III. Available from:[http://venice.cineca.org/documents/latvia\\_ip.pdf](http://venice.cineca.org/documents/latvia_ip.pdf)

<sup>56</sup> The Republic Of Lithuania Law On Health Insurance. Available from:<http://www.vlk.lt/sites/en/legislation/national-legislation/Documents/EN%20SDI%20aktuali%202014-07-10.pdf>

<sup>57</sup> Health Insurance System [Internet]. National Health Insurance Fund under the Ministry of Health. Available from:<http://www.vlk.lt/sites/en/health-insurance-in-Lithuania/health-insurance-system>

<sup>58</sup> Law on Human Communicable Disease Prevention and Control 25 September 1996. Article 40. Special Features of the Funding of Communicable Diseases Prevention and Control from State Budget: The following shall be funded from the sum in the State Budget projected for healthcare:

1) according to the list approved by the Government, communicable diseases prevention and control measures are attributed to vital public healthcare measures;

<sup>59</sup> Medical Route In Lithuania [Internet]. Take Care Project. Available from:[https://www.takecareproject.eu/upload/docs/Medical\\_route/MedicalRoute\\_LT\\_EN.pdf](https://www.takecareproject.eu/upload/docs/Medical_route/MedicalRoute_LT_EN.pdf)

<sup>60</sup> First country globally to do so. Estonia used its time as head of the EU Presidency to encourage other countries to adopt and implement eHealth.

<sup>61</sup> Why Estonia is a good place for eHealth (and why you should attend eHealth Tallinn). HIMSS Europe. (2018). Himss.eu. [cited 3 December 2018]. Available from: <https://www.himss.eu/himss-blog/why-estonia-good-place-ehealth-and-why-you-should-attend-ehealth-tallinn>

<sup>62</sup> Novek A. An Overview of Current Estonian Health Information System Architecture: Pitfalls and Prospects (13 October 2017). Tervise ja Healou Infosusteemide Keskus [cited 4 December 2018].

overall monitoring system that is weaker since it has not been properly introduced, established nor enforced.<sup>63</sup> As a result, Latvia is classified as a system with *mandatory immunization with monitoring and follow-up*.

As noted, Estonia implemented the P4P system thereby establishing a set of financial incentives for doctors. Immunization is an indicator of performance,<sup>64</sup> meaning doctors are incentivized to address the issue of refusals and encourage childhood immunization. There are potential drawbacks to this approach (such as data inflation), but the benefit is proactive dialog to address vaccine hesitancy and provide accurate information about immunization benefits, safety and risks. Neither Latvia nor Lithuania provide such healthcare provider incentives.

Latvia is the only Baltic State with a mandatory immunization approach, classified as *mandatory immunization with monitoring and follow-up*. Despite this mandatory requirement, other aspects of the NIP are weaker than Estonia's. For example, Latvia's healthcare system has historically been and remains one of the most under-funded in the European Union, and many citizens pay for services out-of-pocket.<sup>65</sup> Since lack of financing can undermine the quality of services provided, it is an important difference to take into account when comparing the three countries. Ongoing debate surrounds the proposed change from Social Health Insurance (SHI) in Latvia to a National Health Service (NHS) type system, which has hampered efforts to improve the financing situation. Monitoring is another relatively weak part of Latvia's system. Like Estonia and Lithuania, Latvia has working to adopt e-Health. Initiated in 2007, the project has experienced some setbacks and has not been fully implemented.

Political will is a primary driver of success in the introduction of legislative changes, regardless of a recommended or mandatory approach. Latvia, for example, has not developed the same level of political will and continuity as Estonia for its healthcare and by extension its immunization program reforms. Unlike Estonia, Latvia had a lot of political debate and experienced opposition to changes in the health sector. Managerial capacity, a clear and simple vision and a strong political backing were critical factors of success for the Estonian reforms. Latvia has not had such political will and support; many of the legislative and regulatory changes have not been implemented in a timely manner, efficiently or at all. In Estonia's case, political will contributed to successful NIP implementation. In many ways this is self-evident, as the introduction and implementation of law is easier in countries where there is support and harder where there is opposition.

In terms of immunization coverage, there are currently some differences across the Baltic States, with 93 percent coverage for DTP3 in Estonia, 94 percent in Lithuania and 98 percent in Latvia. This four to five percent difference cannot be easily attributed to a statistical error and the data is illustrative of an increasing trend. Aside from being statistically significant, the five percent difference puts Latvia above the 95 percent threshold for herd immunity. Latvia's figures increased significantly since the beginning of the decade, from 91 percent in 2012 to 98 percent in 2016-2017, Estonia's numbers actually decreased from 94 percent in 2012 to 93 percent in 2014-2017, while Lithuania's increased slightly from 93 percent in 2012 to 94 percent in 2016-2017. In the case of Estonia, it seems the mandatory provision, even with weaker implementation, resulted in higher coverage. However, Estonia is an illustrative example and this study does not provide justification for correlation between legislative approach and immunization coverage.

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<sup>63</sup> Pulmanis E. Implementation of the eHealth Project in Latvia: Project audit perspective. State Audit Office of the Republic of Latvia. PM World Journal. 2018 October; 5(10). Available from: <https://pmworldjournal.net/wp-content/uploads/2016/10/pmwj51-Oct2016-Pulmanis-eHealth-project-audit-perspective-featured-paper.pdf>;

<sup>64</sup> Merilind E, Salupere R, Vastra K, Kalda R. Pay for performance of Estonian family doctors and impact of different practice- and patient-related characteristics on a good outcome: A quantitative assessment. *Medicina*. 2016; 52(3): 192-198.

<sup>65</sup> WHO notes on health system financing policy in Latvia: opportunities and challenges in light of international experience [Internet]. World Health Organization. 2016. Available from: [http://www.vsm.gov.lv/images/files/Latvia\\_meeting\\_report\\_WHO\\_2016\\_final\\_13\\_July\\_%281%29.pdf](http://www.vsm.gov.lv/images/files/Latvia_meeting_report_WHO_2016_final_13_July_%281%29.pdf)

The consensus of literature currently available on the relationship between legislative provisions and immunization coverage is that mandatory frameworks for immunization legislation do not result in higher coverage.<sup>66,67, 68</sup> An ASSET<sup>69</sup> study conducted from 2007 to 2013 across 27 European countries to verify whether mandatory immunization in Europe is associated with better childhood immunization coverage rates concluded that countries where immunization was mandatory did not usually reach better coverage than neighboring or similar countries where there was no such legal obligation. The ASSET study referred to Latvia as an example “where vaccinations are mandatory, [but it] does not get better results than other Baltic countries.” In contrast, this study has determined that Latvia does have a slightly better immunization coverage rate in the long-term and has fared better than its neighbors with recommended legislative approaches (Estonia and Lithuania). It is important to clarify that there are likely many factors behind Estonia’s higher coverage rate and Estonia’s legislative framework alone, is unlikely the cause.

## Conclusion

Estonia, Latvia and Lithuania have established robust legal frameworks to support immunization programs and ensure that immunization is prioritized. Each of the Baltic States have reformed their health systems and NIPs to guarantee financing for vaccines, to improve data collection and monitoring systems, and to make procurement more efficient. All three countries are currently achieving relatively high coverage rates and are each developing ways to address vaccine hesitancy.

This case study illustrates that no one legislative approach alone leads to high immunization coverage. Furthermore, it reinforces the concept that legislative approaches to immunization must be tailored to country-specific needs, including political context and the strength of implementation programs. The success of immunization coverage in each country depends on a comprehensive approach to the immunization system.

Given the similarity in context across the Baltics States, the difference in legislative approaches and up to a five percent variance in immunization coverage rates, further study may be worthwhile to explore the relationship between legislative approaches and immunization coverage in Estonia, Latvia and Lithuania. Additional study may yield insight on the impact of recommended and mandatory legislative approaches on coverage, hesitancy and general strength of immunization programs.

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<sup>66</sup> Shaw J, Mader EM, Bennett BE, Vernyi-Kellogg OK, Yang YT, Morley CP. Immunization Mandates, Vaccination Coverage, and Exemption Rates in the United States. *Open Forum Infectious Diseases* 2018;5. doi:10.1093/ofid/ofy130.

<sup>67</sup> ASSET (Action plan on Science in Society related issues in Epidemics and Total pandemics). “Compulsory vaccination and rates of coverage immunisation in Europe” [Internet]. ASSET; 2016 January [cited 2018 Aug]. 6 p. Available from: [http://www.asset-scienceinsociety.eu/reports/pdf/asset\\_dataviz\\_1.pdf](http://www.asset-scienceinsociety.eu/reports/pdf/asset_dataviz_1.pdf)

<sup>68</sup> D.A. Salmon, S.P. Teret, C.R. MacIntyre, D. Salisbury, M.A. Burgess, N.A. Halsey Compulsory vaccination and conscientious or philosophical exemptions: past, present, and future. *Lancet*, 367 (9508) (2006), pp. 436-442

<sup>69</sup> ASSET (Action plan on Science in Society related issues in Epidemics and Total pandemics). “Compulsory vaccination and rates of coverage immunisation in Europe” [Internet]. ASSET; 2016 January [cited 2018 Aug]. 6 p. Available from: [http://www.asset-scienceinsociety.eu/reports/pdf/asset\\_dataviz\\_1.pdf](http://www.asset-scienceinsociety.eu/reports/pdf/asset_dataviz_1.pdf)

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