# **EXECUTIVE SUMMARY**

# I Epidemiological trends of coronavirus disease (Covid-19) and policies applied to combat the outbreak, March to August 2020

Analysis of any phenomenon assumes that factors which drove change in the past will continue to behave similarly in the future. Nevertheless, the nine months between the declaration of the pandemic and early October have regularly seen sudden changes in infection spread patterns throughout most of the world's countries, and their nature still does not offer sufficient information to project the future course of the outbreak.

In its latest situation update for European Union (EU) and European Economic Area (EEA) countries and the United Kingdom (UK), released on 23 October 2020, the European Centre for Disease Prevention and Control (ECDC) notes that Covid-19 transmission poses a serious threat to public health. Major increases in infections have been registered in younger populations, but growth is also in evidence amongst older age groups. Even though the increased share of younger people in the total number of registered positive cases and enhanced treatment options have **brought death rates down relative to earlier this year, mortality is highly likely to continue rising**.

This epidemiological analysis of the pandemic in Serbia covers the period from early March to early October 2020 and is based on the available official data. Two clear spikes in positive rates are in evidence, one in April and the other from June to July, with infections abating in early August. From 6 March to 3 September 2020, a total of 31,676 cases positive to Covid-19 were recorded in 955,730 tests (on average 174.0  $\pm$  127.5 cases per day), with positive numbers peaking at 467 in Week 21 of the reporting period.

The number of individuals tested for the SARS-CoV-2 virus in the reporting period followed a continuous upward trend, with weekly rates ranging from 1.8 per 100,000 population (in the week of the first reported SARS-CoV-2 case) to 981.9 per 100,000 population (in Week 21 after the first reported case, or 24 to 30 July 2020). The greatest number of hospitalisations due to Covid-19 infection in the reporting period was recorded from 12 July to 2 August, when the figure rose by more than 4,000 daily. From the start of the pandemic to 3 September 2020 inclusive, a total of 718 deaths with Covid-19 were registered (on average 4.0 ± 3.7 deaths per day). The most deaths (18) occurred at the end of Week 18 from date of first reported case, on 10 July 2020. The case fatality rate (proportion of deaths compared to total number of people diagnosed) stood at 2.3 percent in the same period.

Within days from the first reported case of SARS-CoV-2, on 15 March 2020, Serbia introduced a national state of emergency. Borders were closed and public and inter-city transportation suspended. Nurseries, schools, and universities closed and shifted to remote teaching; cafes and restaurants and shopping centres were also shut. The lockdown was lifted on 6 May 2020, and the outbreak again peaked in early June, which may be linked to the sudden relaxation of mandatory measures and their down-grading to recommendations after the restrictions were lifted. This was also the time when a number of public events took place that were accompanied by mass gatherings where no protective measures were observed. In response to the increased infection rate in late June the various recommended measures gradually became compulsory, which led to a steady decline in positive rates in the first half of August, a trend that remained in evidence until the very end of the reporting period.

For the purpose of this report, a cross-sectional study was undertaken in Belgrade to examine the population's attitudes, preventive behaviours, and perceived risks of Covid-19 infection (see Figure 1). The study comprised a survey questionnaire intended to capture the extent to which the population embraced the measures and why they may not have been taken up.

Figure 1. All respondents, September 2020 questionnaire, Belgrade population



The attitudes found in the survey are somewhat concerning, especially as the questionnaire was administered in early September, when the outbreak had already been ongoing in Serbia for some time, and following periods of major spikes in infection and death rates. At the time, 41 percent of those polled were still not worried about becoming infected, with 13.1 percent believing that 'the situation is not as serious as it is made out to be'. By age, the greatest differences in responses were found between the two endpoints on the scale, the youngest and the oldest cohort.

**Compliance with public health measures can be expected to decline** following an initial period of positive response. In a prolonged outbreak, motivation for observing recommended and mandatory measures declines amongst members of the public in what is termed **'pandemic fatigue'**. With this weariness spreading rapidly throughout Europe, **in late August the World Health Organisation (WHO) produced a policy framework** for reinvigorating the public to prevent Covid-19. The key principles to be applied are shown in the table below.

Strategy	Suggested actions
1. Understand people	<ul> <li>Identify priority population groups – those that show signs of demotivation and those with increasing transmission. Use population surveys and surveillance data.</li> <li>Understand what motivates them; understand the barriers they face.</li> <li>Use what you learn to inform pandemic policies, communication and other interventions.</li> </ul>
2. Engage people as part of the solution	<ul> <li>Engaging people in policy selection removes their native perception of measures imposed by authority.</li> <li>Learn from civil society.</li> </ul>
3. Allow people to live their lives, but reduce risk	<ul> <li>Develop guidance and instructions to help the public differentiate between low-risk and high-risk activities.</li> <li>Start preparing for end-of-year celebrations, and think ahead to other large-scale celebrations over the year. Plan to reduce risk at this time in public transportation, shopping centres, and similar settings.</li> <li>Develop guidance on safer options for gatherings inside the home.</li> <li>Shift messaging from 'do not' to 'do differently'.</li> </ul>
4. Acknowledge and address the hardship people experience	<ul> <li>Identify and address the barriers and hardships people face, and understand which measures may be difficult to follow in the long run.</li> </ul>

Cross-cutting principles that underpin all activities				
Transparency	Be transparent in sharing <b>the reasons behind recommendations and restrictions</b> . Knowing the rationale for decisions increases motivation to follow them. Acknowledge <b>the limits of science and government</b> in terms of predicting the development of this pandemic and what restrictions will be necessary at any later stage.			

Consistency	Make sure that measures are always in line with the current epidemiological situation.			
	Ensure the actions of leaders are in line with what is being recommended for the public.			
	Avoid inconsistent responses such as tightening restrictions for restaurants while increasing the number of spectators allowed at sports events.			
Coordination	Avoid mixed messages from experts, spokespeople, government representatives and health workers.			
Predictability	Set objective epidemiological criteria for restrictions.			
	Communicate clearly the timelines for restrictions and follow up on these so people know what to expect.			

The study presents pandemic management practices employed by Germany and Croatia from March to May 2020. Neither country introduced a full lockdown, but instead used a variety of measures to control the spread of the virus that proved more successful than other EU member states. Moreover, both countries relaxed some restrictions in early summer. After a decline in infection and death rates, most EU countries, including these two, again saw the outbreak accelerate to a new peak. As of 23 October 2020, Germany has 403,291 registered positive Covid-19 cases, whilst the figure for Croatia is 29,850.

Key measures in both countries have included:

- a) Limiting contacts (shutting down various service sectors, restricting public gatherings, limiting inter-city transportation, closing borders, and the like);
- b) Introducing physical distancing;
- c) Mandating use of personal protective equipment (face masks) and personal hygiene;
- d) Controlling transmission: mass testing, isolation, appropriate treatment of positive cases and contacts;
- e) Effective co-ordination between the various sectors and all activities at both local and national level;
- f) Timely planning and monitoring of activities, with adjustments made where necessary as the pandemic evolves.

It is worth noting that Germany had prepared and made available guides for testing and risk assessment and other instructions as early as mid-January 2020, well before the first Covid-19 case was reported. This allowed the country to react promptly once the pandemic was under way.

**One best practice that has had a decisive impact on the outcome of the pandemic in this period** is having a national strategy to combat Covid-19. A strategic document of this kind, coupled with decentralised mass testing, many laboratories, and extensive track and trace efforts and contact isolation, helps reduce the incidence and mortality rate of Covid-19.

### Recommendations

The choice of methodological approach for planning future response is crucial for tackling the pandemic. The looming winter poses additional risks and requires greater efforts to curb the outbreak. Apart from providing appropriate testing capacity, the next crucial step in preparing the public health response to the new wave of the pandemic will be to identify vulnerable locations and populations. Current trends call for devoting particular attention to three groups:

- a) Controlling transmission amongst young adults and other under-50s by identifying high-risk locations where non-compliance with protective measures is highly likely and adopting a communications strategy tailored to the behaviour of this population.
- b) **Protecting the medically vulnerable population,** chiefly by giving advice on compliance with protective measures and avoidance of potentially threatening situations.
- c) Protecting health workers due to the elevated risk in primary healthcare owing to the increased incidence of respiratory disease over the winter.

The key directions of pandemic management ought to be: <u>increasing testing capacity, strengthening</u> <u>epidemiological surveillance of the outbreak, and building capacity of the health service.</u>

<u>The objective is to reduce infections to a rate that permits the health service to operate steadily</u>. Planning, decision-making as to which measures to implement, and monitoring implementation all require <u>the involvement</u> <u>of all stakeholders and co-ordination by all institutions</u>.

## Active epidemiological surveillance of Covid-19

<u>The goal of Covid-19 surveillance</u> is to limit the spread of the disease and allow public health authorities to manage the risk of Covid-19, so permitting business and social activities to recover to the greatest extent possible. Surveillance is also necessary to track the long-term trends in Covid-19 transmission and mutation.

- <u>The objectives of Covid-19 surveillance include</u>: a) rapid detection, isolation, testing, and management of suspected cases; b) contact identification and tracing; c) developing guidance for implementing measures to address the outbreak; d) detecting and preventing outbreaks in vulnerable population groups; e) assessing the impact of the outbreak on the health service and society; f) monitoring long-term epidemiological trends and evolution of the SARS-CoV-2 virus; and g) gaining a better understanding of the co-circulation of SARS-CoV-2, influenza, and other respiratory viruses.</u>
- Comprehensive national surveillance of Covid-19 requires adapting and strengthening existing national oversight systems and capacity-building.
- Digital technologies that allow rapid reporting, data management, and analysis are significant assets.
- Once established, robust comprehensive surveillance should be maintained even in areas with few cases, as it is crucial to detect new cases and clusters of Covid-19 promptly before broad transmission occurs.

(Source: Adapted from Ibrahim NK, J Infect Public Health, 2020)

Key recommendations for Covid-19 surveillance include:

- Using, adapting, and strengthening existing surveillance systems;
- Making Covid-19 a notifiable disease;
- Making use of day-zero tracing;
- Performing surveillance at various levels of the health service;
- Setting population denominators to help with data interpretation;
- Setting laboratory testing denominators.
- Performing sentinel surveillance using the Global Influenza Surveillance and Response System (GISRS).
- Current surveillance of influenza-like illnesses (ILIs) and acute respiratory infections (ARIs) is useful for monitoring Covid-19 community transmission trends and ensuring detection of other priority respiratory illnesses;
- Surveillance of Covid-19 can be integrated into the GISRS;
- Virological sentinel surveillance of Covid-19 can be done using clinical samples obtained through sentinel surveillance of ILIs, ARIs, and severe acute respiratory infections (SARIs); and
- Integration of epidemiological and virological surveillance plays a major role in tracking the spread and evolution of SARS-CoV-2.

# II Availability of essential healthcare services during the pandemic

As the outbreak began, governments throughout the world were faced with a need to quickly take action to prevent the pandemic and treat those infected. Time constraints and incomplete awareness of the SARS-CoV-2 virus affected management of the pandemic. Decisions on how to manage the outbreak were highly complex and required taking into account the human, economic, and financial dimensions of the pandemic, issues of personal freedoms, and other considerations important to each society. At the start of the outbreak, decision-makers knew relatively little about the spread of the virus and options for effectively treating infected populations. **Most governments have been re-assessing their decisions** as the public health crisis has progressed, and have been introducing new measures to better respond to the evolving situation. Lessons learnt have thus allowed countries to more efficiently and effectively pursue their objectives in combating the pandemic.

In Serbia, since the outbreak began, healthcare institutions at all levels were placed on a 'Covid footing', which entailed enhanced protective measures and fewer admissions of non-urgent cases. At times, some hospitals and specialised clinics were designated exclusively for Covid-19 patients. The resulting restrictions of capacity are one reason for the reduced availability of essential services, with others including patient behaviour, in particular the reluctance chiefly of chronic patients to visit doctors for fear of serious complications of infection due to compromised immunity.

The extent of change to essential services during the pandemic was assessed using data on primary and inpatient services provided in the first six months of 2020. The analysis focused on services delivered for three types of chronic disease: cardiovascular disease, cancer, and diabetes, which constitute the greatest burden for the health service and in 2018 accounted for 75,1 of overall mortality.

The assessment looked at the number of visits to paediatric, female, and adult healthcare facilities in the first six months of 2020. In this period, outpatient clinics **recorded a decline of one-fifth (21.1 percent)** relative to the same period of the previous year. From April to June (Q2), the **availability of all services fell by nearly one-third (27.7 percent)** in comparison to Q1. The greatest quarterly fall was registered for early childhood and school-age services, where the decline amounted to one-half (48.9 percent). Adult healthcare services witnessed a drop of **26.8 percent** in Q2. A marked fall in preventive health examinations, of 64.2 percent relative to Q1, was registered in Q2 at adult healthcare facilities, whilst the half-yearly decline stood at 45.9 percent relative to the same period one year previously.

This decline in the delivery of adult healthcare services has had an adverse impact mainly on the management of chronic patients, who make more visits to doctors annually than the general population. Given the importance of regular follow-ups of this population to monitor the progress of their diseases, adjust any treatment, and where necessary refer them to higher-level institutions, the irregular and limited contact between these patients and their general practitioners has led to deterioration of the health of some of them.

Between March and September 2020, to address capacity concerns some hospitals were closed to all non-Covid-19 patients. According to preliminary data, some 20 percent of the total of 39,434 hospital beds at inpatient facilities (excluding day hospitals) had at times been placed on a Covid-19 footing.

Data for 79 inpatient facilities (hospitals and specialised clinics) reveal a major fall in services provided in Q2 2020 (April-June) relative to the same period in 2019:

- Number of initial examinations in outpatient departments **fell by 45 percent** relative to the same period in 2019;
- Number of follow-up examinations in outpatient departments fell by 44.6 percent relative to the same period in 2019;
- There were 33 percent fewer bed-days than over the same period in 2019, including Covid-19 patients; and
- Q2 2020 saw one-fifth (22.2 percent) fewer admissions in Belgrade relative to Q1 2020.

A total of 75,036,823 inpatient services were delivered in the first half of 2020, a **decline of 39 percent on the 2016-2019 average**. Relative to the six-monthly average for 2016-2019, services delivered over the first six months of 2020 show the following trends:

1) Cancers

- Reduction of one-fifth (20.6 percent) in both preventive and diagnostic mammography tests;
- Fall of 40 percent in bronchoscopy procedures;
- Fall of 55.6 percent in superficial radiation treatments;
- Decline of 20 percent in issuance of oral antineoplastics.
- 2) Diabetes
  - Fall in insulin administrations of 18 percent.
- 3) Cardiovascular disease
  - Reduction in coronary angiography procedures of 23.4 percent.

Early detection of malignancies through screening programmes is exceptionally important as many cancers are diagnosed in Serbia at advanced stages, which leads to lower survival rates. Delaying treatment may have different consequences on outcomes, depending on cancer type and staging.

During the pandemic, the **case fatality rate rose** to as much as **11 percent for patients with poorly managed diabetes** (a glycaemic index of >10mmol/L), as against **1.1 percent for patients with well-controlled blood glucose** (upper limit <10mmol/L).<sup>1</sup> Once the pandemic had begun, hospitals significantly scaled back appointments to reduce risk of the virus spreading amongst patients and in preparation for admitting Covid-19 cases. As the restrictions were gradually eased and patients with diabetes went back to see their doctors, many were found to have poorly controlled blood sugar, with incidence of ketoacidosis increasing significantly.

Cardiovascular disease is a public health issue globally. The severest form of ischemic heart disease, acute coronary syndrome (comprising acute myocardial infarction, unstable angina, and sudden cardiac death) carries a huge disease burden in Serbia, with over 22,000 people becoming ill and 4,700 dying on average every year. The extent of this reduction in services aimed at chronic patients reveals the magnitude of the problems facing their care, which may, if they persist, lead to significant deterioration in health, or, in serious cases, fatal outcomes.

The possible impacts of the reduction in services during the first half of 2020 at all levels of healthcare are shown in the table below.

	Measure	Impacts on service availability by level		
		Primary	Secondary	Tertiary
March – June	<ol> <li>Movement restrictions</li> <li>Suspension of public transportation</li> <li>Postponement of non-urgent procedures</li> <li>Shift to 'Covid footing'</li> </ol>	<ul> <li>Fewer admissions of chronic and new patients:</li> <li>1. Fewer follow-up examinations and health assessments</li> <li>2. Fewer diagnostic services</li> <li>3. Fewer referrals to higher- level institutions for diagnosis and treatment</li> </ul>	Reduced Fewer ac Fewer diagn Fewer treatmer Fewer procedu	l capacity dmissions ostic services nts administered ures performed
IMPACTS ON HE	ALTH STATUS			
1. Fewer treatr	nent adjustments – reduce	d health improvement and maintena	nce	

2. Fewer new cases identified – delayed treatment – worsening of health status – longer treatments – less likelihood of quick and complete cure

With healthcare availability scaled down in most countries, health services have turned to innovative methods to ensure basic healthcare remains sufficiently accessible to the general population (see Figure 2).

Figure 2. Approaches to overcoming disruptions during the pandemic, WHO Pulse Survey, May – July 2020

<sup>&</sup>lt;sup>1</sup> Cell Metabolism 31, 1–10, June 2, 2020.



Three key principles are recommended to increase service accessibility, where the priority is reducing infection risk: 1) adjusting service provision at all levels; 2) increasing capacity through public-private partnerships; and 3) greater use of telemedicine.

 Adaptation of healthcare institutions primarily means allowing patients to be admitted at minimum risk to both them and medical staff. A special set of safeguards is recommended for patients with chronic diseases, who should spend as little time as possible at the facility and have minimal contact with medical staff. General recommendations include making use of alternative premises in the community and greater reliance on home treatment and care.

How to adapt service provision

- a) Risk-free admission is first priority.
- b) Extend interval between two successive examinations to avoid lengthy waiting times.
- c) Plan for rapid service provision for chronic patients: all required information should be prepared in advance and contact with medical staff minimised.
- d) Timely communicate safety and admission requirements to chronic patients. Regularly reach out to patient associations.
- e) Limit number of patients' accompanying persons.
- f) Regularly test medical staff and hospitalised patients.
- g) Adapt premises, where possible, to increase distance between patients and medical staff.
- h) Promote home care wherever possible.
- i) Community outreach: relocate service provision to better accessible sites (available premises in local communities such as cultural and/or sports centres and the like).
- 2) In most countries, greater public-private co-operation has resulted in efficiency gains in tackling the pandemic and made basic healthcare more accessible. At the start of the pandemic, the WHO recommended taking a 'whole-of-society' approach to responding to the outbreak. Most European countries were quick to involve the private sector in efforts to contain the virus, in particular by using private laboratories to greatly expand testing capability. Many EU member states entered into agreements with private healthcare providers that gave national health services access to private inpatient care capacities, which lessened the pressure on public health institutions and allowed non-Covid-19 patients to receive care.

In Serbia, the involvement of private healthcare in efforts to contain epidemics is regulated by the Healthcare Law. Article 42[2] of this piece of legislation requires private providers to 'take part, where invited to do so by a relevant authority, in the prevention and control of infectious diseases and the

protection of rescue of members of the public in crises and emergencies.<sup>22</sup> Further, Article 21 of the Law on the Protection of the Population from Infectious Diseases, titled 'Laboratory testing for identification of infectious agents', stipulates that '[t]he laboratory testing referred to in Paragraphs [1] and [2] of this Article shall be carried out by healthcare institutions and private practices that meet the microbiological requirements prescribed by the law governing healthcare.<sup>3</sup> Serbia has not involved the private sector in efforts to tackle the pandemic in spite of the notable decrease in the availability of basic healthcare services. Decisions to use public funds were not made transparently, and the criteria applied when deciding that private-sector participation was not necessary still remain unclear. At a time when additional unplanned assets must be secured for use in addressing the outbreak, it is imperative to utilise resources and capacities rationally. There is questionable logic in investing into new public healthcare capacity when the private sector already possesses identical capabilities, together with the necessary equipment and a proven track record.

3) Digital technology, communications, and telemedicine can play a key role in dealing with the pandemic quickly and efficiently. Timely information about outbreaks and the ability to communicate and consult remotely have greatly contributed to containing the virus. Telemedicine has allowed greater access to healthcare during the pandemic, chiefly by facilitating online consultations and so reducing the number of physical doctor's appointments and saving time. Positive experiences with telemedicine during the pandemic highlight its advantages in reducing infection risk and increasing the accessibility of basic healthcare services. A meta-analysis of the available references reveals 73 percent of the studies found using telemedicine was cost-effective, with negative results recorded by 5.6 percent. Positive examples from numerous countries cited in the study indicate huge growth in telemedicine during the pandemic relative to recent years. According to estimates, these remote services are set to continue growing as both health workers and patients have now gained a wealth of encouraging experience. The key factors for successful application of telemedicine are: (a) raising awareness amongst both doctors and patients of the advantages of this approach; (b) incentivising the involvement of partners from other sectors; and (c) regulating cost reimbursement.

**Revenue and expenditure data** released by the National Health Insurance Fund (RFZO) show a decline in revenues, as was only to be expected following the government-mandated suspension of social contributions. The costs associated with the pandemic have significantly altered the structure of expenditures, which may have a major adverse impact on the Fund's ability to meet its debts as they become due unless additional finance is earmarked for it in the central budget.

When planning its expenditure for the coming year, the Fund must look at the likely increase in demand for healthcare services due to their reduced availability in 2020. It also ought to estimate the potential increased demand owing to a worsening health situation on account of services postponed in 2020 and delays in new diagnoses, as well as for treatment of 'long Covid' symptoms. The drop in economic activity expected in 2020 and the probable slowdown of growth in 2021, together with a foreseeable fall in employment, will adversely impact the RFZO's revenues. Ensuring appropriate healthcare financing must be prioritised in the upcoming period over other expenditures from the central budget, as allowing health of the overall population to deteriorate would have wide-ranging detrimental consequences on society and the economy.

#### **III Immunisation**

**Immunisation is one of the most effective means of preventing infectious diseases** and protecting populations from them. Immunisation of children is a pillar of any health service as it safeguards public health in the long run. We assessed Serbia's childhood immunisation coverage using preliminary data for inoculations in the first six months of 2020. Aggregate half-yearly data for this year were compared with six-month averages between 2016 and 2019.

In the first half of 2020, total coverage was **lower than planned by between 5 and 12 percent, depending on vaccine type**. The lowest coverage, of 38.2 percent, was registered for the first dose of the measles, mumps, and rubella (MMR) vaccine (first dose), likely in part due to Serbian parents' concerns and hesitancy in having their children

<sup>&</sup>lt;sup>2</sup> Official Gazette of the Republic of Serbia, No. 25/2019.

<sup>&</sup>lt;sup>3</sup> Official Gazette of the Republic of Serbia, No. 68/2020.

vaccinated. The Belgrade region and Southern and Eastern Serbia saw take-up rates lower than the national average for most vaccines. In the majority of health centres vaccination was almost completely suspended during the first two months of national lockdown, with coverage increasing once the restrictions were lifted. The increase in coverage by vaccines administered before primary school enrolment may have been caused by the fortuitous coincidence between the lifting of the state of emergency and the window for enrolment in primary and nursery schools. As this factor will be absent in the second half of the year, **achieving planned coverage by the end of the year is far from certain**.

The WHO and the United Nations Children's Fund (UNICEF) are seeing similar drops in immunisation rates in most countries. The two global bodies have called for all routine vaccination to continue during the pandemic as planned by national immunisation programmes.<sup>4</sup> In August 2020, UNICEF and the Serbian Paediatric Association held a series of webinars to inform and motivate health workers to redouble vaccination efforts. Questions were collected form 250 paediatricians that clearly show the doubts and concerns of health workers and reveal the impact of the lack of official guidance in the first several months of the pandemic. The relevant authorities ought to issue such guidelines as paediatricians are not ready to take decisions independently in the absence of clear official instructions.

May 2020 saw the adoption of the new Law on Protection of the Population from Infectious Diseases<sup>5</sup> and the Regulation on mandatory and recommended immunisation against certain infectious diseases.<sup>6</sup> These rules have significantly strengthened legal recommendations for vaccines that can play a major role in protecting some populations, yet the statutory framework imperfectly regulates accessibility of the recommended inoculations. The rules envisage neither the funds for purchasing these vaccines nor designate the institutions responsible for administering them. To help assign responsibility and determine how funding should be secured, it would be useful to assess the cost-effectiveness of any recommended vaccines and the savings to the health system if they were to be partially covered by mandatory health insurance.

Coverage of the Serbian population at large with **immunisation against seasonal influenza** has lingered below desired levels for the past decade. Encouraging results were registered initially in 2008/2009 and 2009/2010 with immunisation of the elderly (over-65s), but the first subsequent season saw a 13-percent drop in coverage. In a particularly worrying trend, health workers are poorly covered by immunisation even though they are exposed to greater risk of infection and may transmit diseases to patients. Coverage of the over-65 population is low in Serbia when compared with European figures and no improvement has been made since 2013-2015. The EU average of 41 percent of all over-65s who received inoculations in 2018 is much greater than the registered coverage for Serbia.<sup>7</sup>

At the invitation of the European Commission and the WHO, the Serbian government joined the COVAX facility, an alliance to develop and **supply Covid-19 vaccines**, and twice contributed funds to this global accelerator, re-affirming its desire to actively participate in worldwide efforts to develop a coronavirus vaccine. Participation in COVAX allows Serbia to access vaccines made by reliable manufacturers at a price determined by global supply and demand (assuming a global need to vaccinate two billion people). According to COVAX, for the immunisation programme to be successful, each country ought to inoculate 20 percent of its population, with health workers, over-65s, and chronic patients being accorded priority. The projection is that all countries will receive the first batch of vaccinate health workers and other front-line healthcare providers. The second batch, planned for Q2 2021, is envisaged to be used for another 17 percent of the population, primarily the elderly, those facing heightened health risks, and chronic patients.

Article 3 of the Serbian Regulation on documentary and import requirements for unlicensed medicines and medical devices not listed in the Register of Medical Devices stipulates that '[i]mporters shall apply for the import of an unregistered medicine where [...] (3) sufficient quantities and types of medicines must be secured **in the event of an epidemic**, natural disaster, or other emergency, as defined by law.'<sup>8</sup> Importers must prove that an unregistered

<sup>&</sup>lt;sup>4</sup> See <u>euro.who.int/en/health-topics/disease-prevention/vaccines-and-immunization/q-and-a-on-vaccination-during-the-covid-19-pandemic.</u>

<sup>&</sup>lt;sup>5</sup> Official Gazette of the Republic of Serbia, No. 68/2020.

<sup>&</sup>lt;sup>6</sup> Official Gazette of the Republic of Serbia, No. 65/2020.

<sup>&</sup>lt;sup>7</sup> See <u>ec.europa.eu/eurostat/web/products-eurostat-news/-/DDN-20200915-1</u>.

<sup>&</sup>lt;sup>8</sup> Official Gazette of the Republic of Serbia, No. 107/2012.

medicine is approved in the EU or the third country of manufacture or supply a Certificate of Pharmaceutical Product according to WHO standards. Given the urgency with which Covid-19 vaccines would have to be approved for use in Serbia, these rules could be relaxed whilst ensuring safety of the vaccines and compliance with other requirements. The national regulator, the Agency for Medicines and Medical Devices (ALIMS), can play a crucial role in this regard, and communication must be maintained with the COVAX technical standards group and the European Medicines Agency (EMA) at all times to ensure the regulations can be changed promptly.

By the end of October 2020, UNICEF will issue a worldwide set of methodological instructions for countries to selfassess their preparedness for Covid-19 vaccination. Serbia has committed to financing procurement of a vaccine. Apart from direct and indirect costs (transport to Serbia, insurance, etc.) that are included in the purchase price, warehousing and distribution in Serbia will account for a large proportion of the total expense. (For routine inoculations, these costs are covered by the suppliers and are included in the final price of the vaccine.) In view of the huge impact of successful immunisation on controlling the Covid-19 pandemic worldwide and in Serbia, a social marketing plan ought to be prepared as soon as possible before the inoculation programme begins. **Current assumptions of the coverage required to achieve the desired impact on the pandemic call for immunising between 60 and 70 percent of the population.** 

The cross-sectional study of the general population of Belgrade conducted in September 2020 revealed the views and attitudes towards a possible Covid-19 vaccine (see Figure 3). Most Belgradians (slightly under one-half, or 45 percent) are still undecided as to whether they would receive a vaccine if and when one is approved and made available. One-quarter would not submit to vaccination; no more than one-fifth are ready to do so; whilst for 9 percent the decision will be determined by the vaccine manufacturer.

#### Figure 3. Readiness of Belgrade population to receive Covid-19 vaccine, September 2020



When a vaccine against the SARS Covid-19 virus is approved and available in our country, will you get vaccinated?

To ensure the desired coverage levels are achieved, public trust in the healthcare system and immunisation programmes ought to be promoted through the following actions:

- Particular attention should be devoted to vulnerable groups recommended to be immunised, and communications strategies should be adjusted to their needs.
- Planned inoculation against influenza and pneumococcus for the over-65s could be utilised to launch a Covid-19 vaccination campaign, as the coronavirus vaccine is a priority for this population as well. Basic information about the Covid-19 vaccine can be shared directly with individuals receiving influenza or pneumococcus inoculations.
- **Regular inoculation of children and other groups** according to mandatory and recommended vaccination programmes is another **opportunity to emphasise the benefits of immunisation**.

In March 2020, the WHO Regional Office for Europe released official recommendations for **routine immunisation during the Covid-19 pandemic** that call for prioritising pneumococcus and influenza vaccination of vulnerable groups.

With influenza vaccination coming at a time when the majority of the population are concerned about the Covid-19 pandemic, demand for influenza vaccines is expected to outstrip supply. As influenza vaccination has received political support, the key reason for this scarcity will be a shortage of the vaccine in the global market occasioned by increased demand due to the pandemic and the low immunisation coverage in recent years. To support influenza inoculation programmes, it is important to ensure that anyone can receive this vaccine as soon as possible during the upcoming influenza season. **Options for administering these vaccines away from healthcare institutions should also be considered to reduce stress on the health service.** In many countries, influenza, human papillomavirus (HPV), pneumococcus, and herpes zoster vaccines are given in pharmacies, as are some travel vaccines. This arrangement has been shown to greatly improve coverage, with estimates indicating rates of some 75 percent.<sup>9</sup>

**Pneumococcus** (the *Streptococcus pneumoniae* bacterium) **is a key cause of pneumonia and secondary bacterial pneumonia** following influenza and an agent implicated in many other non-invasive and invasive infections. Its incidence is highest during the winter season, even though vaccines can be administered year-round. As required by the new Regulation on mandatory and recommended immunisation, this vaccine is administered in two doses, one of the pneumococcal conjugate vaccine (PCV13) followed by one of the pneumococcal polysaccharide vaccine (PPV23) within no more than eight weeks. Occupants of collective accommodation facilities (such as care homes) receive only one dose of PPV23. Unlike the influenza vaccine, this single-dose inoculation confers immunity from

<sup>&</sup>lt;sup>9</sup> See <u>tportal.hr/vijesti/clanak/i-ove-godine-bit-ce-organizirano-cijepljenje-protiv-gripe-u-ljekarnama-a-farmaceuti-predlazu-odlicno-rjesenje-za-</u> sve-foto-20200921/print.

pneumococcal disease for several years. Pneumococcus vaccination will lower the risk of respiratory infection caused by this agent in residents of care homes and similar institutions.

In the context of the Covid-19 pandemic and WHO recommendations, and given the recent extension of health insurance coverage to include pneumococcus inoculation, the government ought to appropriately plan for an increase in the supply of these vaccines and explain their benefits to all inoculators, in particular those with no experience with pneumococcal vaccination.