

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

December 2018

France: Moving towards a more coercive approach to immunization

European Region Matrix: Immunization Legislation

	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?
	YES	YES	YES	YES	YES	NO	YES	YES
COVERAGE INDICATORS	DTP3 (2017) 		IPV 		96%	N/A	MEASLES (cases, 7/2017–6/2018)	2741

▼ Answer Verified by Authoritative Secondary Sources ▼ Answer Verified by Survey

Introduction

France has had mandatory immunization legislation in place since the 1950s. A 2017 legislative change required additional mandatory vaccines and led to a classification of *mandatory immunization with robust monitoring and follow-up*, the highest level, on the “Likert Scale: Assessing Levels of Immunization Legislation” developed by the Sabin Vaccine Institute (Sabin) for this study. This differentiates France from most EU neighbors, except for Belgium and Italy, who generally follow more liberal approaches. Although vaccine coverage in France has not decreased significantly in recent years, the country has faced highly publicized measles outbreaks (in 2008-2011 and currently in 2016-2018). One possible reason behind the swift introduction of this legislative change is the political support of the Ministry of Health (MOH), and Minister of Health, Agnès Buzyn. Minister Buzyn, who assumed office May 17, 2017, is a strong and vocal supporter of mandatory immunization, and employed the use of evidence-based methods (surveys) and science-based arguments to support the introduction of the new legislation with the backing of medical societies and experts. Despite the swift passage of the legislation in 2017, France has a strong anti-vaccine movement. Like Greece, Italy and other countries in the World Health Organization (WHO) European Region,¹ populist movements spread anti-vaccine rhetoric and oppose mandatory vaccines. In France, populist politician Marine Le Pen’s National Rally Party, formerly the National Front, opposes mandatory immunization and publicly questions vaccine safety.² If a populist movement should come to power in France, efforts to change the current mandatory law may occur, as they have in Greece and Italy where similar mandates have lost traction (and in Italy’s case was overturned by the Senate) without sustained political support.

Since mandatory legislative changes were passed in 2017 in France, the focus of this study is the rationale and enabling factors behind the introduction of this legislation, as well as the process of adoption and accompanying measures that were put in place to strengthen compliance. Among these factors is the strong political will on the part of the current administration and the public consultations conducted prior to passing legislation. Given the recent passage of this legislation, this study cannot fully assess the impact on immunization coverage and outbreak trends, but the immediate impact and implementation of the 2017 legislation is examined.

Methodology

This study was carried out by the Sabin Vaccine Institute 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).

¹ The WHO Regional Office for Europe is one of WHO’s six regional offices around the world. It serves the WHO European Region, which comprises 53 countries, covering a vast geographical region from the Atlantic to the Pacific oceans (<http://www.euro.who.int/en/about-us>). We will refer to this area as the European Region throughout this document.

² France looks to curb its growing anti-vaccination movement with a new law. (2017). The Verge. [cited 5 December 2018]. Available from <https://www.theverge.com/science/2017/7/13/15964628/france-vaccination-skeptic-law-vaccine-mandate>

Context and findings

Legislation

Since the 1950s, France has required that all children be vaccinated for diphtheria, tetanus and polio. In November 2017, France approved a new law mandating an additional eight vaccines (Hepatitis B, pertussis, pneumococcal, meningitis [Haemophilus influenzae type B, or Hib], meningitis C, measles, mumps and rubella) for all children under two years old. Effective January 2018, children must be vaccinated against 11 diseases. Those who have not had all their immunizations, including booster shots, will be refused admission to nurseries, schools and camps in France.

Rationale for introducing mandatory legislation: Measles outbreaks

Unlike other countries implementing mandatory vaccines as a response to falling rates of coverage, France has not seen a strong decline in its immunization rates.³ Coverage rates for newer vaccines are below recommended levels, but have nonetheless increased steadily over time. The rate of meningitis C immunization, for example, has increased since introduction a decade ago, from just 48 percent among two-year-olds at the end of 2011 to 71 percent in the same group in 2016.⁴ Overall, vaccine coverage in France for most diseases is high. At the same time, over the last six years, the coverage with booster shots has risen from a low of 67 percent in 2010, to 79 percent in 2016.⁵ Further improvement is needed though. For example, 90 percent coverage is recorded for the first measles shot and only 79 percent coverage for the second.

Coverage numbers may make it difficult to explain why France has introduced coercive measures. However, the increasing number of measles cases and measles-related deaths are likely factors.⁶ Since 2008, measles have caused 10 deaths in France.⁷ France is among the countries with the highest number of measles cases and deaths in the European Region. It has recorded more than 2,600 cases of measles in 2018 (until September), including three deaths and high rates of hospitalization (22%).⁸ It has faced large outbreaks in the past, including one where over 4,000 people were infected in 2011.^{9,10} The

³ Immunization country profiles 2017 [Internet]. UNICEF DATA. 2018. Available from: https://data.unicef.org/wp-content/uploads/country_profiles/France/immunization_country_profiles/immunization_fra.pdf

⁴ Laws are not the only way to boost immunization [Internet]. Nature News. Nature Publishing Group; 2018. Available from: <https://www.nature.com/articles/d41586-018-00660-y>

⁵ Immunization country profiles 2017 [Internet]. UNICEF DATA. 2018. Available from: https://data.unicef.org/wp-content/uploads/country_profiles/France/immunization_country_profiles/immunization_fra.pdf

⁶ Ukraine restores immunization coverage in momentous effort to stop measles outbreak that has affected more than 12 000 this year [Internet]. World Health Organization. World Health Organization; 2018. Available from: <http://www.euro.who.int/en/countries/ukraine/news/news/2018/05/ukraine-restores-immunization-coverage-in-momentous-effort-to-stop-measles-outbreak-that-has-affected-more-than-12-000-this-year>; Mcneil DG. Measles Cases in Europe Quadrupled in 2017 [Internet]. The New York Times. The New York Times; 2018. Available from: <https://www.nytimes.com/2018/02/23/health/measles-europe.html>; Epidemiological update: Measles - monitoring European outbreaks, 15 September 2017 [Internet]. European Centre for Disease Prevention and Control. 2017. Available from: <https://ecdc.europa.eu/en/news-events/epidemiological-update-measles-monitoring-european-outbreaks-15-september-2017>; Measles outbreak in Ukraine kills two [Internet]. Medical Xpress - medical research advances and health news. Medical Xpress; 2018. Available from: <https://medicalxpress.com/news/2018-01-measles-outbreak-ukraine.html>

⁷ Santi P, Assekour H. La loi pour rendre onze vaccins obligatoires sera examinée avant la fin de l'année [Internet]. Le Monde; 2017. Available from: https://www.lemonde.fr/sante/article/2017/07/05/la-loi-pour-rendre-onze-vaccins-obligatoires-sera-examinee-avant-la-fin-de-l-annee_5156364_1651302.html#EiCVqpwYzBcF8KA.v.99

⁸ France measles outbreak: babies hit hardest - VaccinesToday. (2018). VaccinesToday [cited 5 December 2018], Available from: <https://www.vaccinestoday.eu/stories/france-measles-outbreak-babies-hit-hardest/>; Measles cases hit record high in the European Region. World Health Organization (20 August 2018). Euro.who.int [cited 5 December 2018]. Available from <http://www.euro.who.int/en/media-centre/sections/press-releases/2018/measles-cases-hit-record-high-in-the-european-region>

⁹ Antona D, Lévy-Bruhl D, Baudon C, Freymuth F, Lamy M, Maine C, et al. Measles Elimination Efforts and 2008–2011 Outbreak, France. Emerging Infectious Diseases 2013;19:357–64. doi:10.3201/eid1903.121360.

¹⁰ World Health Organization (WHO). WHO EpiData: A monthly summary of the epidemiological data on selected Vaccine-preventable diseases in the European Region [Internet]. Geneva: World Health Organization; 2018 [cited 5 December 2018]. [Table], Table 1: Reported measles cases for the period October 2017 — September 2018 (data as of 07 November 2018). Available from: http://www.euro.who.int/__data/assets/pdf_file/0004/386392/epi-data-oct2017-sept2018-eng.pdf?ua=1

country has committed to eliminating measles under the WHO Global Vaccine Action Plan¹¹ and European Vaccine Action Plan¹² goals.

In many countries, including France, the United States, the United Kingdom and others, these measles outbreaks could be due to the percent of vaccinated individuals falling below the 95 percent “herd-immunity” threshold which protects the rest of the population against infectious diseases like measles.¹³ Herd-immunity is the concept that a community must be comprised of enough immune people so if a person contracts a contagious disease, the disease will not spread¹⁴ among the large number of unvaccinated individuals. As noted above, in France the coverage for measles is at only about 79 percent. As several countries have faced vaccine-preventable disease outbreaks in the last couple of years, many have identified vaccine hesitancy or reluctance by parents to vaccinate their children as one of the causes behind the decreasing immunization coverage rates, France with a reported population hesitancy rate of 41% of surveyed citizens disagreeing that vaccines are safe.¹⁵

Process behind introducing the laws: Surveys and public consultations

Prior to introducing legislative measures, several of the European Region countries have commissioned some type of government mandated public consultation, or have surveyed their populations on the topic of immunization to better understand the causes of hesitancy and to strategize methods to increase vaccine demand, given the national context, population attitudes and other factors. France is one of these countries, and according to surveys, it is also one of the most vaccine-skeptical nations.¹⁶ A recent survey showed that nearly one-third of the French population does not trust vaccines and only 52 percent believe that the benefits of vaccines outweigh their negative effects.¹⁷ Vaccine hesitancy is also present among healthcare workers. About “16-43 percent of French family doctors said they never or only sometimes recommended some specific vaccines.”¹⁸

Aware of these trends in France, a government committee was established to carry out a public consultation to further assess vaccine hesitancy.¹⁹ The committee worked on the premise that “immunization has been a victim of its own success”—people do not see the necessity to vaccinate given the rarity of vaccine-preventable diseases. The perception of some is that the risk and negative side effects of immunization outweigh benefits and this belief is promoted by the anti-vaccine voices. In 2015, then Minister of Health Marisol Touraine (served as Minister of Health from 2012 to 2017), a vaccine supporter, tasked the government committee with launching a public consultation to field the viewpoints of vaccine critics and to encourage them to engage with public health professionals and experts on vaccines

¹¹ Global Vaccine Action Plan: Regional reports on progress towards GVAP-RVAP goals. Geneva: World Health Organization; 2016.

¹² European Vaccine Action Plan 2015-2020. Copenhagen, Denmark: WHO EURO; 2014.

¹³ Funk, Sebastian. Critical immunity thresholds for measles elimination [Internet]. World Health Organization; 2017. Available from: http://www.who.int/immunization/sage/meetings/2017/october/2_target_immunity_levels_FUNK.pdf

¹⁴ Plans P, Torner N, Godoy P, Jané M. Lack of herd immunity against measles in individuals aged <35 years could explain re-emergence of measles in Catalonia (Spain). *International Journal of Infectious Diseases*. 2014;18:81–3.

¹⁵ Larson HJ, Figueiredo AD, Xiahong Z, Schulz WS, Verger P, Johnston IG, et al. The State of Vaccine Confidence 2016: Global Insights Through a 67-Country Survey. *EBioMedicine* 2016;12:295–301. doi:10.1016/j.ebiom.2016.08.042.

¹⁶ Larson HJ, Figueiredo AD, Xiahong Z, Schulz WS, Verger P, Johnston IG, et al. The State of Vaccine Confidence 2016: Global Insights Through a 67-Country Survey. *EBioMedicine*. 2016;12:295–301; Cohen Sep J. France most skeptical country about vaccine safety [Internet]. American Association for the Advancement of Science; 2017. Available from:

<http://www.sciencemag.org/news/2016/09/france-most-skeptical-country-about-vaccine-safety>

¹⁷ Les Français font de moins en moins confiance aux vaccins [Internet]. *Le Monde*; 2016. Available from:

https://www.lemonde.fr/sante/article/2016/10/24/les-francais-font-de-moins-en-moins-confiance-aux-vaccins-selon-une-etude_5018964_1651302.html; Katie Forster. France will make all vaccinations compulsory by law [Internet]. *The Independent*; 2017. Available from: <http://www.independent.co.uk/news/world/europe/france-vaccination-mandatory-2018-next-year-children-health-measles-dying-anti-vaxxers-edouard-a7824246.html>;

Vaccins obligatoires: “Entre 10 et 20 millions d’euros”, annonce Agnès Buzyn [Internet]. *RTL.fr*. Available from: <https://www.rtl.fr/actu/politique/vaccins-obligatoires-entre-10-et-20-millions-d-euros-annonce-sur-rtl-agnes-buzyn-7789233053>

¹⁸ Why vaccination rates in the West are too low [Internet]. *The Economist*; 2016. Available from:

<https://www.economist.com/blogs/economist-explains/2016/03/economist-explains-2>

¹⁹ Présentation du rapport de conclusions du comité d’orientation [Internet]. *Concertation Citoyenne Sur La Vaccination*; 2016.

Available from: <http://concertation-vaccination.fr/wp-content/uploads/2016/11/DP-30.11-Concertation-citoyenne-sur-la-vaccination.pdf>

and infectious diseases. This consultation came on the heels of a petition denouncing the use of aluminum adjuvants in vaccines that had reached a million signatures. The consultation curated the knowledge of medical experts, generated recommendations given by citizen juries of both laypeople and experts randomly polled, and fielded ideas solicited from an internet platform. Acting on the results of this unprecedented consultation, in November 2016 the organizing committee made several recommendations for reforming the country's vaccine policies.²⁰

The committee recommended that the number of mandatory vaccines be temporarily increased and underlined that additional measures would be necessary to increase immunization coverage as well as restore confidence in vaccines. It recommended that mandatory health insurance fully cover the purchase of vaccines and that a compensation scheme covering adverse effects be established, since certain vaccines are mandatory. It also stated there must be sufficient supply of mandatory vaccines and that a new electronic immunization passport be implemented to improve monitoring. The government used these recommendations to back the introduction of a bill increasing the number of mandatory vaccines, as well as removing several exemptions.

Another factor influencing the passage of the legislation was the requirement issued by the State Council of France in 2017.²¹ This requirement came after the Constitutional Court ruled that mandatory immunization is legal under the French Constitution. The constitutionality of the mandatory provision was raised by Samia and Marc Larères, who asked the Constitutional Court for a “priority preliminary ruling on the issue of constitutionality” (QPC) after a regional court in Auxere referred their case in January 2016.²² In January 2016, the regional court sentenced the couple to a two-month suspended jail sentence for refusing to vaccinate their two young children.²³ The couple refused to vaccinate their children because non-mandatory vaccines were included in the hexavalent vaccine available.²⁴ In 2015, prior to the new legislation, only diphtheria, tetanus and polio were mandatory, however, the hexavalent vaccine available from vaccine suppliers in France included an additional three antigens against pertussis, Haemophilus influenzae type B and hepatitis B. The parents initially objected to this defacto mandatory immunization with six antigens, since a vaccine with only three mandatory ones was not available and single-antigen vaccines were not available. Later in the trial, the couple confirmed that they received the vaccines containing only the three mandatory antigens from Sanofi Pasteur, but still refused to vaccinate their children with a “toxic product.” They were given a two-month suspended jail sentence. The case became high-profile in France, further fueling anti-vaccine and anti-establishment rhetoric.

Following the Larère case, the French State Council asked the MOH to draft new legislation and harmonize the legal provision with the available vaccine supply.²⁵ This harmonization likely was a factor in eight vaccines becoming mandatory to avoid future instances where non-mandatory vaccines are offered together with mandatory ones in a single polyvalent vaccine.

One of the arguments used against introducing mandatory immunization legislation is that it can cause a backlash in part of the population and/or lead to increased litigation which results in higher costs for the state. Carrying out a proper assessment of the population's attitudes and analyzing the causes behind

²⁰ Ward JK, Colgrove J, Verger P. Why France is making eight new vaccines mandatory. *Vaccine*. 2018; 36(14):1801–3.

²¹ ILR, M., & ILR, M. (2018). Mandatory Vaccination in France. *MSU International Law Review*. Retrieved 19 November 2018, from <https://www.msuir.org/msuir-legalforum-blogs/2017/11/30/mandatory-vaccination-in-france>

²² Vaccination : deux mois de prison avec sursis contre les époux Larère. (7 January 2016). France Bleu [cited 5 December 2018]. Available from <https://www.francebleu.fr/infos/faits-divers-justice/vaccination-2-mois-de-prison-avec-sursis-contre-les-epoux-larere-1452190526>

²³ Browne R. French couple given suspended jail time for refusing to vaccinate children. *Brisbane Times* 2016.

<https://www.brisbanetimes.com.au/world/french-couple-jailed-jailed-for-refusing-to-vaccinate-children-20160108-gm1thy.html>

²⁴ This legal “incoherence” was utilized in court, when Samia and Marc Larère were charged under two legal provisions for refusing to vaccinate their child. First, a provision in the Code of Public Health (*le code de la santé publique*, art. L.3116-4) that imposed a fine of 3,750 euros and up to six months in jail for those who do not receive—or allow those under their guardianship to receive—mandatory vaccinations.²⁴ And second, a provision in the Criminal Code that criminalizes neglect of parental duties “to the point of risking the health... of a minor child,” with a fine of 30,000 euro and up to two years in prisons as penalty.

²⁵ Ward, Jeremy K., et al. “Why France Is Making Eight New Vaccines Mandatory.” *Vaccine*, vol. 36, no. 14, 2018, pp. 1801–1803., doi:10.1016/j.vaccine.2018.02.095.

hesitancy and delays in immunization could potentially help, if not alleviate, these risks. France followed this path, using the conclusions and recommendations from the public consultation to implement legislative changes. Following the backlash to mandatory immunization legislation in Greece and Italy, which in Italy has resulted in the Senate overturning the Italian mandated immunization law,²⁶ the implementation of France's public communications strategy and sustained political will championed by the MOH for such a law may be critical factors to achieving high immunization coverage and mitigating vaccine hesitancy.

Process behind introducing the laws: Political will and support from the scientific community

Political will and the support of the scientific community were key elements in the success of France's legislative initiative. Minister Buzyn advocated for the introduction of mandatory vaccines as the only possible solution given the measles outbreaks.²⁷ She stated: "We are sending a very strong message to the public that the vaccine emergency is driven by fake news, which has spread misinformation about vaccine safety."²⁸ In her argument, she leaned on the results of the public consultation conducted in 2015 on vaccine hesitancy, and the conclusions and recommendations of the government committee. She provided further justification, citing recent opinion polls that showed that if DTP3 vaccine was made voluntary an additional 15 percent of parents would not vaccinate their children.²⁹

In 2016, France conducted open citizen debates and created avenues to voice opinions and present critiques during the public consultation about the law and its contents, leading to greater acceptance on the part of the population. In 2017, French health professionals also mobilized in support of the ministerial initiative, 200 leading doctors signed a petition in June backing the draft legislation rendering 11 vaccines mandatory.³⁰ Furthermore, in the same year, the academic and medical societies and the Medical Academy – for the first time – took a stand in favor of immunization in 2017.³¹ Elected officials also voted favorably; the bill was supported by an overwhelming majority during votes in the National Assembly and Senate.

²⁶ Roberts H. Italy Senate overturns mandatory vaccination law [Internet]. Financial Times; 2018. Available from: <https://www.ft.com/content/afd472be-996c-11e8-9702-5946bae86e6d>

²⁷ Agnès Buzyn : "Contre la théorie du complot, il n'existe malheureusement aucun vaccin" [Internet]. Franceinfo; 2018. Available from: https://www.francetvinfo.fr/sante/soigner/agnes-buzyn-contre-la-theorie-du-complot-il-nexiste-malheureusement-aucun-vaccin_2547043.html ; Faverau E. Vaccins : les onze injonctions d'Agnès Buzyn [Internet]. Liberation.fr; 2018. Available from: http://www.liberation.fr/france/2018/01/01/vaccins-les-onze-injonctions-d-agnes-buzyn_1619833; Vaccins obligatoires : "Entre 10 et 20 millions d'euros", annonce Agnès Buzyn [Internet]. RTL.fr. Available from: <https://www.rtl.fr/actu/politique/vaccins-obligatoires-entre-10-et-20-millions-d-euros-annonce-sur-rtl-agnes-buzyn-7789233053>; La ministre de la Santé assure que les adjuvants ne sont pas nocifs [Internet]. RTL.fr. Available from: <https://www.rtl.fr/actu/debats-societe/vaccins-la-ministre-de-la-sante-assure-que-les-adjuvants-ne-sont-pas-nocifs-7789505216> ; Pourquoi Agnès Buzyn a fait des vaccins obligatoires une priorité du quinquennat [Internet]. RTL.fr. Available from: <https://www.rtl.fr/actu/politique/pourquoi-agnes-buzyn-a-fait-des-vaccins-obligatoires-une-priorite-du-quinquennat-7790587864>

²⁸ Which vaccines are mandatory in Italy? [Internet]. Vaccines Today; 2017. Available from: <https://www.vaccinestoday.eu/stories/vaccines-mandatory-italy/>

²⁹ Cot BD. Agnès Buzyn et les vaccins: "Je n'irai pas mettre un gendarme devant chaque crèche" [Internet]. L'Express.fr; 2017. Available from: https://www.lexpress.fr/actualite/societe/sante/agnes-buzyn-et-les-vaccins-je-n-irai-pas-mettre-un-gendarme-devant-chaque-creche_1964380.html

³⁰ Vaccins: 200 médecins lancent un appel pour une vaccination obligatoire [Internet]. L'Express.fr.; 2017. Available from: https://www.lexpress.fr/actualite/societe/sante/vaccins-200-medecins-lancent-un-appel-pour-une-vaccination-obligatoire_1922643.html

³¹ Cot BD. Agnès Buzyn et les vaccins: "Je n'irai pas mettre un gendarme devant chaque crèche" [Internet]. L'Express.fr; 2017. Available from: https://www.lexpress.fr/actualite/societe/sante/agnes-buzyn-et-les-vaccins-je-n-irai-pas-mettre-un-gendarme-devant-chaque-creche_1964380.html

Measures to support the implementation and impact of legislation mandating immunization

Although stipulated under a separate decree³² from the mandatory immunization law, French parents are now required to provide their child's immunization records upon kindergarten and school enrollment. If a child has not been vaccinated in accordance with the immunization calendar, they are required to catch up within a three-month period or provide a valid medical exemption.³³ France has, however, revoked the previous penalties³⁴ for non-compliance, that ranged from administrative to criminal (as was imposed on the Larères),³⁵ and instead is relying on monitoring and education campaigns for both parents and school or medical establishment workers. Additional measures will be made to persuade rather than impose this decision on the public. Minister Buzyn introduced an annual progress report that will be publicly available, showing the results of the new immunization measures.

Additionally, the Minister assured the public that all mandatory vaccines will be 100 percent funded, as per the Public Health Code,³⁶ with 65 percent of the price reimbursed by Medicare, and 35 percent by complementary insurance. "The additional cost for Medicare of the vaccine extension is estimated between 10 and 20 million euros," detailed the Minister.³⁷ The French government is also committed negotiations with vaccine suppliers to ensure the necessary stocks of vaccines are available.³⁸

Aside from harmonizing the legislation to correspond to the realities of the vaccine supply, the legislative changes introduced by France also update their national immunization schedules in line with current health recommendations and ensure that the newly recommended vaccines are perceived to be as important for children as the previous mandatory ones. There is concern that the mandatory vaccines will be perceived as the only "important ones" to give to a child. This perception is reinforced in cases where the mandatory vaccine costs are fully financed, while the recommended vaccines are partially covered or not covered at all, as was the case in France prior to mandating the additional eight vaccines. Full financial coverage also helps to ensure that vaccines are equally accessible to all regardless of social, geographical or economic status.

The financial provisions covering the costs of the newly mandatory vaccines are an example of the additional measures introduced by or in conjunction with legislation to reinforce the implementation of the law. As described above, other accompanying measures included improved monitoring and stronger

³² Décret n° 2018-42 du 25 janvier 2018 relatif à la vaccination obligatoire [Internet]. Légifrance; 2018. Available from: <https://www.legifrance.gouv.fr/affichTexte.do?cidTexte=JORFTEXT000036543886&categorieLien=id>

³³ Loi sur le financement de la Sécurité sociale (PFSS), l'article 49.

³⁴ A provision in the criminal code that criminalizes neglect of parental duties "to the point of risking the health... of a minor child", with a fine of 30,000 euros and up to two years in prisons as penalty (article 227-17: "Le fait, par le père ou la mère, de se soustraire, sans motif légitime, à ses obligations légales au point de compromettre la santé, la sécurité, la moralité ou l'éducation de son enfant mineur est puni de deux ans d'emprisonnement et de 30 000 euros d'amende").

³⁵ The new law removed the provision of the Public Health Code that foresaw a maximum of 6 months imprisonment and a 3750 euros fine for refusing to vaccinate your children with vaccines mandated by law.

³⁶ Article L3111-11 "Vaccinations carried out by the institutions and organizations authorized under conditions defined by decree are free. Local and regional authorities may carry out vaccination activities under an agreement concluded with the State. This agreement specifies the objectives pursued, the categories of beneficiaries, the means implemented, the amount of the subsidy granted by the State, the data whose transmission to the State is mandatory, the methods for evaluating the actions undertaken as well as that, as the case may be, relations with other bodies working in the same field. Vaccinations carried out under this agreement are free. For the insured persons or their dependents, the expenses related to the vaccines are covered by the health insurance organizations to which they belong and, for the beneficiaries of the medical aid of the State, under the conditions provided for under V of Book II of the Code of Social Action and Families and in the manner provided for in Article L. 182-1 of the [Social Security Code](#) (see [European Immunization Policy Database](#)).

³⁷ Santi P, Assekour H. La loi pour rendre onze vaccins obligatoires sera examinée avant la fin de l'année [Internet]. Le Monde; 2017. Available from: https://www.lemonde.fr/sante/article/2017/07/05/la-loi-pour-rendre-onze-vaccins-obligatoires-sera-examinee-avant-la-fin-de-l-annee_5156364_1651302.html#EiCVqpwYzBcF8KAv.99

³⁸ Santi P, Assekour H. La loi pour rendre onze vaccins obligatoires sera examinée avant la fin de l'année [Internet]. Le Monde; 2017. Available from: https://www.lemonde.fr/sante/article/2017/07/05/la-loi-pour-rendre-onze-vaccins-obligatoires-sera-examinee-avant-la-fin-de-l-annee_5156364_1651302.html#EiCVqpwYzBcF8KAv.99 « Des discussions vont par ailleurs être engagées avec les laboratoires pharmaceutiques pour éviter les pénuries, concernant entre autres le vaccin contre l'hépatite B. Des pénuries qui, bien souvent, freinent la vaccination ».

provisions regarding immunization for school admission. These measures help with follow-up, ensuring that those who hesitate or delay are given another chance to immunize.

Analysis

Although French officials were able to garner political support to pass legislation mandating vaccines, the long-term effects on vaccine coverage are unclear. The key factors in the passage of this law were the widespread consultations and engagement between the public and medical experts, elimination of criminal penalties with simultaneous strengthening of school requirements, addressing further barriers to immunization, such as cost, by mandating full payment for the vaccines by the government and harmonizing the legislation in accordance with the available vaccine supply, as well as introducing public information education campaigns. After assessing the attitudes toward immunization among the population and among health professionals, France has recognized vaccines and public health as critical for investment and created single sources of publicly available, scientifically supported, reliable information for the public and introduced additional instruction opportunities for health professionals.

Minister Buzyn stressed that the coercive measures are a “last resort in the face of an emergency” and that the long-term goal for the French MOH is to change French attitudes towards immunization, educating and convincing the population that the benefits outweigh the associated risks. The results of the 2015 public consultation carried out by the government committee recommended that the mandatory measures be temporary and subject to review. Although the new legislation does not emphasize that the mandate is temporary, the French government has pledged to annually review the compliance with and impact of the new law and make the results of the evaluation public (starting in the last trimester of 2019).³⁹ Monitoring the implementation and impact will help assess whether the mandatory legislative provisions can increase vaccine coverage in France.

Given the reversal of vaccine mandates and poor enforcement in the European region, in the coming years France will need to continue to address vaccine hesitancy and monitor the rise of anti-vaccine movements. Publicizing the results of monitoring and evaluation measures should, in theory, increase confidence in these interventions and ensure government transparency.

One of the challenges of the introduction of more mandatory legislation in France is that it has united two unlikely groups against immunization, far right nationalists and far-left ecologists.⁴⁰ As noted earlier, Marine Le Pen, the conservative French politician, has raised doubts about the safety of vaccines and stated that she is opposed to the new mandatory law as it takes free will away from parents who are opposed to immunization. Anti-establishment parties from across the political spectrum have expressed sympathy with vaccine skeptics and have expressed mistrust of vaccines. This can lead to increased vaccine hesitancy, even in areas where coverage is high. Lack of political support will likely result in delays in adoption or weakening of legal provisions, whether they are mandatory or recommended, leading to a negative impact on coverage. The rise of populist, antiestablishment parties threatens to have further adverse effects as they support and legitimize vaccine refusal. If any of these groups are elected, they may overturn the mandatory provision. In Italy, this has already occurred and immunization is no longer mandatory.

³⁹ LOI n° 2017-1836 du 30 décembre 2017 de financement de la sécurité sociale pour 2018 (1) [Internet]. Légifrance; 2018. Available from: <https://www.legifrance.gouv.fr/eli/loi/2017/12/30/CPAX1725580L/jo/texte>

⁴⁰ Mandatory Vaccination in In France [Internet]. MSU International Law Review. Available from: https://www.msuir.org/msuir-legalforum-blogs/2017/11/30/mandatory-vaccination-in-in-france#_ftn17

Conclusion

Given the recent passage of 2017 mandatory legislation, it is premature to determine if changes in vaccine coverage rates are in part due to strengthening of the mandatory legislation. If in the future a change in coverage is significant and can be shown to have occurred after the introduction, assessing an association between the mandatory legislation introduced and changes in long-term coverage may be possible.

Even if such an association can be shown in the case of France, this does not indicate that similar vaccine mandates will work in other countries in the same way. Many factors need to be considered when reviewing the success of mandatory provisions, including the citizens' attitude toward and acceptance of coercive or mandatory legislation. In most countries reviewed in this study, the introduction of mandatory measures have led to public protests. Knowing that such a backlash is possible, France conducted research to assess the potential fallout, publicize the mandate prior to implementation and gauge whether its impact would be significant enough to negate the potential benefits.

Another factor when considering the success of mandatory law is the assessment of the overall need and immunization system capacity – the calculated burden of diseases and outbreaks, coverage trends, financing mechanisms and available supply, technical capacity to implement and monitor compliance, the education system and its respective reach and regulations. France conducted a thorough assessment to ensure the country had a robust immunization system in place. These and a host of other factors, many of them country-specific, need to be considered by countries contemplating similar changes prior to proposing legislation.

It is important to keep in mind that France enjoyed a favorable political environment and had strong immunization champions for the introduction of the mandates. Legislation introduced in other countries with comparably favorable circumstances, for example, Greece and Italy, was vulnerable to reversals and declining coverage when political dynamics shifted. Sustained political will is an important factor to consider as countries contemplate adopting immunization mandates; introducing legislation may be ineffective, short-lived or unacceptable to the population.

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