



REPUBLIC OF SERBIA

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Belgrade



Protector of Citizens

Ombudsman

Ev.No: 4623 Date: 13.02.2018.

SUBMISSION FROM THE PROTECTOR OF CITIZENS OF THE REPUBLIC OF SERBIA

-Regarding Resolution adopted by the Human Rights Council on 23 June 2017: The right of everyone to the enjoyment of the highest attainable standard of physical and mental health in the implementation of the 2030 Agenda for Sustainable Development-

Target 3.3: By 2030, end the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases;

And

Target 9: Calls upon the international community to continue to assist developing countries in promoting the full realization of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health, including through access to medicines, in particular essential medicines, vaccines, diagnostics and medical devices that are affordable, safe, efficacious and of quality; financial and technical support and training of personnel, while recognizing that the primary responsibility for promoting and protecting all human rights rests with States; and recognizes the fundamental relevant importance of the transfer of environmentally sound technologies on favourable terms, including on concessional and preferential terms, as mutually agreed;

Pursuant to Article 24, paragraph 2 of the Law on the Protector of Citizens¹, the Protector of Citizens submitted Opinion to the Ministry of Health and the National Health Insurance Fund on the need for greater availability of innovative medicines for patients suffering from hepatitis C². Namely, the Association of Patients with Liver Diseases - HRONOS addressed the Protector of Citizens and pointed out the problems faced by citizens with hepatitis C due to the lack of adequate treatment. More specifically, the HRONOS Association pointed out that the Medicines and Medical Devices Agency of Serbia, in 2015 issued licenses hastily for modern hepatitis C medications that are on the World Health Organization ((hereinafter: WHO) list, but Serbia, i.e. the National Health Insurance Fund did not make them available. Also, the HRONOS Association pointed out that Serbia is obliged by the Law on health insurance³ to provide the patients with the minimum of medicines from the *Essential List of Medicines* published by the World Health Organization, which also includes modern therapies for hepatitis C.

¹ Law on the Protector of Citizens, Official Gazette of RS No. 79/05 and 54/07.

² Opinion available at: <http://www.ombudsman.rs/index.php/2011-12-11-11-34-45>.

³ Law on health insurance, Official Gazette of RS No. 07/05, 109/05, 57/11, 110/12, 119/12, 99/14, 123/14, 126/14, 106/15 and 10/16)

In the submitted Opinion, the Protector of Citizens pointed out that changes and amendments to the Rulebook on the List of Medicines which are prescribed and issued by the compulsory health insurance are necessary, having in mind that one of the criteria is that there is no medicine for the stated medical indication in the same pharmacotherapeutic group on the List of Medicines as well as the public health importance of the medicine; as well as that the Ministry of Health in its future work must participate more actively in the procedure of placing or removing the medicine on the List of Medicines in accordance with the legal authorities, to whom it is enabled to submit proposals for placing or removing medicines from the List of Medicines.

Furthermore, the Protector of Citizens considers that the National Health Insurance Fund, when placing medicines on the List of Medicines, has to take into consideration the *Essential List of Medicines* WHO, because the medicines with direct acting on viruses⁴ (hereinafter: DAA regimen) are listed as the essential medicines for the treatment of viral hepatitis C infection. The National Health Insurance Fund did not take into account *the Guidelines for the Screening, Care and Treatment of Persons with Chronic Hepatitis C Infection, April 2016*, i.e. new recommendations (2016) that recommended therapy with the direct action of antiviral agents⁵. Specifically, in certain genotype of hepatitis C infection, the DAA regimen is a priority while interferon-based therapy is one of the alternative regimes⁶. On the other hand, interferon therapy⁷ is recommended for certain population of the diseased.

However, the current regulations of the Republic of Serbia do not allow persons with hepatitis C virus to be treated with the priority regimen, but the only available therapy is the one recommended by the WHO as an alternative and only for certain genotypes of the virus, that is, recommended only for a certain population of the diseased.

Within the **Target 9** we also inform you about the following:

The coverage of children in Serbia for mandatory vaccination is lower than recommended (by WHO) 95% in relation to all infectious diseases from which they are protected by compulsory immunization, except in relation to tuberculosis, where vaccination coverage is adequate (over 95%). In recent years, there has been a downward trend in vaccination coverage in Serbia (data obtained from the Institute of Public Health "Dr Milan Jovanović Batut")⁸.

On 13 February 2018, a total of 2,119 cases of measles were registered on the territory of the Republic of Serbia, out of which 1,080 were laboratory confirmed. The youngest ill person is a 15-day-old baby,

⁴ Direct acting- antiviral medicines – medicines with direct influence on viruses (DAA).

⁵ Guidelines for the screening, care and treatment of persons with chronic hepatitis C infection, April 2016 New recommendations (2016) Treatment with direct-acting antiviral agents: it is recommended that DAA regimens be used for the treatment of persons with hepatitis C infection rather than regimens with pegylated interferon and ribavirin.

⁶ Guidelines for the screening, care and treatment of persons with chronic hepatitis C infection, April 2016 *Recommendation on treatment – Preferred and alternative regimens for the treatment of persons with chronic hepatitis C virus infection.*

⁷ Guidelines for the screening, care and treatment of persons with chronic hepatitis C infection, April 2016 *Special considerations for specific population*

⁸ <http://www.batut.org.rs/index.php?lang=2>

and the oldest is 65 years old. The majority of patients are in age groups younger than five and over 30. The majority of patients (94%) are not vaccinated, incompletely vaccinated or of unknown vaccine status. Out of the total number of patients, 33% were hospitalised or hospitalisation is ongoing. From the severe complications of measles, 252 cases of pneumonia were reported.⁹ On 27 December 2017, the Clinic for Infectious and Tropical Diseases in Belgrade reported death of a 30-year-old person who was not vaccinated. The disease was laboratory confirmed, and in the clinical course there was a development of lung inflammation. This is the first death toll from measles registered after 20 years in Serbia. On 3 January 2018, the Clinical Centre in Niš reported a death of a 2-year-old child who was not vaccinated. The disease was laboratory confirmed, and in the clinical course there was a development of lung inflammation.

Target 7: Further encourages States to empower users of health-care services to know and demand their rights, including through health and human rights literacy, and to provide human rights education and training for health workers, with special focus on non-discrimination, free and informed consent, confidentiality, privacy and the duty to provide treatment, and to exchange best practices in this regard;

Protector of Citizens, in cooperation with the USAID Judicial Reform and Government Accountability Project (JRGA), in the period from October 2014 until May 2015, carried out 12 training courses for patient rights advisors and members of local health council in which 146 representatives from 86 local self-governments participated (81 patient rights advisors, 51 president/members of health council, 14 others – associates, members of the municipal council, patient associations representatives, non-governmental organizations etc.). The training course program consisted of several segments: general information about patients' rights from the aspect of jurisdiction of Protector of Citizens, child rights in the health care system, gender aspect of health care, improvement of attainability of health care to Roma, health care of persons with disabilities. The participants were pointed to specific needs of certain vulnerable groups to which special attention needs to be paid in working on patient complaints¹⁰.

Based on the gathered data and its analysis, a *Special report of the Protector of Citizens on the work of mechanisms for the protection of patients' rights with recommendations* was prepared in 2016, which contains the assessment of situation and recommendations. The Protector of Citizens established that the system of newly created mechanisms for the protection of patients' rights did not come into practice because the competent bodies of the local self-government units and the Ministry of Health did not take measures within their competence in the manner and within the deadline stipulated by the Law on Patients' Rights. This led to omissions that could aggravate the legal position of patients and result in violation of their rights and the creation of legal uncertainty. By this Law, the protection of patients' rights was transferred from the health institution to the local self-government unit, which was supposed to provide greater autonomy and objectivity of the responsible persons for handling patients' complaints. However, it led to the reduction of the number of citizens' addresses, due to lack of information and due to the fact that they have to go to the municipality to seek counsel.

⁹ <http://www.batut.org.rs/index.php?content=1629>

¹⁰ *Special report of the Protector of Citizens on the work of mechanisms for the protection of patients' rights with recommendations*, Protector of Citizens, Official Gazette, Belgrade, 2016.