

of People's Advocate took its own initiative regarding the issue of identifying the beneficiary categories and financial impact (in terms of easing the financial burden) that generated in citizens infected with COVID-19, the approval of the Decision of the Council of Ministers no.908, dated 18.11.2020 "On the approval of the pharmaceutical package for outpatient treatments of persons diagnosed with COVID-19".

We would like to draw attention to the protection of health and the right to health care is a right protected not only by the Constitution of the Republic of Albania and its legal acts, but also by international acts series to which our country has acceded, such as the Universal Declaration of Human Rights, the European Convention on Human Rights, the European Social Chartes, the International Covenant on Economic, Social and Cultural Rights, etc.

The Constitution of the Republic of Albania, article 55 provides that :

- *Citizens enjoy in an equal manner the right to health care from the state;*
- *Everyone has the right to health insurance pursuant to the procedure provided by law.*

Law No. 15/2016 "On the prevention and control of infectious diseases", Article 4; sets out the principles for preventing and combating (treating) infections and infectious diseases as follows:

- (i) *Prevention of communicable diseases in the territory of the Republic of Albania is mandatory;*
- (ii) ***Prevention and control of infections and infectious diseases is provided without any discrimination;***
- (iii) *Protection from infectious diseases is realised according to a planning, programming, organizing, implementing measures for the prevention, diagnosing, treating, fighting, eradication of infectious diseases and providing the means and infrastructure necessary for their health protection;*
- (iv) ***Everyone has the right to benefit from measures for protection against infectious diseases;***
- (v) ***Everyone suffering from the infectious diseases with epidemic character has the right and obligation to be treated free of charge in any public or non-public institution;***

Also, in law no. 10138, dated 11.05.2009 "On Public Health", article 28, it is provided that: "*Prevention and control of infectious diseases includes epidemiological surveillance of these diseases and risk factors, as well as the total measures aimed at preventing the development of infectious agents, minimizing the occurrence of infections, reducing the susceptibility of individuals and population to infectious diseases, preventing the development of biological and clinical signs of these diseases, **early diagnosis and evidence-based treatment of infectious diseases** and preventing or minimizing complications from these diseases*".

With reference to the subject mentioned above, in order to meet the obligations generated by the existing legal framework for dealing with epidemic situations and more specifically the obligations expressly defined in the Law No.15/2016 "For the prevention and control of infections and infectious diseases", the government approved the Decision of the Council of Ministers ("DCM") No.908, dated 18.11.2020, "*For the approval of the COVID-19 treatment package for outpatients diagnosed with COVID-19*".

The above-mentioned DCM was implemented but not without challenges, identifying from an early stage, clear problems and with a negative impact on citizens, especially in relation to:

- (i) *categories of individuals diagnosed with COVID-19, as beneficiaries of the pharmaceutical package for which a reimbursement is offered in terms of outpatient treatment at home;*
- (ii) *guideline (protocols) of pharmaceutical treatments for individuals infected with COVID -19, by not including, laboratory tests and imaging examinations in diagnosing and monitoring the patient's clinical progress.*

DCM no. 908, dated 18.11.2020 “ For the approval of the COVID-19 treatment package for outpatients diagnosed with COVID-19”, determines the reimbursement of two packages for outpatient treatment at home, according to stages.

For the mild form of symptoms (Stage I) a refund was set up in the amount of 1,650 ALL, while for the moderate form of symptoms (Stage II) a refund was set up in the amount of 10,900 ALL.

Further, in the instruction of the Ministry of Health, approved under the Order No. 579, dated 14.10.2020 “ For the approval of the guidelines for outpatients cases with COVID-19 infection ”, where it is detailed the procedure of patients' treatment at home by the family doctor, for the stage I and II, once **patients are diagnosed with positive test by public health institutions**. This guideline also explicitly defines the scheme/protocol of their treatment with medicines.

More specifically, this guideline sets out the treatment for stage I and II, as follows:

Stage I. Vitamino therapy (C Vit.), 2. Juices, 3. Antipyretics for managing temperature, 4. Trisol in case of diarrhea, 5. Cough syrup to treat cough. Antibiotics can be used for terminally ill patients (azithromycin or levofloxacin) as well as anticoagulants.

Stage II: 1. Antibiotics, 2. Cortisone, 3. Anticoagulants, 4. Vitamin therapy, 5. Antipyretics, 6. Cough syrup. The guideline, for stage II also includes the image examination (CT Scanner), on the fifth day.

In the analysis of the provisions of DCM no. 908, dated 18.11.2020 and Order no. 579, dated 14.10.2020, with reference to the categories of citizens who are classified as beneficiaries of the pharmaceutical package, for which a reimbursement is offered in terms of outpatient treatment at home, we note that in order to be qualified as a beneficiary category, citizens must meet cumulatively, two conditions:

- (i) diagnosed as infected with COVID-19, after the entry into force of DCM no.908, date 18.11.2020;
- (ii) confirmed with positive test of COVID-19 by public health institutions;

As it can be easily ascertained, in light of the provisions provided in the above-mentioned legal acts, there are not qualified as beneficiary category of a refundable prescription given by the family doctor for stage (I) and (II) **patients diagnosed with COVID-19 for the period March-November 2020, before the entry into force of the DCM no. 908, dated 18.11.2020, as well as patients, after DCM entered into force, that have been confirmed with positive test of COVID-19 by private (non-public) health institutions.**

The DCM has significantly limited, to the detriment of citizens, the categories of beneficiaries of a refundable prescription, given by the family doctor for stage I and II, by not considering individuals diagnosed with Covid-19, for the period March-November 2020, before the entry into force of DCM no. 908, dated.18.11.2020 who have received medical treatment during this period by paying entirely with their own income.

Equally problematic is the financial situation faced by individuals diagnosed with COVID-19, after the entry into force of DCM no. 908, that resulted as positive of COVID-19 test but confirmed from *private health institutions*.

This category turns out to be excluded as a beneficiary of the pharmaceutical package for which reimbursement is offered in terms of outpatient treatment at home, drastically limiting the number of citizens diagnosed with Covid 19 who effectively benefit from reimbursable medicines as part of outpatient treatment, compared to the number of those in real need who should receive reimbursement, thus eliminating the possibility of considering the test analysis performed in private health institutions.

Also in the information officially received from Compulsory Health Care Insurance Fund regarding the number of beneficiary patients from the period 19.11.2020 to 31.01.2021 it turns out that 2988 prescriptions with reimbursement have been executed. While the real number of people affected by Covid 19 and made public every day by MHSP: from the period November 19, 2020 to January 31, 2021 it results 47 982 people, an average of 648 affected per day¹. Whereas this number until 10.03.2021, results **85 406** persons². So, it appears that the number of beneficiaries is extremely smaller in relation to the number of infected persons. This statistical evidence should engage you as MHSP, to undertake national awareness campaigns through audiovisual media, social networks as well as other internal mechanisms of the system itself, that infected patients but also other citizens be informed about the benefits of medicine reimbursements and the procedure of receiving these from the family doctor. From our point of view, it results that this mechanism to date is ineffective for the beneficiary category of citizens.

We bring to your attention that Albania is ranked last in the region for conducting tests per million inhabitants, compared with neighboring countries such as Kosovo, Macedonia, Croatia, Montenegro etc.³

As noted previously, concerning the non-beneficiary categories, it turns out that there is inconsistency with the provisions and legal obligations set out in the Constitution of the Republic of Albania, Law No. 15/2016 “For the prevention and fight against infectious diseases” and in Law no.10138/2009 “On Public Health”, this decision of the Council of Ministers is maintaining and reinforcing a discriminatory attitude towards equal access that citizens should have to health care (diagnostic and treatment) provided by the state.

To emphasize, the Constitution of the Republic of Albania stipulates that “... *citizens enjoy in an equal manner the right to health care from the state ...*”. Furthermore, article 4 of Law No.15/2016 “For the prevention and fight against infectious diseases”, provides that “...*the prevention and control of infections and infectious diseases is provided without any discrimination ... everyone has the right to benefit from protection*”

¹ Coronavirus.al/statistika

² Coronavirus.al/statistika

³ Source: <https://www.worldometers.info/coronavirus/>

measures against infectious diseases ... everyone suffering from infectious diseases with epidemic character has the right and obligation for free of charge treatment in any public or non-public health institution. Following Law no.10138, dated 11.05.2009 “On Public Health”, foresees that “.....prevention and control of infectious diseases includes epidemiological surveillance, as well as the set of measures aimed at preventing the development of infectious agents, minimizing the occurrence of infections, reducing the susceptibility of individuals and the population to infectious diseases, preventing the development of biological and clinical signs of these diseases, **early diagnosis and evidence-based treatment of infectious diseases ...**”

With reference to schemes (protocols) of refundable pharmaceutical treatment of infected individuals with COVID -19, DCM no. 908, dated 18.11.2020 “For the approval of the COVID-19 treatment package for outpatients diagnosed with COVID-19”, decided to reimburse two packages for outpatient treatment, respectively for stage I and II. For the Stage I it was set up a refund in the amount of 1,650 ALL, while for the Stage II was in the amount of 10,900 ALL.

We estimate that these values do not reflect the real costs of outpatient treatment, as they do not consider reimbursement of other laboratory tests and imaging examinations **for diagnosing and monitoring the clinical progress of the patient**, which although “*de jure*” are not part of COVID 19 treatment schemes/protocols, “*de facto*” are performed routinely in the context of the necessary diagnosis and monitoring of the disease progression.

The recommendations of WHO, systematically refers to the clinical-imaging diagnosis for cases with COVID-19, hence the diagnosis also through imaging examination (CT Scanner), in order to increase patients' access to reimbursable⁴ medicines.

Albania and 192 other United Nations member states in September 2015, approved the 2030 Agenda for Sustainable Development. The 2030 Agenda is a 15-year global framework focused on 17 Sustainable Development Goals. The 2030 Agenda aims to end poverty and hunger in the world, quality education, universal health care, to achieve gender equality and the empowerment of all women and girls, and sustainable environment. Goal no. 3 “Ensure healthy lives and promote well-being for all at all ages”, of the 2030 Agenda for Sustainable Development, determines the state obligation for universal health coverage, including protection of citizens from financial risk, their access to quality essential health care services and safe, effective, quality and affordable medicines and vaccines for everyone.

The existing legal framework for dealing with epidemic situations, and more specifically Law no.15/2016 “For the prevention and control of infections and infectious diseases”, clearly defines the obligation that the state has to cover any expenses of citizens in relation to treatment and specifically article 4, letter e) specifies that:

“everyone suffering from infectious diseases with epidemic character has the right and obligation for free of charge treatment in any public or non-public health institution”.

Claiming that reimbursable medicines treatment schemes for patients with COVID-19 have been a challenge to health systems since the early stages of pandemic identification, referring to the numerous complaints registered for months in order to be considered by the institution of the People’s Advocate (the identified main cause is the inability to afford the costs of medical treatment), as well as taking into account the data and reports of civil

⁴ <https://www.who.int/>

society organizations operating in the field of patients' rights the institution of the People's Advocate considers that the Ministry of Health and Social Protection should be committed to taking immediate and necessary measures to enable the effective exercise of citizens' right to health care and equal access to state-provided diagnostic and treatment health services under the COVID-19 pandemic.

Regarding the subject mentioned above, the People's Advocate, following the performance of the legal mission in the role of promoter of the highest standards of human rights and freedoms in the country, based on Article 63/3 of the Constitution which provides that: "*The People's Advocate has the right to make recommendations and propose measures when he observes violations of human right and freedoms by the public administration*"; as well as article 21 / b of law no.8454 dated 04.02.1999 "*The Law on the People's Advocate*", amended, where it is provided that: "*The People's Advocate submits recommendations on how to remedy the infringement to the administrative organ that in his judgment has committed violation of rights and freedom*",

RECOMMENDS:

- *Expanding the pharmaceutical package for outpatient treatment at home of persons diagnosed with COVID-19, including laboratory tests and imaging examinations to diagnose and monitor the patient's clinical progress;*
- *Guaranteeing the provision of health care without discrimination, including as beneficiary category the individuals diagnosed with COVID-19 during the period March-November 2020.*
- *Ensuring healthcare service without discrimination– pharmaceutical package, without limiting it to the patients who have been tested positive from public health institutions but offering it to all patients diagnosed with this infectious disease regardless the way of conducting the examination or health institution when it is performed..*
- *Finding appropriate mechanisms to enable the reimbursement of these costs.*
- *Taking measures to find instruments for undertaking awareness campaigns for citizens benefiting from the state reimbursement of the COVID- 19 medicine package.*

For the position you will take towards this recommendation and the measures that will be taken for its implementation, please let us know within the best deadlines

While hoping on your understanding and cooperation,

PEOPLE'S ADVOCATE

ERINDA BALLANCA