Explanatory Memorandum

Tuberculosis (TB) is a public health issue in Romania.

Despite the progress achieved over the last 12 years, which meant a progressive decrease of TB incidence from 142.2 in 100.000 inhabitants in 2002 (30.986 new cases and relapses) to 72.9 in 100.000 inhabitants in 2013 (15.523 new cases and relapses)[1], Romania continues to be the country with the highest incidence in the EU (five times above the EU average), accounting for approximately 20% of TB cases reported in the EU, while it has 4% of the EU population.

Mortality decreased from 10.8%000 in 2002 to 5.3%000 in 2013, and the treatment success rate in bacteriologically confirmed new pulmonary cases increased from 78.8% in 2002, to 85.4% in 2012.

Romania annually reports around 13.000 new cases and over 1,100 deaths caused by tuberculosis and, at present, the most important challenge is represented by multidrug- and extensively multidrug-resistant tuberculosis (MDR/XDR TB) caused by:

- the lack of universal access to rapid and correct diagnostic,
- the lack of universal access to complete and continuous treatment regimens adequate for the identified resistances to anti-TB drugs,
- the absence of social and psychological support for the patients.

However, tuberculosis incidence varies across the country and is relatively influenced by the socioeconomic status of the regions, having higher values in the east, west and south, and lower in the centre and the north-west.

Compared to the European countries, the magnitude of the phenomenon in Romania cannot be attributed to migration (only a few cases are reported each year in persons born outside the country), nor to HIV infection (the share of HIV-infected patients in the number of reported TB cases has been below 0.5% in recent years), but an important factor influencing the severity of the TB endemic in Romania is represented by the socioeconomic problems affecting the patients. The decrease of the living standard has had an impact on incidence, as proven also by the fact that the highest incidence is found in the counties in the south-eastern part of the country and in Moldova, which are also the counties facing the most important socioeconomic problems.

According to the IMF Report[2], despite the fact that the guaranteed minimum wage increased in 2014, it continues to be low in Romania compared to the other countries in the region. The same Report shows that, given the country's high unemployment rate among young persons (an average 23.2% in the first nine months of 2013) and the increasing share of fixed-term employment contracts, higher minimum wages could

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[1] Source: National TB database updated for the 2014 reporting to the European Centre for Disease Prevention and Control (ECDC) via the TESSy system

[2] http://www.imf.org/external/pubs/ft/scr/2014/cr1487.pdf

have a have negative impact on employment. The unemployment rate grew to an average of 7.3 percent in 2013, compared to 7 percent in 2012.

According to the data provided by the National Tuberculosis Prevention, Surveillance and Control Programme, in Romania, as in fact all over the world, the cases of disease in men are 2.1 times more frequent than in women. Age group distribution indicates gender differences: the most frequent cases in adult men occur between the ages of 20 and 54, while in women they occur at younger ages, between 20 and 34.

Persons with TB can infect up to 10-15 others, through close contact, over a period of one year.

From a legal perspective, patients with TB and persons at risk have access to prophylactic healthcare services, diagnostic and treatment, as well as to certain social services free of charge, as a result of a set of legal provisions set out in several general legislative acts.

Nevertheless, the major challenge for TB control in Romania relates to the chronic underfinancing of the National Tuberculosis Prevention and Control Programme, which, in time, has translated into shortcomings with regard to:

a) ensuring a quick and complete diagnostic;
b) ensuring a complete treatment in accordance with the treatment regimens recommended by the World Health Organization, on a continuous basis and correctly administered;
c) ensuring treatment adherence by means of patient-centred interventions (medical and psychosocial support).

a. Shortcomings in ensuring a rapid and complete diagnostic

Based on the data provided by the "Nationwide first-line drug chemoresistance survey" conducted in Romania in 2003-2004, the World Health Organization (WHO) estimates a number of at least 800 new MDR TB cases that should be diagnosed annually in Romania (2.8% of new TB cases and 11% of relapses). In reality, only around 400 new multidrug-resistant tuberculosis (MDR TB) and extensive multidrug-resistant tuberculosis (XDR TB) cases are identified annually, because only 50% of new cases and of relapses are tested for drug resistance.

Furthermore, although there are rapid diagnostic methods available worldwide, which decrease diagnostic time from 6 months to 2 weeks, in Romania, access to these methods is possible only under internationally-funded projects, for a limited number of patients.

b. Shortcomings in ensuring a complete, continuous and correctly administered treatment

In accordance with the national legislation in force, TB treatment is free of charge for all patients. TB treatment may take between a minimum 6 months (treatment-sensitive tuberculosis) and 24 months (for treatment-resistant tuberculosis).

According to the WHO reports assessing the National TB Prevention, Surveillance and Control Programme, while all drugs are available for treatment-sensitive tuberculosis, only part of the drugs are available for treatment-resistant tuberculosis, and this is a major setback in ensuring patient cure and, implicitly, in limiting the spreading of tuberculosis to the general population in Romania. Under these circumstances, over the last few years the cure rate for resistant tuberculosis patients in Romania has been one of the lowest in the world, namely 20% (equal to the spontaneous cure rate). As a result, Romania is unable to contain the reservoir of infectious patients, on the contrary, this reservoir is continuously increasing from year to year.

In addition to the drugs needed for the treatment of tuberculosis, ancillary drugs are also required for the treatment of side effects, and these are not entirely refunded from the state budget.

a. Shortcomings in ensuring treatment adherence by means of patient-centred interventions (medical and psychosocial)

Studies[3] have shown that during the treatment period, the main needs of the patients diagnosed with tuberculosis relate to the provision of the medical, social and psychological support required for a successful completion of the treatment.

The high rate of treatment abandonment (the treatment abandonment rate varies between 6% for new cases and over 25% for resistant tuberculosis patients) is explained by the absence of medical and psychosocial support services that provide support to the patient throughout the treatment and address the following needs: the sometimes very severe adverse side effects of anti-TB medication, the absence of material means for the patient's transport to the TB dispensary/family doctor on a daily basis, the absence of material means for ensuring a nutrient-dense diet rich in calories, proteins and vitamins, and of a lifestyle that would enable the cure, the absence of material means for procuring ancillary drugs for the treatment of side effects, the absence of directly observed treatment, the absence of the counselling and psychosocial support that the tuberculosis patient needs in order to complete the treatment until cured.

Treatment adherence, defined as the administration by the patient of the recommended therapy, taking all the drugs prescribed throughout its entire duration, is important because tuberculosis is almost always treatable if the patient follows the treatment, whereas the patient's refusal or impossibility to take the prescribed drugs in accordance with the instructions ("*non-adherence*") is the most important challenge in the control of tuberculosis and may have severe consequences. As a result, a patient who is non-adherent to the treatment may:

- experience a longer duration or a more severe evolution of the disease;
- transmit TB to others;
- develop and transmit MDR/XDR TB;
- die as a result of treatment discontinuation.

[3] The report „Mapping the needs of tuberculosis patients in Romania" - Bucharest, 2014

The patients and the medical staff are equally responsible for ensuring treatment adherence. The patient's and the family's decision whether to administer the drugs or not is highly dependent on the support they receive or not from the healthcare staff when they request it, and patient education is vital in this case.

In conclusion, the shortcomings referred to above cause the following negative effects:

- On budget expenses: because the entire expenditure incurred by the Romanian state for the patient concerned fails to achieve its purpose, as the patient must resume the treatment from the initial stage when his or her condition inevitably worsens, thus multiplying the treatment burden for the Romanian state.
- On citizens' public health: the patient who is not diagnosed, who is incompletely treated or who abandons the treatment exposes to the risk of tuberculosis contagion all the persons with whom he or she comes into contact: family members, work colleagues, travellers in the public transportation means, etc. In a vicious circle, the exposure of healthy persons to this risk leads to the increase of the number of TB patients and, implicitly, of the budget expenses for the treatment of these new cases.

The needs of a tuberculosis patient are multidimensional, and the medical and support services provided under the current legislation are not sufficient to cover them. Moreover, although the legislative provisions are to a certain extent exhaustive, the patients' actual access to the healthcare services is far from being adequate, due to a multitude of socioeconomic and cultural limitations, and the other support services are very little represented.

In order to reduce the risk of expansion of the tuberculosis endemic and reduce the budget expenses required for the funding of TB control in Romania, as well as in order to increase the degree of public safety for the citizens, this law proposes a cost-effective solution for reducing TB transmission.

This law proposes:

1. Universal access to diagnostic and complete and free treatment for all forms of tuberculosis;
2. The increase of treatment adherence by means of integrated patient-centred medical and psychosocial interventions.

This law seeks to ensure the right of the tuberculosis patient to meal allowance, financial support offered to the patients who are unable to cover from their own income the costs required during the treatment period representing expenses generated by the complete and continuous administration of the treatment, as well as expenses for transport from home to the outpatient facility and back (for directly observed treatment in accordance with the recommendations of the World Health Organisation), for the medication necessary for side effects, as well as for other needs determined by the patient's work incapacitation during the period when the anti- tuberculosis treatment is administered.

For a judicious use of the funds allocated for the implementation of this law, as well as in order to raise patient awareness with regard to the importance of treatment administration, the granting of the meal allowance will be subject to the compliance with the prescribed treatment, without discontinuation, during the month in question. If the patient diagnosed with tuberculosis fails to be present for the treatment during the time interval prescribed, the patient will no longer be entitled to the meal allowance.

This solution is of a nature to reduce budget expenses for the treatment of tuberculosis, and its effects will implicitly be reflected in the improvement of the public health status as well.

At present, the Romanian state spends approximately RON 21,262 for the financing of the complete treatment necessary for the sensitive-tuberculosis treatment (namely, treatment and hospitalisation costs, as well expenses due to lack of productivity), approximately RON 91,000 for the MDR TB patient, (treatment and hospitalisation costs, plus lack of productivity) and RON 143,000 for XDR TB (treatment and hospitalisation costs, plus lack of productivity).

Considering an additional expense of approximately RON 73 million for patient motivation (monthly allowance and counselling services) aimed at treatment observance, the result is an actual decrease of total costs (direct and indirect) for treatment of approximately 12.33%, noticeable in the second year from the entry into force and implementation of this law, and an annual decrease of 18.47% in the 3rd, 4th and 5th year from the entry into force.

Given that the patients diagnosed with tuberculosis are not provided with material support for the food necessary for the completion of the treatment, tuberculosis risks not being treated and the patient in question may develop treatment resistance, with three severe indirect consequences: the patient remains contagious, is unable to return on the labour market and budget costs increase due to the provision of a new treatment and the fact that the person in question remains inactive.

As a conclusion, having regard to the respect of human rights and the rights of the patient, as consecrated by European and international treaties and legislation, additional financial measures must be adopted in order to decrease the number of tuberculosis cases in Romania, by granting a meal allowance to patients diagnosed with tuberculosis, as well as psychosocial support services.