

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

December 2018

Moldova:

Reviewing a recommended approach with mandatory requirements for school attendance

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	NO	NO	NO	YES	YES	YES	YES
COVERAGE INDICATORS		DTP3  88%					MEASLES (cases, 7/2017–6/2018)	37
		IPV  N/A						

Answer Verified by Authoritative Secondary Sources

Answer Verified by Survey

Introduction

The case of Moldova provides an interesting example of the benefits and challenges of a recommended approach that incorporates some mandatory requirements for specific groups. In Moldova, vaccines on the national immunization calendar are free and voluntary, although children must meet all routine immunization requirements to enter educational and other collective institutions. Moldova is classified as a *recommended with mandatory requirements for school attendance* approach on the “[Likert Scale: Assessing Levels of Immunization Legislation](#)” developed by the Sabin Vaccine Institute (Sabin) for this study. Although there is no mandatory provision in health- and immunization-related legislation, a provision addressing school entry exists in education-related legislation. An enforceability mechanism is implemented through the school or kindergarten entry restriction.

Moldova’s National Immunization Program (NIP) is an example of a gradual approach to introducing new vaccines, with mechanisms in place to ensure that the government has adequate financing to pay for them and that coverage rates are sustained and improved over time. With planning organized through a five-year NIP, new vaccines have been added to the immunization calendar and accompanying measures have been introduced to ensure program viability.

Coverage trends

After declaring its independence from the Soviet Union in 1991 and adopting its constitution in 1994, Moldova’s health programs, including the NIP, faced many challenges. However, immunization coverage was high (at or above 85 percent) from the end of the 1990s until a recent dip.¹ This strong performance is likely linked to the fact that Moldova has prioritized immunization through its legal framework by guaranteeing immunization as a public good, defining the immunization calendar and establishing general regulations for vaccine procurement and administration. Introduction of health insurance in 2004 improved financing of the health system, access to services and financial protection of the population.

However, around 2009, immunization rates started dropping and vaccine hesitancy became more pronounced. It has been observed not only among parents, but also among some nurses and doctors who have doubts about the effectiveness of vaccines. Parents and healthcare providers may also have a negative perception about the quality of some vaccines. Even though all vaccines available in Moldova are World Health Organization (WHO) prequalified products and follow recognized safety standards, some people believe that vaccines available through public providers are low quality and they prefer to go to private clinics for vaccination. Given such perceptions and the fact that the law² requires a child to be immunized prior to attending kindergarten, several parents have voiced concern that their children’s right to education is being infringed upon. The Constitutional Court has upheld the mandatory immunization requirement for kindergarten attendance several times, ruling that it must be enforced in 2013,³ and as recently as October 2018. However, this has not increased coverage,⁴ illustrating that in this case, a purely legislative or coercive approach does not necessarily directly impact coverage. With the new NIP

¹ Anon. Moldova: WHO and UNICEF estimates of national immunization coverage (WUENIC) [Internet]. World Health Organization, 2017. Available from: http://www.who.int/immunization/monitoring_surveillance/data/mda.pdf

² Law of the Republic of Moldova [Internet]. Law on State Supervision on Health, 2009. Available from: <http://cis-legislation.com/document.fwx?rgn=27147>

³ In 2013 the Constitutional Court upheld the constitutionality of the vaccination requirement for educational institution attendance: <https://www.balcanicaucaso.org/eng/Areas/Moldova/Resistance-in-Moldova-to-health-law-on-mandatory-vaccination-133929>; in October 2018 the Constitutional Court held that the provisions of Article 52 para. (6) of the Law no. 10 of 3 February 2009 on State oversight of public health in that they are consistent with Articles 28, 35 and 16 of the Constitution: Press release of the Constitutional Court of Moldova - <http://constcourt.md/libview.php?l=en&id=1317&idc=7&t=/Media/News/The-Constitutional-Courts-Solution-on-the-Issue-of-Childhood-Vaccination-and-Their-Access-to-Educational-and-Recreational-Institutions/>

⁴ Anon. Moldova: WHO and UNICEF estimates of national immunization coverage (WUENIC) [Internet]. World Health Organization, 2017. Available from: http://www.who.int/immunization/monitoring_surveillance/data/mda.pdf

(2016-2020), the government introduced measures to improve communication and educate healthcare providers to increase vaccine uptake and counter vaccine hesitancy. For the first time, the NIP also included a budget for a communication strategy. With the communication strategy in place for such a short period of time, it is too soon to determine tangible impact in improving coverage.

With the current legislative framework for immunization, the government's commitment to immunization, including consecutive NIPs and interventions, and technical support from donors and partners, Moldova reversed a declining trend for the first time in the early 2000s. Authorities are retaining the current immunization requirements and supplementing them with a communications strategy. The goal of such renewed efforts is to bolster compliance with immunization requirements, improve health literacy among the population and ultimately, expand immunization coverage.

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, and 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

Immunization legislative framework

Moldova has clear and targeted legislative provisions that have helped prioritize immunization. Further, Moldova has prioritized immunization and leverages the NIP to help strengthen vaccine uptake which, to date, has negated the need to strengthen the legislative framework toward a stronger mandatory approach.

The right to health

Moldova's 1994 Constitution guarantees the right to health⁵ (see Database) and requires the state to provide a basic level of health protection to all citizens. This is the foundation for the country's immunization policy (see Database).⁶ In order to further improve health outcomes, the Parliament approved the Law on Mandatory Health Insurance (1998)⁷ and introduced a state-funded free health service package in 1999.⁸

⁵ Art 36 : «Right to Health Protection

(1) The right to health protection is guaranteed.

(2) The minimum health insurance provided by the State shall be free of charge.

(3) The structure of the national health security system and the means aimed at protecting the physical and mental health of the individual shall be provided for by organic law.”

⁶ Constitution of the Republic of Moldova Article 36 Right to Health Security July 29, 1994. Available from:

http://www.wipo.int/wipolex/fr/text.jsp?file_id=427200#LinkTarget_1673

⁷ Parliament of Republic of Moldova. Law On Mandatory Medical Insurance-No. 1585 (1998). Available from: <http://www.law-moldova.com/laws/rus/obeazatelinom-meditinskom-strahovanii-ru.txt> [Accessed 5th March 2018].

⁸ Law on the Minimum Package of Free-of-Charge Health Care Guaranteed by the State 1999: Chisinau, Moldova. 1999.

Health system financing and immunization

Given the economic challenges that Moldova faced after the collapse of the Soviet Union, limited funding was available to implement many of the laws that address immunization. The introduction of mandatory health insurance⁹ (see Database) and the establishment of the National Health Insurance Company (CNAM) in 2004 (see Database)¹⁰ improved financing of the health system, access to services and financial protection of the population. As a result of the introduction of mandatory health insurance, the financing scheme included the Government Health Insurance Fund, which now covers all expenses for the maintenance and overhead costs of healthcare facilities at the sub-national level (district and municipal levels), including items such as payroll, outreach efforts and immunization.¹¹

The National Health Policy (2007-2016) (see Database) was followed by the Health System Development Strategy (2008-2017)¹² specifically aimed at expanding insurance coverage through financial incentives and requiring an insurance policy when renewing government-issued licenses. It also decreed that children should have universal access to essential health services, including immunization.

Strengthening surveillance and introduction of mandatory immunization for children to enroll in kindergarten

The Sanitary Epidemiological Service was traditionally oriented toward communicable disease prevention and control, regulation over exposure to risk factors, surveillance and law enforcement. In 2009, this entity was reformed by Law no. 10 on February 3, 2009 into the State Service for Public Health Surveillance.¹³ The reformed State Service for Public Health Surveillance comprises the National Public Health Center, two municipal Public Health Centers (Chişinău and Bălţi) and 34 district Public Health Centers. The reform was oriented toward aligning national legislation and institutional structure and capacity with international and European community norms, International Health Regulations (2005) and to respond to new challenges that affect the population's health status. This included strengthening surveillance, prevention and control over communicable and non-communicable diseases, health promotion, information and health education, and assessment of the social determinants of health. Management of the NIP remains one of the leading areas of work of the State Service for Public Health Surveillance. The Law on State Surveillance of Public Health (see Database)¹⁴ strengthened the government's ability to monitor communicable diseases and also introduced the requirement that children need to receive all vaccines included in the national schedule to enroll in kindergarten.

In accordance with Government Decision no. 705 dated September 6, 2017 on the creation of the National Public Health Agency and the reorganization of some legal entities,¹⁵ the National Public Health Agency was created. The new Agency is an administrative and legal authority within the Ministry of Health, Labor and Social Protection and was created by merging a number of older authorities.¹⁶ It remains to be seen how this reform will impact immunization, but the primary role given to the National

⁹ Law on Mandatory Health Insurance 2004. Chisinau, Moldova.

¹⁰ Law on Mandatory Health Insurance 2004. Chisinau, Moldova.

¹¹ Government of the Republic of Moldova. Comprehensive Multi-Year Plan for Immunization Programme 2011-2015. Chisinau, Moldova. Available from: http://www.nationalplanningcycles.org/sites/default/files/country_docs/Moldova/moldova-comprehensive_multi-year_plan_for_2011-2015_-_year_2011.pdf

¹² Republic of Moldova National Public Health Strategy 2014-2020. Chisinau, Moldova (2014)

¹³ State Service for Public Health Surveillance Law No. 10 February 3, 2009. State Service for Public Health Surveillance. Chisinau, Moldova (2009)

¹⁴ Law on State Surveillance of Public Health No. 10-XVI, 3 February 2009. State Service for Public Health Surveillance. Chisinau, Moldova (2009).

¹⁵ Decision No. 705 on the creation of the National Agency for Public Health and the reorganization of some legal entities June 9, 2017. Official Gazette Nr. 329 art No: 809. Chisinau, Moldova 2017. Available from: <http://lex.justice.md/md/371297/>

¹⁶ The merged authorities included National Assessment and Accreditation Council, National Center for Health Management, National Public Health Center, the municipal Public Health Centers from Chisinau and Balti, 34 district Public Health Centers and the Pharmaceutical and Medical Devices Inspectorate of the Medicines and Medical Devices Agency.

Public Health Agency suggest that immunization, as the key preventative intervention available to public health policy makers post-reform, should remain strong in Moldova.

Immunization-specific legislative provisions and the evolution of the NIP

The government specifically prioritized immunization through the implementation of several medium-term NIPs.¹⁷ They helped define goals, objectives and targets in the area of preventing diseases by concerted immunization activities and commitments made by the National Government sectors and institutions, local authorities, civil society and international partners. The two latest NIPs also refer to “obligatory immunization.”

The first ever NIP was approved for the period 1994-2000. This program introduced universal immunization against hepatitis B in newborns and adolescents and led to a 15.4-fold reduction in hepatitis B morbidity in children and adolescents (from 1002 cases in 1989 to 65 in 2004).¹⁸ The immunization program for 2001-2005 represented a new phase and aimed at the permanent protection of the population against multiple infectious diseases, namely: polio, diphtheria, tetanus, pertussis, viral hepatitis B, measles, mumps, rubella and tuberculosis in children. The NIP for 2006-2010 guaranteed immunizations free of charge against 10 infectious diseases by adding meningitis (Haemophilus influenzae type B, or Hib).

Immunization has been and remains one of the government’s prioritized interventions and as a result, coverage increased to 95-98 percent in 2003-2007. However, the existence of vaccine hesitancy and anti-vaccine sentiment among parents and medical personnel,¹⁹ and a decrease in coverage, became evident during the 2011-2015 NIP. The plan states: "Under the influence of the anti-vaccination propaganda, which has grown in the country since 2009, the level of immunization was reduced from 95-98 percent in 2003-2008 to 90-92 percent in 2015, lower in certain municipalities, as well as in the left bank of the Dniester (80-90 percent)."²⁰ The decreasing coverage has been partially attributed to anti-vaccine rhetoric and a lack of effective practices to educate parents and address their concerns. The coverage declined to 80-97 percent in 2015 and was even lower in certain municipalities.²¹ The present NIP for 2016-2020 is the fifth, and aims at “eliminating or reducing morbidity, disability and mortality from preventable diseases by ensuing mandatory immunization for 13 antigens guaranteed by the state.”²² The goal is to achieve and sustain 95 percent immunization coverage by 2020. The Ministry of Health approved an accompanying Communication for Behaviour Change Strategy in February 2017, aiming to achieve high levels of sustained and equitable immunization coverage, improve public trust in vaccines and create higher demand for immunization.

¹⁷ National Immunization Plans are passed by government decree and hence constitute legislation.

¹⁸ Anon. Moldova: WHO and UNICEF estimates of national immunization coverage (WUENIC) [Internet]. World Health Organization, 2017. Available from: http://www.who.int/immunization/monitoring_surveillance/data/mda.pdf

¹⁹ Vaccine communication review in the Republic of Moldova “Communities of primary caregivers who question the quality and necessity of immunization are becoming an increasing challenge in the Republic of Moldova” [Internet]. World Health Organization Regional Office for Europe. 12 Oct 2014. Available from: <http://www.euro.who.int/en/health-topics/disease-prevention/vaccines-and-immunization/news/news/2014/12/vaccine-communication-review-in-the-republic-of-moldova>

²⁰ Government of the Republic of Moldova. Comprehensive Multi-Year Plan for Immunization Programme 2011-2015. Chisinau, Moldova. Available from:

http://www.nationalplanningcycles.org/sites/default/files/country_docs/Moldova/moldova-comprehensive_multi-year_plan_for_2011-2015_-_year_2011.pdf

²¹ Anon. Moldova: WHO and UNICEF estimates of national immunization coverage (WUENIC) [Internet]. World Health Organization, 2017. Available from: http://www.who.int/immunization/monitoring_surveillance/data/mda.pdf

²² The program is elaborated in accordance with the provisions of the Health Protection Law no.411-XIII of 28.03.1995 (Monitor Rule Official of the Republic of Moldova , 1995, no.34 art.373) , Law no.10-XVI of February 3, 2009 on state public health surveillance (Official Gazette of the Republic of Moldova, 2009, No. 67, article 183), the Law no. 263-XVI of 27 October 2005 on the rights and responsibilities of the patient(Official Journal of Moldavian Mold Ova , 2005,n . 176-181 , art .867) , the National Health Policy, approved by the Government Decision no.886 of 6 August 2007 (Official Gazette of the Republic of Moldova, 2007, No. 127-130, Article 931), the National Public Health Strategy for 2014-2020, approved by the Government Decision no.1032 of 20 December 2013 and Recommendations of the World Health Organization

Analysis

Despite its commitment to immunization, a number of challenges threaten Moldova's progress and may prompt adjustments to the legislative framework for immunization.

Skewed perceptions of vaccines and vaccine hesitancy

As mentioned above, in 2009 with the Law on Public Health Surveillance, the government introduced the requirement that children be immunized in order to attend educational institutions. Protest has been a common reaction to the introduction of more compulsory clauses or legislation in every country where such clauses have been introduced. The introduction of legislation containing immunization as a requirement has led to protests in several countries, including France, Lithuania, Poland and Romania. In Moldova's case, vaccine hesitancy can be partially attributed to anti-vaccine campaigns in social media, parents not receiving sufficient information from family physicians and lack of awareness about the dangers of vaccine-preventable diseases.²³ The 2011-2016 NIP also mentions that anti-vaccine propaganda has grown in the country since 2009. In addition to parents' hesitancy, physicians have questioned the quality of vaccines administered in the public domain.²⁴ A recent article captured this viewpoint: "Laura Turcan works at the National Center for Preventive Medicine and says that Moldova meets all the conditions for risk-free immunization. However, she said she recognizes that private clinics often buy vaccines from countries with higher standards, where products are of better quality. 'Vaccines in public clinics are purchased with state funds, which are limited, so they are bought at cheaper prices and therefore are of lower quality. They are made in countries such as India, Vietnam and Indonesia, and often cause side-effects in children.'" ²⁵

Controversy surrounding school attendance provision

Great controversy in Moldova remains around the mandatory provisions for school attendance. After implementation of that provision, many parents felt their children's right to education was being infringed upon and submitted complaints to the Ombudsman's office. While parents submitted complaints that the law is unconstitutional, the Ministry of Education also opposed the provision.²⁶ In 2013, the Moldovan Centre for Human Rights filed a complaint at the Constitutional Court to challenge the constitutionality of such a requirement.

The constitutionality that conditions children's access to collectives, educational and recreational facilities by their immunization, under the Law on Public Health Surveillance, (Article 52 para. (6) of the Law no. 10 of February 3, 2009, ²⁷ has been examined several times by Constitutional Court; the first time in 2013 and the last time as recently as October 2018. The Court examined the subject of compulsory immunization of the population from several perspectives, including alleged discrimination of non-vaccinated children compared to those vaccinated, in terms of access to educational institutions. In 2013,

²³ Gavi, the Vaccine Alliance. Moldova: Gavi support documents - Proposals, reports, plans, decision letters. Gavi, the Vaccine Alliance 1AD. <https://www.gavi.org/country/moldova/documents/> (accessed November 17, 2018).

²⁴ Ghilascu N. Resistance in Moldova to health law on mandatory vaccination. Osservatorio balcani e caucaso transeuropa. 17 April 2013 [cited 7 July 2018]. Available from: <https://www.balcanicaucaso.org/eng/Areas/Moldova/Resistance-in-Moldova-to-health-law-on-mandatory-vaccination-133929>

²⁵ Ghilascu N. Resistance in Moldova to health law on mandatory vaccination. Osservatorio balcani e caucaso transeuropa. 17 April 2013 [cited 7 July 2018]. Available from: <https://www.balcanicaucaso.org/eng/Areas/Moldova/Resistance-in-Moldova-to-health-law-on-mandatory-vaccination-133929>

²⁶ Ghilascu N. Resistance in Moldova to health law on mandatory vaccination. Osservatorio balcani e caucaso transeuropa. 17 April 2013 [cited 7 July 2018]. Available from: <https://www.balcanicaucaso.org/eng/Areas/Moldova/Resistance-in-Moldova-to-health-law-on-mandatory-vaccination-133929>

²⁷ Namely Art. 52 para. (6) of Law No. 10 from 3 February 2009 on State Surveillance of Public Health, that stipulates, "Children access to collectives, educational and recreational facilities is conditioned by the fact of their systematic preventive immunization.

the Constitutional Court suspended the case²⁸ because there were no majority Court judges votes (a tie), and eventually the norm was maintained as being constitutional. In 2018, the constitutionality of Article 52 was once again challenged and was upheld to be constitutional by the Court in a ruling that was announced on October 30, 2018. The division of votes of constitutional judges in 2013 and the continued challenges to this provision demonstrate how complex and controversial the subject of immunization requirements for participation in educational institutions is and why it has been debated in several courts across Europe.

Examining the details of a constitutional challenge

In 2013, three judges found Article 52 to be constitutional. They based their decision on the legitimate aim pursued by the public authorities "to protect human lives and health" by ensuring "community immunity" as one of the most effective ways to prevent diseases and protect the population. Stating that the requirement for the compulsory immunization of children is proportionate to the purpose set forth, the judges concluded that "the differentiation between vaccinated and non-vaccinated children with regard to the access to collectives relies on objective criteria and does not deny equal protection under laws" (paragraph 143), hence the legislation is not discriminatory. The legislation allows an exception to the compulsory immunization only in case of medical contraindications (item 10 of Government Decision no. 1192 on the approval of the NIP for 2011-2015, December 23, 2010). The legislation does not provide exceptions from immunization for those who are against it due to religious or philosophical reasons. Those three judges did not consider the absence of such provisions unconstitutional, noting that "the state can adopt laws that stipulate compulsory immunization, because the freedom of the individual must sometimes be subordinated to the common well-being and may be subjected to the state control" (paragraph 159).

The three opposing judges found Article 52 unjustified and discriminatory in relation to children's access to education because systematic preventative immunization was a condition for children to access collectives, educational and recreational facilities. In their opinion, the state has various means to promote immunization for children, and by setting restrictions on the access to educational institutions for non-immunized children, the state failed to fulfill its obligations (paragraph 181 and 182).

In October 2018, the Constitutional Court ruled on case brought by the Parliamentarian Vladimir Odonostalco regarding the constitutionality of Article 52 (para. (6) of the Law no. 10 of February 3, 2009 on state oversight of public health and para. 21 subparagraph (1) let. e)), and the NIP for years 2016-2020 (approved by the Government Decision no. 1113 of October 6, 2016).²⁹ The challenged legal texts state that the admission of children to communities, educational and recreational institutions is being made contingent upon their systematic prophylactic immunization. The Court declared admissible the provisions of Article 52 para. (6) of Law no. 10 of February 3, 2009 on State oversight of public health and it declared constitutional the provisions of para. 21 subparagraph (1) let. e) of the NIP for 2016-2020 years. The constitutionality of the immunization requirement for attending educational and recreational institutions was therefore upheld. The judiciary supported mandatory immunization requirements in both cases, under the Law and the NIP.

²⁸ Constitutional Court, Judgement No.1 from 22 January 2013 on suspending the process for the review of the constitutionality of Art. 52 para. (6) of Law No. 10-XVI from 3 February 2009 on State Surveillance of Public Health.

²⁹ The Constitutional Court's Solution on Children's Vaccination and Their Access to Educational and Recreational Institutions. (2018). Constitutional Court of the Republic of Moldova [cited 4 December 2018].

Conclusion

Moldova's recommended approach to immunization law may be tested. As evidenced by challenges to the school entry restriction provision, public consensus is lacking on the introduction and strengthening of enforcement mechanisms supporting immunization. However, as recently as October 2018, the Constitutional Court upheld mandatory provisions for school attendance. While legal challenges and vaccine hesitancy likely make moves toward a mandatory legislative approach in Moldova unlikely; the recent outbreak of measles heightens the need to address declining or stagnant coverage rates.

If history is any guide, Moldova will likely continue to prioritize immunization through the implementation of a strong NIP and its current health reform to strengthen the health system. The 2016-2020 NIP includes behavioral change and communication plans, as well as a financing clause for the first time. Efforts are already underway to implement the communications plan and increase the opportunities for educating the public about vaccines in the media

A recent analysis conducted by Sabin identified additional areas where Moldova may implement changes to address public demand for immunization and increase coverage rates.³⁰ Improving communications about the benefits of immunization was recommended, including between healthcare providers and parents, as well as engaging government officials and parliamentarians to build support for immunization. More effective, accurate and timely coverage of immunization is needed in mainstream and social media, including public health experts as sources for media coverage. Furthermore, incentive mechanisms may be explored with family doctors to increase support for and champion immunization services. Finally, there is a growing recognition that clear guidelines are needed to address adverse events following immunization and minimize false contraindications.

Given the challenges to public confidence in vaccines and measles outbreaks following a period of reduced immunization coverage, the case study on Moldova demonstrates that in this situation, a purely legislative or coercive approach does not necessarily positively impact coverage. Ultimately, Moldova's experience may help illustrate the value of targeted activities to strengthen the immunization system rather than a wholesale change of the legislative framework for immunization. Moldova is attuned to challenges the country faces and has prioritized immunization at the national level through the National Health Strategy 2014-2020,³¹ which states that "immunization coverage needs to be increased despite anti-vaccine propaganda."

<http://www.constcourt.md/libview.php?!=en&idc=7&id=1317&t=/Media/News/The-Constitutional-Courts-Solution-on-Childrens-Vaccination-and-Their-Access-to-Educational-and-Recreational-Institutions/>

³⁰ Sabin Vaccine Institute. Findings following a workshop held on September 6, 2018 in Chişinău with Moldovan immunization stakeholders on increasing public demand for immunization. Unpublished.

³¹ Government of the Republic of Moldova. Comprehensive Multi-Year Plan for Immunization Programme 2011-2015. Chisinau, Moldova. Available from: http://www.nationalplanningcycles.org/sites/default/files/country_docs/Moldova/moldova-comprehensive_multi-year_plan_for_2011-2015_-_year_2011.pdf

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