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DRAFT LAW ON PREVENTION AND CONTROL OF TUBERCULOSIS

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**Project elaborated by The Association for Supporting MDR-TB Patients and
Romanian Angel Appeal Foundation**

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Statement of reasons

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

Despite the advancement from the past 12 years, of a progressive decrease in the incidence of TB, from 142.2 per 100,000 inhabitants in 2002 (30,986 new cases and relapses) to 73.3 per 100,000 inhabitants in 2013 (15,629 new cases and relapses), Romania remains the country with the highest incidence in the EU (five times above the EU average), providing about 20% of TB cases reported in the EU, given that it has only 4% of the population.

The TB incidence varies across the country and is relatively influenced by socio-economic status of the regions, with higher values in the east, west and south and lower in the centre and northwest.

Compared to other European countries, in Romania, the extent of this phenomenon is not due to migration (every year, only a few cases are reported in people born outside the country) or to HIV (the percentage of HIV infected cases in the number of TB cases that were reported in recent years was below 0.5%), an important factor in the severity of TB endemic in Romania being the socio-economic problems faced by patients. The decline in the living standards influenced the incidence evolution, the proof being the fact that the highest incidence is recorded in the counties in the south and in Moldova, which also have the most significant socio-economic problems.

According to the IMF¹ report, despite the increase in the minimum wage, in 2014 Romania continues to have a low wage level compared to other countries in the region. The same report noted that given the high unemployment rate among young people in Romania (23.2% on average in the first nine months of 2013) and the growing proportion of fixed-term contracts, higher minimum wages could have negative implications for employment. Unemployment rate increased from an average of 7.3% in 2013, compared to 7% in 2012.

According to the data provided by the National Tuberculosis Control Programme, in Romania, as well as worldwide, the cases of disease among men are 2.1 times more frequent than among women. Distribution by age indicates differences by gender: most diseases occur in adult men between 20 and 54 years old and in women at younger ages, between 20 and 34.

From a legal standpoint, tuberculosis patients and people at risk have access to free prophylactic health services, diagnosis and treatment and to some social services, through a sum of provisions, mentioned in several general laws.

Nevertheless, the major challenge in TB control in Romania is related to the chronic underfunding of the National TB Control Programme, which translated over time in deficiencies in:

- a) Providing a rapid and complete diagnosis;
- b) Providing a full, continuous and properly administered treatment;

¹ <http://www.imf.org/external/pubs/ft/scr/2014/cr1487.pdf>

c) Ensuring treatment adherence through interventions focused on patient needs (medical and socio-psychological support).

a. Deficiencies in providing a rapid and complete diagnosis

Based on the data from the "National first-line drugs chemo-resistance survey" conducted in Romania in 2003-2004, the World Health Organization (WHO) estimated that a minimum of 800 new cases of MDR-TB should be diagnosed annually in Romania (2.8% of new TB cases and 11% of relapses). In fact, annually, there are identified only about 400 new cases of multi-drug resistant tuberculosis (MDR-TB) and extensively resistant tuberculosis (XDR-TB) since only 50% of new cases and relapses are tested for drug resistance.

In addition, while there are methods of rapid diagnostic worldwide, which decrease the diagnostic time from 6 months to 2 weeks, in Romania, the access to these methods is available only through projects with international funding, for a limited number of patients.

b. Deficiencies in providing a full, continuous and properly administered treatment

According to the national legislation, the TB treatment is free for all the patients. The TB treatment can last from a minimum of 6 months (for drug-sensitive tuberculosis) to 24 months (for drug-resistant tuberculosis).

According to the WHO evaluation reports of the National TB Control Programme, while for sensitive tuberculosis all the drugs are available, for resistant tuberculosis only some of the drugs are available in Romania, which represents a major challenge for curing the patients and thus for containing the spread of tuberculosis in the Romanian population. Under these circumstances, in recent years, Romania had one of the lowest success rates for drug-resistant TB patients in the world: 20% (equal to the rate on spontaneous cure). Thus, Romania can not contain the pool of infectious patients; on the contrary, this reservoir is growing every year. Additional to the necessary drugs to treat tuberculosis, other drugs are required for the treatment of side effects, which are not fully reimbursed from the state budget.

c. Deficiencies in ensuring treatment adherence through interventions focused on patient needs (medical and socio-psychological support)

Studies² show that, throughout treatment, the main needs of the patients diagnosed with tuberculosis are related to medical, social and psychological support necessary for the successful completion of treatment.

The high rate of treatment default (between 6% for new cases and more than 25% for patients with resistant tuberculosis) is explained by the lack of medical-socio-psychological services to support the patient throughout treatment and to address the following needs: side effects sometimes extremely severe caused by the anti-TB drugs, patient's lack of means for daily transportation to the TB clinic / GP practice, lack of means for additional nutritional support needed for healing (minimum 4,000 calories / day), lack of funds for drugs to treat side effects, lack of directly observed treatment, lack of social and psychological counselling and support for completing the treatment until cure.

² The Report "Mapping of TB patients' needs in Romania", Bucharest, 2014

Treatment adherence, defined as the patient following the recommended therapy, taking all the prescribed drugs for the entire duration, is important, because TB is almost always curable if the patient undergoes treatment, while the patient's refusal or failure to take medication as prescribed ("non adherence") is the biggest problem in TB control and can have serious consequences. In these circumstances, a non-adherent patient can:

- have a longer or more severe evolution of the disease;
- spread TB to others;
- develop and spread MDR TB;
- die as a result of default.

Patients and medical staff are equally responsible for ensuring adherence to treatment. The decision of the patient and the family to administer or not the medication depends heavily on the help they receive or not from the health professionals when they require it, in these cases patient education being vital.

In conclusion, the above mentioned deficiencies cause the following negative effects:

- On budget expenditure: because all the expenses incurred by the Romanian state for that patient no longer achieve their goal, the patient must, when the condition inevitably worsens, resume treatment from the initial stage, thus doubling the Romanian state expenditure for treatment.
- public health of the citizens: undiagnosed patients treated incompletely, incorrectly or who defaulted, expose everyone they come in contact with: family members, co-workers, passengers of public transport etc. to the risk of infection with tuberculosis. In a vicious circle, exposure to these risks of healthy individuals increase the number of patients infected and hence the public expenditure for treating these new cases.

The TB patient's needs are multidimensional and the medical and support services provided by the current legislation are insufficient to cover these needs. Moreover, although the legal provisions are somewhat comprehensive, the real access of patients to health care is far from adequate due to multiple socio-economic and cultural constraints and the remaining support services are very poorly represented.

To reduce the risk of infection and the public expenditure needed to finance the TB control in Romania, including the funds for increasing public health safety for citizens, this bill proposes an effective solution in terms of reducing the TB transmission .

This bill proposes:

1. universal access to diagnosis and complete and free treatment for all forms of tuberculosis;
2. Increased treatment adherence through integrated medical-socio-psychological interventions focused on the patient's needs.

This solution has the potential to reduce the budgetary expenditure for TB treatment, and thus its effects will be found in the improvement of public health. Currently, the Romanian public expenditure to fully fund the necessary treatment for sensitive TB patients is about 21,250 Romanian lei (i.e. costs with medication and the lack of productivity), for MDR-TB -

around 91,000 Romanian lei (i.e. costs with medication and the lack of productivity) and for XDR-TB - 143,000 Romanian lei (i.e. costs with medication and the lack of productivity).

Considering an approximate additional expenditure of 82 million Romanian lei for motivating the patients (monthly food allowance and psychosocial support services) in order for them to comply with therapy, this results in a decrease in real total costs for treatment (direct and indirect) of about 31.78% observable in the fourth year after the entry into force and application of this law, leading to budget savings of 62.41% in the sixth year.

If the patients diagnosed with tuberculosis are not provided with support for food necessary to complete the therapy, then tuberculosis is not treated and the patient may develop drug resistance with three serious indirect consequences: the patient stays contagious, the patient cannot return on the labour market and budgetary costs are increased due to providing a new treatment and keeping the person inactive.

Therefore, in order to ensure patient and human rights, as sanctioned by national laws and European and international treaties, additional financial measures are necessary in order to reduce the TB cases in Romania, through the provision of food support to the patients diagnosed with tuberculosis, as well as psycho-social support services.

DRAFT LAW ON MEASURES FOR PREVENTION AND CONTROL OF TUBERCULOSIS

Chapter I

General Provisions

Section 1 - This law regulates the framework for the prevention and control of tuberculosis at the individual and general population level, in order to protect human health.

Section 2

(1) Tuberculosis is a major public health challenge in Romania, and prevention and control are strategic objectives of national concern.

(2) The Ministry of Health, as the central authority in public health, is responsible for coordinating and taking all necessary measures to prevent and control tuberculosis.

(3) To achieve the provisions of paragraph (2) the Ministry of Health, in collaboration with the other central and local public authorities, public and private institutions and NGOs, regularly develop a national strategy to be applied through a decision of the Romanian Government.

(4) The objectives of the national strategy the prevention and control of tuberculosis must meet the strategic directions in the field, established by the World Health Organization, the European Union and the national laws.

Section 3 - The Ministry of Health is responsible for the implementation of the National Programme for Tuberculosis Prevention, Surveillance and Control.

Section 4 - Meeting all legal measures to prevent and control tuberculosis is a duty of the local authorities and central government, as well as all of individuals and legal entities.

Section 5

(1) In Romania, each person is guaranteed free access to correct and complete services for medical, social and psychological support to prevent and control tuberculosis.

(2) For the purposes of this law, services for prevention and control of tuberculosis are as follows:

- a) Tuberculosis prevention services,
- b) Tuberculosis diagnostic services,
- c) Tuberculosis treatment services,
- d) Social and psychological support services for people with tuberculosis.

Section 6 - For the purposes of this law, the words and phrases below have the following meanings:

- a) the treatment adherence - the patient follows strictly the recommended therapy, taking all the prescribed drugs for the entire duration;

- b) suspect case / suspect - is the person who shows signs or symptoms suggestive of tuberculosis before diagnosis confirmation;
- c) tuberculosis contact - is the person sitting near a contagious patient, at a conversation distance, for at least 4 hours;
- d) strategic documents for the tuberculosis management in Romania - all the documents developed under the National Programme for Tuberculosis Prevention, Surveillance and Control that govern the tuberculosis control in Romania and methodological regulations for the implementation of the National Programme for Tuberculosis Prevention, Surveillance and Control, clinical guidelines, the National Strategy for Tuberculosis control in Romania and other regulations in force in the field;
- e) closed circuit pharmacy - is a pharmaceutical unit that provides access to medication for human use to patients admitted to hospitals from the health network of the Ministry of Health and other ministries, institutions and associations with their own health network;
- f) active identification of tuberculosis suspects and contacts - is the activity of identifying suspects by the primary healthcare services, school doctors, physicians providing health surveillance for employees or practitioners working with groups considered at risk for tuberculosis;
- g) group considered at risk for tuberculosis - designates people among the contacts of the tuberculosis patients, extremely poor people, the homeless, people on social benefits, HIV positive people, drug users, people in prisons or other correctional institutions, individuals chronically hospitalized in psychiatric units, cases of neoplasm, diabetes, cirrhosis and chronic B or C hepatitis with specific treatment, people receiving immunosuppressive treatment for various diseases, organ transplants, collagenosis and other disorders treated with immunosuppressors, chronic alcoholics, the staff working in hospitals, the workers exposed to coniosis / pneumoconiosis toxic substances, those on construction sites, those living in dormitories, commuters, people in foster care and nursing homes, haemodialysis patients;
- h) bacteriology laboratories - are laboratories in which the bacteriological test for tuberculosis is performed;
- i) the patient who has followed the complete treatment for tuberculosis - the patient who has undergone full treatment, but does not meet the criteria to be considered cured or the disease was located extra-pulmonary;
- j) the patient who has followed the complete treatment for multidrug-resistant tuberculosis - is the patient who has undergone full treatment but does not meet the criteria to be considered cured or failure due to lack or insufficient number of bacteriological results;
- k) patient cured of tuberculosis - the patient diagnosed with bacteriologically confirmed pulmonary tuberculosis who took a complete treatment and is still culture negative at end of therapy and at least another previous control;
- l) patient cured of multidrug-resistant tuberculosis - is the patient who took a complete course of treatment according to the protocol in force and had at least five consecutive negative cultures taken at minimum 30 days in the last 12 months of treatment;

- m) prevention - any action that interrupts, stops or reduces the spread of tuberculosis at the individual or general population level;
- n) National Tuberculosis Prevention, Surveillance and Control Programme - national public health programme funded systematically by the Ministry of Health;
- o) treatment - all the medication necessary to treat tuberculosis as mentioned in practice protocols for treatment prescribing and monitoring, issued by the Ministry of Health and recommended by the World Health Organization;
- p) directly observed treatment - is the treatment administered to a tuberculosis patient under direct observation of a health worker, community nurse, social worker, health mediator or any other person identified in the community by the tuberculosis health services, to whom the patient is referred;
- q) Tuberculosis - any form of infection with *Mycobacterium tuberculosis* which shows symptoms, regardless of location, infectious potential or sensitivity to treatment;
- r) treatment resistant tuberculosis or multi-drug resistant tuberculosis - the tuberculosis caused by organisms resistant to at least Isoniazid and Rifampicin.

Chapter II

Tuberculosis prevention

Section 7

(1) Tuberculosis prevention can address both the individual and the population as a whole, or the groups at risk.

(2) The main measures for the tuberculosis prevention consist of, but are not limited to:

- a) continuous information and education of the general population about the risk of tuberculosis, the ways of transmission of the disease, the main signs and symptoms, available services as well as measures to prevent and fight the infection;
- b) education and counselling for the tuberculosis patients on hygiene measures in order to prevent the spread of the infection;
- c) periodic health checks and screening tests, as appropriate, for groups considered at risk, in line with the strategic documents for the tuberculosis management in Romania;
- d) Rapid intervention in tuberculosis outbreaks carried out in line with the strategic documents for the management of tuberculosis in Romania, with the free examination of all people with whom patients diagnosed with tuberculosis came in contact and prophylactic treatment, as appropriate.

(3) In order to implement the measures mentioned in paragraph (2), the public institutions with responsibilities in tuberculosis prevention, surveillance and control permanently collaborate with national and international NGOs.

Chapter III

Tuberculosis diagnosis

Section 8 - Diagnosis of tuberculosis is done according to the algorithm and diagnostic methods mentioned in the strategic documents for the management of tuberculosis in Romania, in line with the principles and recommendations of the World Health Organization.

Section 9 - Any person with tuberculosis symptoms may go directly to the pneumoftiziologie dispensaries, without a referral from the family doctor.

Section 10

(1) All the healthcare providers are required to detect signs and symptoms of TB in patients who present themselves for examination and to refer the suspect cases to the territorial pneumoftiziologie dispensary for diagnosis, in line with the strategic documents for the management of tuberculosis in Romania.

(2) All healthcare providers are required to notify in writing the territorial pneumoftiziologie clinic of a suspected case of tuberculosis in a person.

Chapter IV

Tuberculosis treatment

Section 11

(1) The people diagnosed with tuberculosis have the right to the medical care of the highest quality that the society can provide, without any discrimination on grounds of race, nationality, ethnicity, religion, social status, disadvantaged category, beliefs, age, gender or sexual orientation of the persons concerned.

(2) Treatment of tuberculosis is carried out according to the national practice protocols for prescribing, monitoring and reimbursement of treatment, developed in accordance with the legal provisions.

Section 12 - The medical care provided to people diagnosed with tuberculosis is guaranteed by the state and is based on the principles of respect for human dignity, confidentiality, total gratuity, and accessibility.

Section 13 - Treatment of tuberculosis is provided free of charge to all people diagnosed, appropriate to the form of the disease, and the necessary drugs are made available through closed circuit pharmacies.

Section 14

(1) Medical treatment is given to people diagnosed with tuberculosis continuously until they are cured.

(2) During the period of medical treatment, the patient diagnosed with tuberculosis has the right to psychosocial support and counselling.

Section 15 - The treatment of the patient diagnosed with tuberculosis is administered under direct observation, in accordance with World Health Organization recommendations.

Chapter V

Social protection measures for people with tuberculosis

Section 16 - The people diagnosed with tuberculosis, insured in the public health social security system, are entitled to a leave and temporary disability allowance without employment record restrictions, throughout the period of treatment, until cure.

Section 17

(1) In order to ensure treatment adherence of patients diagnosed with tuberculosis, they are given a monthly food allowance while they receive the treatment in out-patient facilities.

(2) The food allowance for the tuberculosis patients is approved by Government decision, and the methodology and conditions of granting it is approved by joint order of the Minister of Health and Minister of Labour, Family, Social Protection and the Elderly.

Section 18 Monthly food allowance is provided from the state budget through the Ministry of Labour, Family, Social Protection and the Elderly and is paid monthly:

- a) by postal order;
- b) in the personal account;
- c) through another form of payment mentioned in the application by the adult beneficiary or by the legal representative of the child;
- d) in the special account opened for this purpose by the county or district General Directorates for Social Assistance and Child Protection or by the authorized private organisations, for children in foster care or custody of a public social care institution or a private authorised organization.

Section 19

(1) Monthly food allowance is granted to the patient provided that they follow the prescribed treatment without interruption, for that month.

(2) In order to provide the monthly food allowance, the pneumoftiziology dispensaries work with the Ministry of Health, the Ministry of Public Finance and the Bucharest and county agencies for payments and social inspection, to calculate the amounts necessary for each patient undergoing treatment in the medical unit, throughout the entire period of treatment.

Section 20

(1) If the patient diagnosed with tuberculosis does not come for treatment within the appropriate time period, they are no longer entitled to a monthly food allowance.

(2) The medical units will inform the Ministry of Health and the Bucharest and county agencies for payments and social inspection on the number of patients who defaulted.

Section 21 - The amount of the monthly food allowance payable for adults and children diagnosed with tuberculosis is increased at the same time as the amount for food allocations for collective consumption in the public health facilities.

Chapter VI

The public institutions' responsibilities related to the prevention and control of tuberculosis

Section 22 - The Ministry of Health is the manager of the national pneumoftiziologie network of pneumoftiziologie clinics, in-patient hospitals, bacteriology laboratories, and primary healthcare units, being responsible for the implementation and monitoring of the National Programme for Tuberculosis Prevention, Surveillance and Control.

Section 23 - The National Institute for Pneumoftiziologie "Prof. Dr. Marius Nasta" of Bucharest is the methodology coordinator of the pneumoftiziologie network and the Central Management Unit for the National Programme for Tuberculosis Prevention, Surveillance and Control.

Section 24

(1) The pneumoftiziologie clinics within the Ministry of Health network provide diagnosis, treatment, recording, reporting and monitoring of the tuberculosis cases as well as tuberculosis infection control through participation in epidemiological surveys.

(2) The pneumoftiziologie clinics work with family doctors and supervise their activities in identifying tuberculosis and administering the treatment under direct observation and, for the epidemiological surveys, they collaborate with both family doctors and the county public health department.

Section 25 - The Ministry of Justice, the Ministry of Defense and the Ministry of Interior shall implement, within their own healthcare networks and pneumoftiziologie units, the responsibilities related to the National Programme for Tuberculosis Prevention, Surveillance and Control.

Section 26 - The personnel of public institutions and private bodies responsible for preventing, monitoring and control of tuberculosis are required to comply with legal requirements on confidentiality of persons diagnosed with tuberculosis.

Section 27 - All primary healthcare providers are required to actively identify tuberculosis suspects and contacts and to administer treatment to patients under direct observation, according to the pneumoftiziologie doctor's recommendations.

Section 28 - Public county or local authorities that administer in-patient healthcare units that treat resistant tuberculosis cases are required to establish, budget and maintain psychosocial support services for those patients in the healthcare units.

Section 29 - Public social care services subordinated to county councils, local councils of towns and cities, district councils of Bucharest and the Bucharest General Council provide psychosocial support services for patients diagnosed with tuberculosis living in the respective territorial administrative units.

Chapter VII

Public information on the risks of tuberculosis transmission

Section 30.

(1) The Management Unit for the National Programme for Tuberculosis Prevention, Surveillance and Control develops an annual national public awareness plan on the risks of Tuberculosis transmission and the prevention measures as well as on the counseling, care and treatment services for patients diagnosed with tuberculosis.

(2) The annual public awareness plan on the risks of tuberculosis transmission and infection prevention as well as on counseling, care and treatment services for the patients diagnosed with tuberculosis is developed and implemented within 90 days from the entry into force of this law.

Section 31 - The patient that was declared cured with full treatment receive free information and counseling services from family doctors in order to prevent the relapse.

Section 32 - The people who are under treatment for tuberculosis are provided with information, career counseling and mediation in order to establish employment or work rapports.

Section 33 - The Ministry of Health is continuously working with the Ministry of Education and the Ministry of Labor, Family, Social Protection and the Elderly in developing annual strategies to inform the population about prevention measures to be observed in schools and work places.

Chapter VIII

Financing of tuberculosis prevention, control and treatment

Section 34 - The actions taken to prevent, control and treat tuberculosis are financed from the state budget, from the budget of the national fund for social healthcare insurance and from any other sources, according to the law.

Section 35 - The Ministry of Health provides the necessary funds to finance the National Programme for Tuberculosis Prevention, Surveillance and Control.

Chapter IX

Final provisions

Section 36. - In order to implement the measures for prevention and control of tuberculosis in Romania, the central and local public authorities with responsibilities in prevention,

surveillance and control of tuberculosis will permanently collaborate with all healthcare providers and with national and international NGOs.

Section 37

(1) Within three months from the entry into force of this law, the National Strategy for Tuberculosis Control is approved by Government Decision.

(2) Within three months from the entry into force of this law, the amount of food allowance for adult and children patients with tuberculosis is approved by Government Decision as well as the Joint Order of the Minister of Health and Minister of Labor, Family, Social Protection and the Elderly concerning the methodology and the conditions for granting the food allowance to tuberculosis patients.

(3) Within three months from the entry into force of this law, the Ministry of Health, the Minister of Labor, Family, Social Protection and the Elderly, the Ministry of Finance, the Ministry of Education, the Ministry of Justice, the Ministry of Defense and the Ministry of Interior will elaborate the methodological rules of application of this law and will submit them for approval through a Government Decision.

Section 38 - This law shall enter into force three days after its publication in the Official Gazette of Romania, Part I.

This law was passed by the Parliament of Romania, in compliance with Section 65, paragraph (2) and Section 76, paragraph (1) of the Romanian Constitution.

President of the Chamber of Deputies

President of the Senate

Bucharest

Date:...../...../2014

No. ...