

Response

of the Bulgarian Government to the report of the European Committee for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment (CPT) on its visit to Bulgaria

from 21 to 31 March 2023

The Government of Bulgaria has requested the publication of this response. The CPT's report on the 2023 visit to Bulgaria is set out in document CPT/Inf (2024) 06.

Strasbourg, 31 January 2024

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LIST OF ABBREVIATIONS USED IN THE INFORMATION

Abbreviation	Full form
CPT	European Committee for the Prevention of Torture, Inhuman or Degrading Treatment or Punishment
MLSP	Ministry of Labour and Social Policy
SAA	Social Assistance Agency
OQSS	Ordinance on the Quality of Social Services
TFP	Transitional and Final Provisions
OPSS	Ordinance on the Planning of Social Services
NLTCS	National Long-Term Care Strategy
HRDOP	Human Resources Development Operational Programme
RGOP	Regions in Growth Operational Programme
CSRI	Centres for Social Rehabilitation and Integration
FACAMR	Family-type Accommodation Centres for Adults with Mental Retardation
FACAMD	Family-type Accommodation Centres for Adults with Mental Disorders
FACE	Family-type Accommodation Centres for Elderly
SSQA	Social Services Quality Agency
HAMR	Home for Adults with Mental Retardation
IIS	Integrated Information System
HDA	Home for Disabled Adults
HAMD	Home for Adults with Mental Disorders

Establishments under the authority of the Ministry of Health

Regarding the findings and criticisms in the Report of the European Committee for the Prevention of Torture and Inhuman and Degrading Treatment (CPT), we would like to note that the Ministry of Health highly values the cooperation with the CPT and with regard to the comments made in the said Report, provides the following information:

Mental health support is a top priority in the Ministry of Health's policy. With Decision No. 388 of April 23, 2021 of the Council of Ministers of the Republic of Bulgaria, the *2021 - 2030 National Strategy for Mental Health of the Citizens of the Republic of Bulgaria* was adopted, with a general financial resource foreseen for the entire period of operation (2021 - 2030), amounting to BGN 57,655,000, with the main strategic goals aimed at:

- reduction of morbidity, illness and mortality of mental disorders;
- integration of psychiatric services into general medical care (deinstitutionalization);
- creation of a network of services for complex services for people with severe mental illness near the place of residence, centres for the treatment of disorders related to the way of eating;
- reducing the use of alcohol and narcotic substances, and reducing the manifestations of aggression and auto-aggression;
- development of child-adolescent psychiatry, psychiatry in old age and forensic psychiatry;
- respecting human rights and combating stigma and discrimination.

In addition, with Decision No. 158 of July 7, 2022 of the Council of Ministers of the Republic of Bulgaria, a *National Council for Mental Health* was established under the Council of Ministers, which is a permanent advisory body to the Council of Ministers for coordination, cooperation and consultation in the implementation and the monitoring of the *2021 – 2030 National Strategy for Mental Health of the Citizens of the Republic of Bulgaria*. In this way, the involvement of various institutions and departments is ensured for purposeful coordination and convergence of all policies and resources.

The *National Mental Health Council* at a meeting considered and discussed the Report of the CPT to the Bulgarian government, and the members of the council made a number of proposals based on the findings and recommendations in the Report. In this regard, the Minister of Health plans to commission through orders and letters the proposed specific measures, which is a step in solving the pressing issues in the State Psychiatric Hospitals (SPH), in the country, namely:

- Development of multiple tools to support SPH, aimed at providing staff, improving conditions for prevention, diagnosis and treatment of mental disorders;
- Development of a uniform methodology for training SPH personnel,
- Foreseeing that the *Expert Council on Psychiatry* will develop and present to the Minister of Health training programs for the staff;
- Providing methodological support for conducting collegiums for modern approaches to treatment - medical and nursing.

In connection with the findings and criticisms in the CPT Report, the Ministry of Health has assigned the competent institutions - the Regional Health Inspectorates (RHI), the Executive Agency Medical Supervision (EAMS) and the Bulgarian Drug Agency (BDA) to carry out inspections in psychiatric hospitals mentioned in the Report: the State Psychiatric Hospital in the village of Tserova Koriya (SPH-Tserova Koriya) and the State Psychiatric Hospital in the town of Byala (SPH-Byala).

In the course of the inspections, the inspection teams made on site visits to the indicated medical facilities with a view to confirming the stated findings of the CPT, as well as verifying the compliance of the treatment carried out and the measures taken, in relation to the patients, to the requirements of the Bulgarian legislation regulating social relations in the field of mental health. In this regard, we provide detailed information on the points of the Report relating to SPHs on the territory of the Republic of Bulgaria.

Regarding the recommendation under point No. 13:

At the SPHs, teams work closely with patients' relatives and the *Agency for Social Assistance* to refer them to social services.

In connection with the above, in SPH-Tserova Koriya, in the period after the visit of the CPT, 8 /eight/ patients have been transferred to new social services in the town of Pernik and the town of Kula, and at the beginning of October 4 /four/ more patients are to be transferred in newly opened social services. In addition, in SPH - Byala, from the beginning of 2023 until now, a total of 14 patients have been transferred to social services.

Regarding the recommendation under point No. 17:

The Ministry of Health is taking many decisive steps for zero tolerance towards SPH staff, to various manifestations of ill-treatment of patients, and will monitor the strict implementation of the current normative documents regulating the activities of SPHs, as follows:

- Daily visits by SPH managers and conducting conversations with patients in all wards about conceivably applied forms of violence;
- Introduction of a system for reporting and registering oral complaints from patients;
- Moving the cleaning inventory to inaccessible and lockable places - in rooms designated for cleaning agents;

In implementation of the recommendation given, the Minister of Health requires the directors of the SPHs to show zero tolerance towards all employees exercising physical violence or humiliating treatment at patients and take, if necessary, disciplinary measures provided for in the laws of the Republic of Bulgaria.

In order to control the implementation of the measures taken by the management of the medical facilities in the direction of preventing omissions and violations and in connection with the topics on which the recommendations of the CPT are focused, it is planned to carry out subsequent inspections by the control bodies in all state psychiatric hospitals.

Regarding the recommendation under point No. 23:

In relation to the said recommendation, the budget of the SPHs for 2023 compared to 2022, for subsistence and other current expenses, has been increased by an average of 24.7%, which will contribute to the improvement of living conditions in the SPHs, including SPH -Byala and SPH-Tserova Coriya.

In connection with the recommendation that patients should be encouraged to wear their own clothes, we draw attention to the fact that a large number of patients in the SPHs are placed on mandatory and forced treatment for a long period of time, and during their placement, the majority of patients live in severe social living conditions (there are reports that some of them are homeless and arrive at the medical facility scantily clad).

In addition, the *Recovery and Resilience Plan* (RRP) foresees a specific measure "Modernization of psychiatric care in Bulgaria", for which the total planned resource is BGN 28.5 million (BGN 23.8 million at the expense of the Mechanism for Recovery and Resilience and BGN 4.7 million national co-financing). This investment will be aimed at improving the material and technical base in the structures of the psychiatric care system for providing quality health care, providing modern opportunities for treatment and rehabilitation of patients, as well as developing opportunities for their inclusion in society. It is planned to intervene in the infrastructure of at least 18 medical facilities providing psychiatric care. According to the annex to the Implementation Decision of the Council approving the evaluation of the RRP of Bulgaria, the text of Component 12 "Healthcare", for the psychiatric care investment indicated that "The facilities are to be renovated and equipped, and the equipment needs of each facility are determined based on an analysis of the needs of the psychiatric care facilities." In this regard by order of the Minister of Health, the *National Centre for Public Health and Analyses* was commissioned to organize the implementation of the Assessment of the needs of the population (in general and those in psychiatric hospitals) for mental health services and their provision at the territorial level and to prepare an analysis of the number of adults and children in need of specialized social services, in order to determine the number and territorial distribution of services by municipality, as well as the number of specialists to be engaged. The assessment of needs is part of the activities of the Action Plan for the 2021 – 2030 *National Strategy for Mental Health of the Citizens of the Republic of Bulgaria*.

Regarding the repair request from SPH-Byala, the Director of the medical facility has stated the need to repair the women's wards for long-term treatment and the men's wards for the elderly in the hospital is in the amount of BGN 303,000. The decision to provide the funds will be made after completion of the commissioned assessment of the needs of the population for mental health services and their provision at the territorial level in order to avoid the risk of double funding.

In addition, the management of SPH-Byala, in connection with the finding of overcrowding of the hospital rooms, took measures, whereby the unoccupied beds were moved to the first block, and three beds were left in the second block, which ensured the necessary standard of 6.5 sq. m. per bed.

In line with the recommendations given, the Ministry of Health tasked the directors of the SPHs to create a better organization to comply with the prohibition of smoking in closed rooms of hospitals, paying particular attention to measures that support patients to quit smoking.

Regarding the recommendation under point No. 30:

In terms of staffing, the Ministry of Health is constantly making efforts to attract qualified specialists, taking measures to increase the pay of SPH workers and improve working conditions in medical facilities, including by improving the material base and providing additional social benefits. The number of staff at the SPHs is determined by the Regulations for the organization and operation of medical institutions for inpatient psychiatric care, pursuant to Art. 5, paragraph 1 of the Law on Medical Institutions. There is an uneven distribution of medical specialists on the territory of the country and territorial imbalances in available resources, which is a major problem. In this regard, the Ministry of Health focuses on the problem of staffing SPHs, not only by doctors, but also nurses, psychologists and social workers who are needed to care for patients. The *National Council on Mental Health* plans to discuss a proposal to change the normative documents regulating the right to acquire the Psychiatry medical specialty in order to attract and retain young personnel in the psychiatric care system.

In addition, we note that some growth has been achieved in the labour remuneration of SPH workers, with an average 22% increase in SPH's personnel cost budget for 2023 compared to 2022. We would like to note that in addition to the measures that are taken at the national level, the Ministry of Health has given the SPHs the opportunity to implement their own policy for attracting specialists by offering certain social benefits - food vouchers, free insurance, free transport, continuing education of the medical staff, etc.

Regarding the recommendation under point No. 32:

According to a decision of the *National Mental Health Council*, a working group was created, which was assigned to develop algorithms together with the Bulgarian Psychiatric Association, for the most severe and common psychiatric nosological units.

In connection with the recommendations made, during the inspections carried out at the SPHs, it was established that the individual treatment plans are in accordance with the Psychiatry medical standard, and that the medical documentation is formed according to the requirements of the standardized documentation and contains: procedure, mental status, neurological status, physical status, psychiatric syndrome, diagnosis according to ICD-10, diagnostic and treatment plan, supervisions, regimen. Attached to the disease histories (DH) are: Declaration of Informed Consent for Inpatient Treatment, signed by the patient; Doctor's assessment during hospitalization; Nursing assessment on admission; Initial assessment of suicidal risk and aggression. Observation and follow-up of the patients is reflected in the disease history, as well as is the prescribed drug therapy. Disease histories are informative about the mental state, medications, vital signs and consultations with specialists. The condition of the patients is followed by a minimum of two disease histories per week.

In addition, psycho-social therapies such as art therapy (there is a drawing room), social celebrations with the participation of the patients (such as singers, etc.) and individual celebrations are organized for the patients. In SPH–Byala, there is a furnished gym with a massage chair available, there is a room where patients make toys, play chess, etc., whereas the stabilized patients are allowed to walk freely in the adjacent park (a significant part of the SPHs have parks in which

the Ministry of Health plans to create conditions for rehabilitation activities, occupational therapy and sports).

In view of the recommendations made and having in mind the deficit due to the insufficient number of psychologists and social workers in the SPHs, the *National Council for Mental Health* plans to discuss the preparation of normative documents regulating the activities of clinical psychologists in the SPHs.

Regarding the recommendation under point No. 36:

The Ministry of Health commissioned the BDA to prepare an explanatory note with answers to the questions raised and a copy of the requested information. Signed and dated informed consent forms are available for each patient screened in a clinical trial, with names entered and signature affixed. For each participant, the date on which the informed consent was signed precedes the date on which the trial procedures were performed, and for clinical trials in which the presence of caregivers for the participants is required according to the protocol, signed forms are available for them in this capacity in the trial.

As an appendix¹ to this position, we are also providing the BDA's response, along with copies of the Ethics Committee Opinions on the individual clinical trials.

Regarding the recommendation under point No. 39:

In the SPHs, the active work continues, aimed at maintaining and improving the treatment of patients by the nursing staff, with the aim of preventing physical and mental abuse of patients. The application of measures of temporary physical restraint is carried out only as a last resort to prevent immediate harm to the patients themselves or to others. Immobilization is carried out in compliance with the requirements of Ordinance 1 of July 28, 2005 on the procedure for applying measures for temporary physical restraint of patients with established mental disorders.

Regarding the recommendation under point No. 44:

In connection with the appeal to the Bulgarian authorities to take the necessary legislative steps regarding the informed consent for treatment, by order of the Minister of Health, an interdepartmental working group was established with representatives of members of the *National Council on Mental Health*, the Ministry of Health and the Ministry of Justice, with the task to carry out a review of the regulatory framework of psychiatric care in the Republic of Bulgaria and prepare proposals for regulatory changes in order to optimize the *Health Act*, in its part on emergency and mandatory psychiatric treatment (Chapter Five - Mental Health, Art. 145 - Art. 165), as well as other legal acts related to the effectiveness and quality of psychiatric care.

In addition to the above, by order of the Minister of Health, working groups were created, which were assigned the development of the draft laws provided for in the Health sector of the *Management Program of the Republic of Bulgaria for the period June 2023 - December 2024*, adopted with Decision No. 506 of the Council of Ministers of 2023.

¹ The BDA's response is to be found in the Appendix attached to this document.

Regarding the recommendation under point No. 46:

The SPHs have permitted and provided phone access to patients at specific time intervals. Restrictions have been introduced for some of the patients, which are imposed when relatives refuse to communicate with the SPH patient; if relatives do not want to be disturbed at any time of the day, incl. during working hours; in the presence of risks from the uncontrolled use of mobile phones for psychotic reasons; using mobiles for providing means for injury, self-harm, medicinal and narcotic substances that are not permitted by the hospital's security regime; the possibility of making abusive phone calls to institutions such as 112, institutions, etc. The procedure for the use of mobile phones by patients at the SPHs is regulated in the Rules for the organisation, activity and internal order of the SPHs.

As can be seen from the above information, mental health support is a top priority in the Ministry of Health's policy, with a major emphasis on a complete shift of the paradigm with regard to the care for patients with mental illnesses.

Establishments under the authority of the Ministry of Labour and Social Policy

The presented information builds on the materials submitted at previous stages, including the Bulgarian government's response to the recommendations made in the Preliminary Observations for improving the care of persons with disabilities living in the Home for Adults with Mental Retardation (HAMR) in the village of Draganovo, Gorna Oryahovitsa Municipality, and the HAMR in the village of Tri Kladentsi, Vratsa Municipality, visited by the CPT delegation.

First of all, we would like to note that the Ministry of Labour and Social Policy (MLSP) continues to monitor the implementation of the following priority measures outlined in the response of the Bulgarian government published on the official website of the Council of Europe (dated 18.10.2022):

- ✓ Continuation of continuous monitoring and control for effective spending by municipalities of the funds provided by the state and for ensuring quality care for people using social services for residential care in homes for adults with disabilities, as well as in residential care services for elderly people;
- ✓ Provision by the competent authorities of the necessary assistance and methodical support of the municipalities;
- ✓ Continuation of the actions to categorically change the model of care for people with disabilities, related both to the undertaken reform for deinstitutionalization and to real improvement of the living conditions in the homes and the care of the people accommodated in them.

In the monitored period after March 2023, the implementation of the above-mentioned priority measures in the country has continued with the main emphasis on implementing the reform in the field of social services in accordance with the Social Services Act (SSA)² and the by-laws to it. In this sense, we emphasize the systemic nature of the adopted approach to the above-mentioned measures, by ensuring synchronization between the requirements of the applicable legislation in the field of social services, the implementation of long-term care policies and the provision and use of funding from the state budget and European funding.

The Ordinance on the Quality of Social Services (OQSS)³, for the first time in the country, standards and criteria for the quality of all types of social and integrated health and social services are legally established and applied, regardless of their financing method and their ownership. An important stage in the reform process was the deadline (June 2023) by which social service providers had a commitment to bring their services in line with the quality standards set in the OQSS. This process includes activities on the introduction, compliance and control of the standards and criteria for the quality of services provided, including in homes for people with disabilities, according to the regulation of Appendix No. 25 to § 2, para. 1 of the Transitional and Final Provisions (TFPs) of the OQSS. In this sense, accompanying actions were planned and carried out to increase the capacity of employees involved in planning, implementation, monitoring and control of social services, as well as the activities for the development of programmes for the

² Prom, SG, no. 24 of 2019, effective from 01.07.2020

³ Adopted by Decree of the Council of Ministers (DCM) No. 135 of 22.06.2022, promulgated, SG No. 48, no. 49 and no. 50 of 2022

quality of social services for each individual service. The developed independent quality standards and criteria in homes for persons with disabilities also guarantee the provision of increased control until the closure of these homes, which according to § 34, para. 1 of SSA's TFP shall end by 01.01.2035.

As of mid-September 2023, a draft of the National Map of Social Services (the Map) was prepared, for which full or partial funding from the state budget has been provided, in accordance with the requirements of the Ordinance on the Planning of Social Services (OPSS).⁴ There is a public presentation and public discussion of the draft of the Map, before its adoption by the Council of Ministers, which is expected to happen before the end of 2023. With the adoption of the Map, the process of planning social services at the national level, for which full or partial funding from the state budget is secured, will be completed. The process was carried out with the methodological and organizational guidance of the Social Assistance Agency (SAA), within which the municipalities carried out analyses of local needs for social services and developed proposals for the planned services at the municipal and district level. The real needs of the population are placed at the centre of the planning. The map will make it possible to balance the existing significant territorial differences and disparities in the distribution of social services, taking into account the size of the population and its age structure, the potential users of different types of social services and the existing ones. The final version of the Map will include all services with their corresponding minimum and maximum number of users - the currently existing social services and the necessary ones that should be created in the future. It is important to note that pursuant to Art. 47, para. 1 of OPSS, SAA has the right to include in the proposal for the Map social services at the municipal level and social and integrated health and social services at the district level, for which the analysis of the needs of a given municipality indicated a need, but the municipality did not plan them, as well as the right not to include in the proposal for the Map social services at the municipal level and social and integrated health and social services at the district level, for which the analysis of the needs of a given municipality did not show a need, but the municipality has planned them. In a 10-year long-term plan, the Map will serve as a prerequisite for the creation of a complete network of social services, which are fully or partially financed by the state budget, with a view to meeting the needs of the population at municipality, district and the entire country level.

As a final element within the framework of the preparation and adoption of the regulatory framework for the SSA and in accordance with Art. 123 thereof, the upcoming development of standards for the workload of the provider's employees performing activities in the provision of social services and the employees of the Social Assistance Directorate, and the municipalities that perform the activities of referral for the use of social services, should be noted. Workload standards should determine the maximum number of cases that one employee can work on within a month, depending on the specifics of the activity performed by this employee. It is expected that the adoption of the workload standards will happen within six months after the adoption of the National Social Services Map in the country.

Deinstitutionalization of care for people with disabilities and the elderly is among the main goals of the National Long-Term Care Strategy (NLTCS)⁵, which has a horizon until 2035, and of the

⁴ Adopted by DCM No. 133 of 06.04.2021, promulgated, SG No. 29 of 2021

⁵ Adopted by Decision of the Council of Ministers (DCM) No. 2 of 07.01.2014.

action plans thereof. The process of reforming is a complex one and requires time to be implemented step by step and consistently, with careful planning, implementation and evaluation, and it needs to be backed by human and material resources. As a result of the implementation of the first Action Plan for the period 2018-2021 for the implementation of NLTCS⁶ (the First Plan), 9 specialized institutions have been closed and the number of places in the largest specialized institution for adults with mental retardation has been reduced. The financing of the First Action Plan was carried out with funds from the state budget, the 2014-2020 Human Resources Development Operational Programme (HRDOP), and the 2014-2020 Regions in Growth Operational Programme (RGOP). The following institutions will be closed in 2023:

Table 1: Homes for people with disabilities closed in 2023

No.	Type of institution	Address	Number of places	Closing date
1.	Home for adults with mental retardation (HAMR)	village of Samuil, Samuil municipality, Razgrad district	27	09.03.2023
2.	Home for Adults with Mental Disorders (HAMD)	village of Lakatnik station, 243, Svrazhen Str., Svoге municipality, Sofia district	83	02.03.2023
3.	HAMR	village of Pchelishte, 26 14-th Str., Veliko Tarnovo municipality	59	01.05.2023

In order to meet the strategic objectives of the NLTCS in 2023, SAA has issued pre-approval orders for the establishment of 52 new social services: 3 Day centres for adults with disabilities, each with a maximum number of 20 to 40 users; 7 Day care centres for adults with severe multiple disabilities, each with a maximum number of 30 users; 6 Centres for Social Rehabilitation and Integration (CSRI), of which one CSRI with a maximum number of 50 users and the others with a maximum number of 40 users, 14 Family-type Accommodation Centres for Adults with Mental Retardation (FACAMR), each with a maximum number of 12 to 15 users; 2 Sheltered housings for persons with mental retardation, each with a maximum number of 8 users; 1 Sheltered housing for persons with mental disorders with a maximum number of 8 users; 16 Family-type Accommodation Centres for Adults with Mental Disorders (FACAMD), each with a maximum number of 15 users; 3 Family-type accommodation centres for adults with dementia, each with a maximum number of 15 users.

In accordance with the measures laid down in the First Action Plan, SAA has been implementing since 01.07.2019 the BG05M9OP001-2.038-0001-C01 project New Long-term Care for the

⁶ Adopted by DCM No. 28 of 19.01.2018.

Elderly and Disabled, financed under the 2014-2020 HRDOP. With this operation, implementation of preparatory actions for the removal of disabled people from specialized institutions, prevention of the institutionalization of these persons, assessment, communication strategy, etc. As part of the implementation of the project, a Methodology for the assessment of persons with mental disorders and mental retardation was developed, containing specialized criteria for assessing their condition, a Methodology for closing specialized institutions for people with disabilities and a Methodology for reforming homes for the elderly, containing specific steps, methods and principles that will support the municipalities in the overall process of closing the specialized institutions for people with disabilities and reforming the homes for the elderly, has been developed. Training packages have been developed with materials for continuing education of specialists from the social and health system in programmes for social work with people with mental disorders and mental retardation. These training materials are compiled into a manual and include principles and methods of operation; work rules with a view to ensuring the personal dignity of the users; actions in aggressive and auto-aggressive state of the persons from the target group; types of support; involvement in various activities of the users of the services; case management training; acquisition of social skills; motivation of employees to work with persons with mental disorders and mental retardation, etc.

The Action Plan for the period 2022-2027 for the implementation of the NLTCS (the Second Plan) covers the measures in the second and most important stage of the implementation of the process of deinstitutionalization of care for the elderly and people with disabilities, which is in line with the Common European guidelines for the transition from institutional care to community care, as well as with the UN Convention on the Rights of Persons with Disabilities. The main target groups of the Second Plan are: adults with mental disorders; adults with mental retardation; persons with various forms of dementia; elderly people, including adults unable to care for themselves; adult persons with various forms of disabilities, including persons with disabilities who have not been certified by the medical examination authorities. The main groups of measures included in the Second Action Plan are for: provision of support in the home environment to persons with disabilities and elderly people dependent on care; development of quality and accessible social and integrated health and social services and closing 41 out of a total of 70 homes for people with disabilities and reforming 82 existing homes for the elderly; increasing the efficiency of the long-term care system; building the necessary infrastructure to provide the services. In line with the NLTCS, the priority of the plan is the development of a network of quality and accessible social and integrated health and social services in the home environment and in the community. The services will comply with the principles of deinstitutionalization of care for persons with disabilities and the elderly while respecting their rights according to their needs. A new emphasis in the action plan is the implementation of innovative measures for the introduction of modern information and communication technologies in the provision of services in a home environment, such as telecare and teleassistance. New approaches to support independent living for people with disabilities such as "shared living organization" and "active care" will also be piloted. The measures related to the creation of social and integrated health and social services for residential care users for whom, most often, as a result of prolonged institutionalization in their lives and lack of interest on the part of their relatives and friends, it is impossible to find opportunities for integration or reintegration into a family environment or into the community.

The Action Plan for the period 2022-2027 for the implementation of the NLTCS⁷ (the Second Plan) covers the measures in the second and most important stage of the implementation of the process of deinstitutionalization of care for the elderly and people with disabilities, which is in line with the Common European guidelines for the transition from institutional care to community care, as well as with the UN Convention on the Rights of Persons with Disabilities. The main target groups of the Second Plan are: adults with mental disorders; adults with mental retardation; persons with various forms of dementia; elderly people, including adults unable to care for themselves; adult persons with various forms of disabilities, including persons with disabilities who have not been certified by the medical examination authorities. The main groups of measures included in the Second Action Plan are for: provision of support in the home environment to persons with disabilities and elderly people dependent on care; development of quality and accessible social and integrated health and social services and closing 41 out of a total of 70 homes for people with disabilities and reforming 82 existing homes for the elderly; increasing the efficiency of the long-term care system; building the necessary infrastructure to provide the services. In line with the NLTCS, the priority of the plan is the development of a network of quality and accessible social and integrated health and social services in the home environment and in the community. The services will comply with the principles of deinstitutionalization of care for persons with disabilities and the elderly while respecting their rights according to their needs. A new emphasis in the action plan is the implementation of innovative measures for the introduction of modern information and communication technologies in the provision of services in a home environment such as telecare and teleassistance. New approaches to support independent living for people with disabilities such as "shared living organization" and "active care" will also be piloted. The measures related to the creation of social and integrated health and social services for residential care concern users for whom, most often, as a result of prolonged institutionalization in their lives and lack of interest on the part of their relatives and friends, it is impossible to find opportunities for integration or reintegration into a home environment or into the community.

The construction of the new infrastructure will be provided with funding under the National Recovery and Resilience Plan (NRRP) and the 2021-2027 Regions Development Programme (RDP). 250 new social services for residential care and specialized services for persons with disabilities (for day care, information and counselling, advocacy and mediation, therapy and rehabilitation, training for skills acquisition, support for the acquisition of work skills) will be created and provided for 7,500 users. The creation of the services will be aimed at ensuring greater autonomy and independence of people, so that they will be stimulated to lead a relatively independent lifestyle. Residential care social services will not be remote and/or isolated from the community. In the specialized environment for the provision of social services for residential care, there will be premises for living, sleeping, daily activities and preparing food/meals, which are sufficient in number, accessible, furnished, equipped with the necessary aids, appliances and technologies, according to their functional purpose and the needs of users and promoting their independent living and social inclusion. The OQSS also introduced standards aimed at the safety, security and accessibility of the service environment. The newly created services will fully meet

⁷ Adopted by DCM No. 509 of 21.07.2022.

the requirements for an accessible environment for people with special needs (for example, when moving). In order to ensure sufficient personal space and privacy for the users of social services for residential care, no more than two users can be accommodated in one room, and the number of employees will depend on the number of users of the service. The principle that will be applied is that in the municipalities where a new social service for residential care is being created, a corresponding accompanying specialized and advisory social service for persons with disabilities will be established. Under the NRRP, the reformation of 82 homes for the elderly with 5 598 places has also been planned. The activities that are planned are related to the implementation of construction activities and the delivery of equipment and furniture with a view to bringing the existing material base of the DSH in full compliance with the standards of quality of residential care for elderly people of an age beyond working age.

After building the infrastructure of the new social and integrated health and social services, the so-called "soft measures" will be implemented under the 2021-2027 Regions in Growth Operational Programme (RGOP). After the completion of the project financing, the sustainability of the new services will be guaranteed with funding from the state budget. The process is timed so that all measures can be implemented also before the construction of the infrastructure is completed, people can be prepared for evacuation.

In addition, under the National Recovery and Resilience Plan (NRRP), activities for energy efficiency and renovation of equipment and furnishings in the existing social services in the community are planned, aiming to increase their quality. As indicated, these core investments will be complemented in parallel by activities under the 2021-2027 RDP and 2021-2027 RGOP.

The SSA enables the municipalities to make their own decisions regarding the organization and management of the social services provided in their territory. According to the law, the organization of the provision of social services may depend on the age of the users, their specific needs and the way the service is managed. In this way, greater flexibility in the provision of the services and an opportunity to satisfy the individual needs of the persons who use them to the fullest extent are ensured.

In August 2023, the SAA made recommendations to the mayors of the municipalities, on the territory of which specialized institutions for persons with mental retardation and persons with mental disorders function, with a view to taking measures to improve the living conditions of users, employee-user relationships, user relationships, support for access to health care, provision of the necessary qualified professionals and staff, expansion of user activities, as well as user awareness. One of the highlights of the recommendations is in relation to the detailed familiarization of all employees with the Code of Ethics for employees carrying out activities in the provision of social services, approved by Order No. RD-06-45 of 28.05.2021 of the Minister of Labour and Social Policy. The Code of Ethics has been developed in accordance with the principles laid down in the SSA and defines the norms of ethical behaviour of employees who carry out activities of management and provision of social services, social service providers, volunteers and trainees in their professional relations with persons who use social services, with colleagues, with the institutions with which they interact and society. Its purpose is to contribute to increasing public confidence in the professionalism and morale of those working in the field of social services and to create relationships of understanding and empathy towards the specific needs of the persons who

use the services. It is reiterated that no form of corporal punishment, physical, mental or sexual abuse, or neglect, including passive, should be tolerated by social service providers. Causing harm to persons using social services in any way by action or inaction, as well as carrying out activities that violate or limit their legal rights, are unacceptable and inadmissible. Attention has been drawn to the fact that municipalities, as providers of social services, can use an individual approach regarding the implementation of the Ordinance on the standards for the remuneration of employees carrying out activities in the provision of social services, which are financed from the state budget,⁸ through which the minimum amounts of remuneration of employees are determined in order to stimulate and motivate them for a better performance of their official commitments.

In addition, in compliance with the provisions of § 34, par. 2 of the SSA's TFP, the Social Services Quality Agency (SSQA) carries out and will continue to carry out periodic inspections of the quality of services provided in homes. In the course of carrying out the inspections, as well as when providing the finding protocols with their results, the SSQA continues to provide methodical support and give methodical guidelines for improving the quality of care and living conditions in residential care services. The SAA also provides methodological support in assessing the needs of social services, planning, creating, providing and developing social services.

With regard to the comments and recommendations made in the Report on improving the care for persons with disabilities living in the areas visited by the CPT, the HAMR delegation in the village of Draganovo and the HAMR in the village of Tri Kladentsi, we present to you the following summary information in the areas monitored by the Committee:

In relation to the recommendations made in the monitored area of ill-treatment, relating to the taking of steps by all social service providers to ensure ongoing training of staff in this area, with a view to achieving effectiveness in the prevention of ill-treatment and violence to develop programmes to enable residents to express themselves and be understood, to have the opportunity to communicate and express their feelings and needs:

The SSA regulates the obligations of social service providers to develop a programme for introductory and upgrading training for employees, and for employees who are first engaged in the provision of social services, the social service provider must appoint mentors to assist them methodically for a period of 6 months from the date of their appointment. Employees engaged in the provision of social services have the right to regular supervision in the work process, which is provided by the provider of the social service through employees of the provider engaged in the provision of the service or persons external to the specific social service. Standards for qualification and professional development of the employees who carry out activities for the provision of the service are laid down in section B of each of the Appendices in the OQSS, containing the standards and criteria for the quality of the relevant social service, including for homes for people with disabilities. For example, criterion 9.2 of Appendix No. 25 to § 2, para. 1 of the OQSS TFP requires the service provider to provide induction and refresh/specialized training for employees under the Employee Induction and Refresher Training Programme. The indicators for this criterion also determine the required number of training hours that employees of the various categories should undergo in training within each cycle of 12 consecutive calendar months: newly appointed

⁸ Adopted with DCM No. 343 of 07.12.2020, promulgated, SG No. No. 105 of 11.12.2020, in effect from 01.01.2022. 022

employees - a minimum of 36 training hours (indicator 90), specialists - a minimum of 24 training hours, support staff – a minimum of 12 training hours (indicator 91), the house manager – at least one training related to management functions (indicator 92). Similar detailed quantitative and qualitative indicators are defined also for the supervisions, which are external and internal, and for mentoring (criterion 9.3).

According to the SSQA data, there is a positive trend of commitment from providers regarding the steps taken to increase the qualifications of staff in homes for people with disabilities. The SSQA's Annual Analysis of the State and Performance of Social Services reported that despite the reduced number of homes in 2022, the number of staff trainings increased, with induction training increasing by 57, upgrade training by 60 and managers training by 31. As can be seen from the data below, the number of homes in which staff training was not conducted in 2022 is relatively small.

Trainings conducted in 2022 in homes for people with disabilities and supervisions in social services

Introductory training

Number of homes in which training was conducted – 72%

Number of homes in which training was not conducted – 28%

Advanced training

Number of homes in which training was conducted – 93%

Number of homes in which training was not conducted – 7%

Managers training

Number of homes in which training was conducted – 93%

Number of homes in which training was not conducted – 7%

Supervisions

Number of homes in which training was conducted – 51%

Number of homes in which training was not conducted – 49%

The data cited indicate that the share of the number of trainings in homes for people with disabilities is over 70%, and for specialists the share is even over 90%; the share of social services in which supervisions were carried out is slightly over 50%.

The SSA and the regulations for its implementation regulate the right of individuals to be informed and consulted about the existing social services they are entitled to use, the conditions and terms for their use, the conditions for payment and full and partial exemption from payment of a fee for their use, as well as and choosing a service provider. The information should be provided in an accessible format, according to the condition and health status of the person. The current legislation contains detailed provisions regarding the possibilities for information and ensures the right of all users, regardless of whether they are fully capable of acting or have some type of restriction

imposed on them, to be informed in a way accessible to them, including in relation to the possibilities of submitting complaints.

With the quality standards laid down in the OQSS, standards have also been introduced regarding the activities of providing specialized support to research, understand and overcome the identified problems and difficulties of users, and the decisions and actions to overcome them are with the personal participation of each user and tailored to their age, level of risk, special needs and individual characteristics. The providers of social services have the commitment to organize the overall activity of providing the services, including also accompanying documentation, in an accessible and understandable form, format and language for the users. In Appendix No. 25 to § 2, para. 1 of the TFP of the OQSS Standard 14 refers to the relationship between users and staff in homes for people with disabilities, including the HAMR. The standard requires the service provider to provide conditions for building relationships based on mutual respect and understanding between users and employees, and for employees to have knowledge and implement strategies to deal with unacceptable user behaviour. According to one of the applicable indicators of criterion 14.2 (according to which "The provider implements an effective communication system, understands the communication limitations and behaviour of users and responds appropriately in the relevant situations") to the same Standard 14, the provider should have developed the basic documents concerning each user, in a language/format he understands, taking into account the specifics of his communication difficulties. The provider creates conditions for listening to the opinions of users in the home, ensuring that the opinions expressed by them will not lead to negative consequences for them and supports the participation of users in decision-making on matters important to them (criterion 14.3).

The fulfilment of these obligations by suppliers is subject to control by the SSQA in the course of inspections performed by its inspectors. Please note that for the purposes of compliance with the standards and criteria for the quality of social services, not only document verification methods are applied, but also interviews with employees, including the management of the social service and with users, and monitoring the provision of the specific service, the latter method being more time-consuming and presupposing the presence of specific knowledge of the monitoring person in the particular subject area. These methods are used in the paradigm of three-level monitoring and control, which should be carried out by the provider, the municipality and the SSQA, as regulated in sections I, II and III of the OQSS.

Regarding the recommendations made in the Living Conditions monitored area, related to taking immediate measures to provide the residents and the HAMR staff in the village of Tri Kladentsi, Vratsa municipality with a clear perspective for their future, as well as obtaining confirmation for its closure:

First of all, it should be noted that according to the regulation of § 34, para. 3 of the SSA's TFP in connection with the phasing out of homes for people with disabilities, the SSQA conducts periodic reviews of the quality of services provided in them. In the period 2021 - 2023, three inspections were performed at the HAMR in the village of Tri Kladentsi, Vratsa municipality, as a result of the established facts and circumstances, from which recommendations were made for its closure. On the basis of § 34, para. 3 of the TFP of the SSA, an Indicative Action Plan for the closure of the

home was developed and adopted, with an implementation deadline no later than 31.12.2023, signed by the executive directors of the SAA and the SSQA and by the mayor of the Vratsa municipality (28.08. 2023). The SSQA's commitments under the Indicative Plan for Closure are related to conducting systematic monitoring of the state and effectiveness of the social services provided in the HAMR in the village of Tri Kladentsi until its final closure. The plan lists the commitments of the involved parties and the deadlines for the implementation of all specific activities under it.

In connection with the recommendations made by the CPT regarding the established unacceptable living conditions in the HAMR in the Tri Kladentsi village, a number of concrete actions have already been taken by all involved parties to close this home. Actions have also been taken to extend the duration of the project "New long-term care for the elderly and people with disabilities" funded under the 2014-2020 HRDOP and to expand its activities. As a result, the HAMR in the village of Tri Kladentsi is included among the specialized institutions designated for closure under the project. In accordance with the activities set out in the closure plan, 40 individual assessments of the needs of the HAMR users have been prepared. Teams are in the process of being formed to prepare individual support plans for the removal of users accommodated in the HAMR in the village of Tri Kladentsi. It is planned that those accommodated in the HAMR will be transferred to newly created social services in the town of Vratsa and in the village of Tserova Korja, Veliko Tarnovo municipality.

On the territory of the municipality of Vratsa, under the project "Complex for the elderly and people with disabilities in the municipality of Vratsa", financed under the 2014-2020 HRDOP, four social services have been opened - two Family-type Accommodation Centres for Adults with Mental Disorders (FACAMD), one Family-type Accommodation Centre for Adults with Mental Retardation (FACAMR) and one Family-type Accommodation Centre for the Elderly (FACE). At the time of writing this report, for three social services – one FACAMD, FACAMR and FACE – orders for prior approval have been issued for the establishment of social services that are financed from the state budget. According to the project implemented by the municipality of Vratsa, infrastructure was built and another FACAMD was set to be created, but the activities to provide the service have not been started due to various reasons preventing its opening. Actions have been taken and an opinion has been requested from the Governing Body of the HRDOP to the MLSP to change the target group from persons with mental disorders to persons with mental retardation, with a view to moving the users from the HAMR in the village of Tri Kladentsi to the FACAMR in the city of Vratsa. On 11.07.2023, the Governing Body of HRDOP expressed a positive opinion on changing the target group from persons with mental disorders to persons with mental retardation, provided that the infrastructure built meets the standards of the quality of social services regulated in the OQSS.

On 20.07.2023, the mayor of the Vratsa municipality submitted an application to the SAA on the grounds of Art. 78, para. 1 of the Regulations for the Implementation of the Law on Social Services⁹, for the creation of a new social service FACAMR, starting from 01.09.2023 with 15 places. The location of the service is located in an area with well-developed infrastructure, transport and communication links and access to various health and social services in the community. The

⁹ Adopted by DCM No. 306 of 09.11.2020, promulgated, SG No. 98 of 11/17/2020

premises guarantee free and easy access and the users moving, there is an internal courtyard space equipped with a garden gazebo and benches, and the layout of the courtyard space allows for walks, gardening, floristry and other individual or group activities. The number and positions of the employees who will perform the activity of providing the service is also planned. According to the SSA regulation, the SSQA by letter No. 05-20-267 dated 07/21/2023 expressed a positive opinion on the compliance of the social service with quality standards, as a result of which by order No. ПД-01-1367 dated 07/28/2023 the SAA's Executive Director was given prior approval to set up the social service.

In relation to the monitored area, regarding the living conditions found in the HAMR in the village of Draganovo, Gorna Oryahovitsa municipality and the recommendations made for taking measures to ensure that:

- the living conditions are favourable for the well-being of the inhabitants and provide visual stimulation and allow personalization;**
- all residents have a personal lockable space in which they can store their belongings;**
- every residential building has a sufficiently spacious and comfortable indoor living area where residents can gather if they wish;**
- all rooms are furnished with blinds or curtains;**
- rooms with multiple occupants shall accommodate no more than four people:**

According to information from the SSQA, since the beginning of 2023, a total of three inspections have been performed in the HAMR in the village of Draganovo, Gorna Oryahovitsa municipality, during which the quality of the provided social services was monitored. Improvements in living conditions have been noted as a result of the refreshing renovations both in the users' bedrooms and in the common areas. Conditions have been created for personal storage of users' personal belongings and individualization of the atmosphere in their bedrooms, according to their expressed desire.

Improving living conditions in homes for disabled adults is a topic covered by the SSQA's periodic inspections of the quality of services provided in these homes and is the subject of analysis included in the Annual Analysis of the State and Performance of Social Services, produced in fulfilment of the provisions of Art. 118 of the SSA. Annual analyses are publicly available and can be found on the official SSQA website at: <https://aksu.government.bg/godishen-analiz-za-sastoyaniето-na-efektivnostta-na-soczialnite-uslugi/>.

In 2022, the SSQA carried out inspections of all existing specialized institutions - 77 in number, and during these inspections it was found that in some of them the recommendation for improving the material base and the conditions of user life has not yet been fully implemented. After the inspections performed by the SSQA and the methodological guidelines given, for a large part of the homes, actions have been taken to carry out repair work both on the buildings as a whole (repair of roofs, replacement of plumbing and window frames, installation of air conditioning systems) and on the internal premises in the buildings - bedrooms, sanitary and common areas. In some of the homes, new equipment was also purchased - beds, wardrobes, individual lockers, chairs, upholstered furniture, television sets. Efforts are also being made to maintain the yard spaces - new facilities have been built, lawns, flower beds are maintained, benches and gazebos have been installed.

From the beginning of 2023, during follow-up inspections by the SSQA, it was found that the living conditions of the users have improved, in line with the capabilities of the material bases in which these homes are housed - partial renovations of the bedrooms are being carried out, old and depreciated equipment, incl. sanitary was replaced, efforts are made to maintain the courtyard spaces. Actions taken to improve the sanitary-hygienic condition of the premises in the homes and the service of users who need support are reported.

Regarding the recommendation that all residents shall have a personal lockable space in which they can store their belongings, we cite as an example the requirement for suppliers to comply with criterion 2.2 of Standard 2 (Organization of Activities) of Annex No. 25 to § 2, para. 1 of the TFP of the OQSS, which states that: "The provider shall provide users with a living environment that respects their right to personal space and privacy in terms of security and respect for their dignity. Where possible, users shall take care to maintain the living quarters." All users are required to have personal belongings, clothing and shoes stored in a designated wardrobe/locker to which they have continuous access (indicator 8). Privacy conditions must be provided for each user (for bathing, dressing, personal grooming, confidential conversation, etc.) while guaranteeing protection from abuse of users (indicator 9). There are other provisions in the OQSS aimed at guaranteeing personal space and individualizing care in the context of its provision in a special setting.

In view of the recommendation that every residential building should have a sufficiently spacious and comfortable indoor living area where residents can gather if they wish, we would like to refer to Standard 3 (Service delivery environment in Homes for Disabled Adults (HDA) from the already cited Annex No. 25 of the OQSS, in which the requirements for common and personal spaces are regulated in detail. As a minimum, the dining room and the room for day activities must be sized to allow the gathering of at least half of the users in each of them.

In connection with the recommendation that all rooms shall be furnished with blinds or curtains, we note the requirement of criterion 2.2 of Standard 2 cited above. We draw attention to the fact that not in all cases the presence of blinds and/or curtains is safe and advisable for users of the service, given their particular condition or individual preferences.

Regarding the recommendation that no more than four people can be accommodated in rooms for several occupants, we specify that such a requirement is absent in Appendix No. 25 to § 2, para. 1 of the TFP of the OQSS, which is tied to the existing situation in the homes and their impending closure. However, we draw your attention to the fact that the quality standards and criteria of specialized social services for residential care for people with disabilities, including adults with intellectual disabilities, include the requirement that "all users shall spend the night in a room with no more than two beds for sleeping" (indicator 32 to Standard 4 "Specialized Environment" of Appendix No. 12 to Article 11, Paragraph 1 of the OQSS).

Regarding the findings made in the area of "Staff and care provided to residents" and a request from the CPT for comparative information from each home for people with mental disorders and home for people with intellectual disabilities on the number of care staff and multidisciplinary staff (including paramedics, nurses, orderlies, social workers, psychologists, occupational therapists, teachers, etc., all categories separately) as of October 1, 2023, compared to the number of these personnel before the implementation of the Ordinance on the Quality of Social Services:

In the HAMR in the village of Draganovo, after the inspection performed by the SSQA concerning the staff of the home, it was found that the largest (18) is the share of employees who have supporting functions without being directly involved with the users, with a partial similarity or complete overlap in job descriptions. In this regard, a recommendation was made to the supplier for the implementation of a flexible approach to human resource management, which would guarantee the distribution of staff numbers according to the needs and specifics of the target group, which would lead to an increase in the efficiency of the overall work in the service. In the HAMR in the village of Tri Kladentsi, the total number of employees according to the official staffing list is 23 full-time employees, but in the last two years there has been a trend of long sick leaves, alternating with other paid and unpaid leaves, as a result of which in the home actually works an insufficient number of employees. It was also established that the specialists: social worker, special pedagogue, psychologist and occupational therapist, assigned to carry out the main activities of providing social services to users, have prepared annual work plans, but they are mostly formal and no activities are being reported on a daily, weekly or monthly basis. Work with the users is most often in groups and not individual, and no meaningful information is kept about the achieved/unachieved results. Good work has been noted in terms of occupational therapy activities, but the sessions are conducted with the one and the same group of users.

In the course of the inspections performed by the SSQA in both homes, it was established that the management of human resources is ineffective and does not guarantee the distribution of staff numbers according to the needs and specifics of the target group. In connection with the findings, methodological support has been provided, and the SSQA will follow the actions prescribed by the directors of the two homes in terms of updating the staffing tables and the effective management of human resources, as well as increasing the qualifications of employees.

It should be noted that Section B of Appendix No. 25 to § 2, para. 1 of the TFP of the OQSS provides that the supplier shall provide employees in sufficient numbers and with the necessary professional training, whose minimum number in the main categories of employees should be consistent with the number of users in the HAMR. A coefficient for determining the number of employees according to the HDA profile is also regulated, whereas for sensory disabilities it is 0.5, for physical disabilities - 0.54, for intellectual disabilities - 0.56, for mental disorders - 0.6 and for dementia - 0.6, and the ratio of specialists/general positions should be 40/60. It can be seen that the regulations clearly define the minimum numbers for the main categories of employees in the HDA.

The information requested by the CPT for comparison for each home for persons with mental disorders and home for persons with mental disabilities, of the number of staff providing care and multidisciplinary staff (including paramedics, nurses, orderlies, social workers, psychologists, occupational therapists, educators, etc., all categories separately) as of October

1, 2023 with the number of this personnel before the implementation of the Ordinance on the Quality of Social Services, cannot yet be provided.

The information available to the SSQA is based on data reported by social service providers in the first half of 2023. After analysing the available data, it appears that the total number of full-time employees in the HAMR as at December 31, 2022 is 2 582, and the actually occupied positions are 2 594. The employees appointed on freelance service contracts are 84. The total number of all employees appointed under employment and freelance service contracts is 2 678. The number of specialists (including medical specialists) is 855 (33% of all appointed employees), and the number of non- specialist employees is 1 732 (67% of all appointed employees). The ratio of specialists to non-specialists in these Social Services is 33/67. Compared to the data from the previous year, it is noticeable that the share of specialized personnel decreased by 2% at the expense of non-specialized personnel. There are 24 more freelance service contracts in 2022 compared to 2021, which is an increase of 29%.

A detailed report on the question posed by the CPT will be possible to be generated after the introduction of the SAA's Integrated Information System (IIS) regarding social services on the territory of the country. Pursuant to Art. 86, para. 2 of the SSA in the IIS social service providers will enter information about:

1. the activities carried out by the supplier;
2. employees carrying out management activities and provision of social services;
3. users;
4. concluded contracts for the use of social services;
5. those waiting to use social services;
6. revenue and expenses by types of activities;
7. activity costs by type of services provided.

In addition to the above, the SSQA informs that under BG05M9OP001-3.021-0001 Project "For better quality and efficiency of social services in Bulgaria", financed under a procedure through the direct provision of grant BG05M9OP001-3.021 "Guarantee the quality and efficiency of social services" under HRDOP 2014-2020, with MLSP as the specific beneficiary, the development and commissioning of an information system is planned in the implementation of activity 5 of the project, concerning activities for the pilot introduction of annual national monitoring of the state and effectiveness of social services. Within this information system, it is intended to maintain information regarding employees providing social services, namely:

- ✓ employees carrying out management activities and provision of social services;
- ✓ employees carrying out management activities and provision of social services - by types of social services;
- ✓ employees carrying out management activities and provision of social services - by type of position held;
- ✓ number of employees - by type of educational degree;
- ✓ number of employees - by age and gender;
- ✓ number of vacant positions - by types of positions.

Regarding the recommendations made in the field of “Legal guarantees”:

- **governing the accommodation and stay of persons in social institutions, and introducing a requirement for the relevant person to be represented by a lawyer. The disadvantaged should benefit from free legal representation and be exempt from court fees incurred in the context of appeal/review proceedings.**
- **Bulgarian authorities should make efforts to ensure the implementation of the new legislation and to find alternative solutions for placing the residents under the care of the institution, which would better guarantee the independence and impartiality of the guardians.**
- **introducing accessible and comprehensible complaints systems, including registering oral complaints in a complaints register. The CPT recommends that the Bulgarian authorities shall ensure that the prescriptions described above regarding mechanisms for lodging complaints and informing residents are effectively implemented in practice:**

Art. 9 of the SSA regulates that in the provision of social services, the rights, freedoms, dignity and personal integrity of individuals shall not be violated. Social services shall be provided only according to the desire and personal choice of the persons. In the provision of social services, the right of the persons who use them to freely express their opinion regarding the method of provision and the effectiveness of the services, the possibilities for improving their quality and all issues related to their rights and interests in use of social services shall be guaranteed. Pursuant to Art. 11 of the SSA, social services shall be used compulsorily only by order of the court and only in the cases defined by law, and compulsory use of social services for residential care by adults shall not be allowed. In this sense, it is clear that the use of social services is an opportunity that depends exclusively on the free will and desire of all persons who need support through social services. Pursuant to Art. 154 of the Family Code, which is in the sphere of competence of the Minister of Justice, guardianship and custody authority is the mayor of the municipality or an official designated by him/her.

With regard to court fees incurred in the context of judicial appeal/revision proceedings, we would like to clarify that the MLSP is not a competent authority in this matter. Again, we draw your attention to the fact that persons using social or integrated health and social services for residential care are entitled to free legal aid, provided through the National Bureau of Legal Aid in accordance with the Law on Legal Aid (Article 22, Paragraph 1).

Appendix No. 25 to § 2, para. 1 of the OQSS’ TFP provides a standard (Standard 15) which requires the Home for Disabled Adults (HDA) to support users to know and assert their rights and the provider to ensure the inclusion of users as active participants and key partners during the provision and assessment of the quality of services, including the Quality Development Programme. The provider of social services has the obligation to ensure access to the social service "advocacy and mediation" in all cases of conflict between the guardian/legal representative and the user placed under limited or full interdiction (indicator 167 to criterion 15.2: "The provider shall ensure access to justice and legal protection for all users in the home."). According to § 7 of the Supplementary

Provision of the SSA, "advocacy" is an activity to support the person to protect and defend his/her rights and needs within the framework of available legal and administrative procedures, and pursuant to § 8 of the same provision of the SSA, "mediation" means carrying out interaction and coordination between an employee carrying out activities for the provision of social services, with an employee/employees from other services or from various institutions, organizations and administrative bodies in the interest of an interested person who needs specific support to realize his/her rights and needs.

In connection with the notes of the CPT, related to the establishment of guardianship and trusteeship of persons placed under full or partial interdiction by employees from the home, we draw attention to the fact that this problem is normatively addressed with indicator 166 to criterion 15.2 of Appendix No. 25 to § 2, para . 1 of the TFP of the OQSS, which regulates that persons placed under limited or full interdiction should have legal representatives outside the circle of the home employees. The SSQA notes that when carrying out HDA inspections, methodological guidelines were given and a large number of staff in the homes took action to trace the relatives of the housed users in order to establish guardianship and trusteeship, but there were not a few cases in which users placed under full or partial guardianship had no relatives or had refusals from their relatives to represent them.

In the above-cited Appendix No. 25, which refers to the standards and criteria for the quality of social services provided in the HDA, commitments of the providers related to the development of a Complaints Procedure, presented in a way accessible to users, the introduction of register of complaints and formation of committees for their examination, are provided for. The fulfilment of these commitments by suppliers is included in the scope of SSQA's control activity, and in cases of non-fulfilment on their part, methodical support is provided on the spot or written guidelines are issued to eliminate the non-conformities.

As for the procedure for filing complaints and reports at the national level for violated rights under the Social Services Act, it is regulated in the OQSS. Complaints and reports of violated rights under the SSA and the regulations on its implementation are intended to be submitted orally - on site or by telephone, or in writing, including electronically, with the person identifying himself to the employee. When filing the complaint or report, the person shall indicate the social service provider against whom the complaint or report is filed, as well as the place where the social service is provided, specific complaints or requests, evidence, if the complainant has any, the name and contact details. Regardless of the fact that in the OQSS it is regulated that anonymous complaints or reports are not considered, the SSQA shall carry out inspections also in such cases, when they concern the quality of social services provided and compliance with the rights of users. The term for considering complaints and reports is 10 days from the date of their submission and one month if an on-site inspection is necessary. The person who filed the complaint or report shall also be notified of the results of the inspection and the actions taken on the complaint or report. At the beginning of each calendar year, an analysis of the complaints and reports received in the previous period shall be prepared, which shall be made public on the official site of the SSQA, in the Control Activity section.

In 2021, there were 57 inspections initiated based on a report, and those in 2022 were 116, where the received complaints and reports refer to all social services, including HDA. In 2021, there were

5 complaints and reports related to the HDA, and after the relevant inspections, it was found that the allegations made in them about the poor quality of the provided social service were unfounded. In 2022, 2 signals were received, one of them, referring to the poor quality of the social service provided, was unfounded, and the second, related to transparency regarding the storage of personal funds of users, was partially confirmed. In the latter case, methodical support was provided to the Social Services provider to improve documentation management and timely notification of users on how their personal funds are stored and spent. Since the beginning of 2023, seven inspections have been carried out on complaints and reports related to the quality of social services provided in HDA. As a result of the inspections carried out, for 6 of them it was established that the allegations of violated user rights mentioned in the reports were groundless, and in 1 report the allegations of poor sanitary and hygienic conditions were confirmed and sanctions were imposed by the responsible control body.

APPENDIX

Courtesy translation

<Logo of the Bulgarian Executive Drug Agency (EDA)>

REPUBLIC OF BULGARIA

Bulgarian Drug Agency

IAL 36382/28.08.2023

**TO ASSOC. PROF. MIHAIL OKOLIYSKY
DEPUTY MINISTER OF HEALTH
MINISTRY OF HEALTH
5, SVETA NEDELYA SQR., 1000 SOFIA**

*To your Ref. No. 0-4-14-36/11.08.2023
(Inc. No. IAL-34344/11.08.2023)*

SUBJECT: Report of the European Committee for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment (CPT) from the extraordinary visit to Bulgaria held in the period 21-31 March 2023

DEAR DEPUTY MINISTER,

With regard to your letter under the above number, please be notified as follows: regarding the requested copies of the conclusions of the Bulgarian Drug Agency (BDA).

Inspections: At the time of the inspection in the period 19-21.04.2023, seven clinical tests were conducted in the research centre of the State Psychiatric Hospital, Tserova Koria. The findings on the inspection, concerning the issues indicated in the Preliminary Opinion stated by the delegation of the European Committee for the Prevention of Torture and Inhuman or Degrading Treatment or Punishment (CPT) (at the end of its *ad hoc* visit to Bulgaria in the period 21-31 March 2023) were already presented in our Report with Your Inc. No. 04-14-26/28.04.2023, which we do not object to being provided to the CPT. The graded inconsistencies across the board in the EDA's reports on Good Clinical Practice matters are irrelevant to the findings raised by the CPT and are to be interpreted only in the context of the conduct of clinical tests with medical products in the sense of the relevant test design, relevant only to conduct and delegation procedures of the inspected party, clinical test research teams and test sponsors, and they are not subject to disclosure to third parties.

With regard to the requested copies of the ethical approvals of all seven clinical tests conducted in the hospital in the village of Tserova Koria: In an appendix, we present a list of the positive opinions issued by the Ethics Commission for Clinical Tests for conducting the clinical tests.

With regard to the additional questions raised, regarding the conducted inspection:

1) How many inpatients were privately interviewed during the inspection about their participation in all seven clinical trials to understand how well they were informed about them;

2) How the Agency ensured that all patients who participated in the trials had the necessary mental capacity and understanding to give fully informed consent to participate, including that they would understand any possible side or other adverse effects they might experience;

As previously stated in our Report with Your Inc. No. 04-14-26/28,04,2023 during the inspection by the BDA inspectors, the documents were checked. In relation to the informed consent procedure, signed and dated informed consent forms were available for each participant. Screened in one of the seven clinical trials, the forms being in the current approved version at the time of signing the consent. For each participant the dates on which the informed consent was signed precede the dates of the documented screening procedures performed. For clinical trials in which, according to the protocols of consent, caregivers are provided for the participants in the trials, signed consent forms are found to be available on their part.

The assessment of the extent to which patients are aware of their participation and the extent to which they understand the informed consent process is made by the principal investigator or sub-investigator member of the trial team at the time of taking the consent. This is also the stipulated requirement in the sense of item 4.8.7. from the rules of Good Clinical Practice (ICH GCP E6, R2) which states that "before written informed consent is obtained, the principal investigator or a person authorized by him/her must provide the participant or his/her legal representative with sufficient time and opportunity to discuss the details of the clinical trial and to decide whether or not to participate. All questions asked by the participant or his/her legal representative must be answered comprehensively."

Due to the above, carrying out a subsequent assessment of the condition and mental capacity of the persons, including by the inspectors, would appear irrelevant and could not constitute a verification or proof of their condition at another, previous moment, namely the moment of giving informed consent for participation in the clinical trial. Insofar as there is no evidence that the persons have been placed under full or limited interdiction, in the sense of the law they are considered fully capable persons, having the ability to express a legally valid will.

The Agency has ascertained these facts by requiring and providing from the principal researchers reports on the status of each participant – able to act, limitedly interdicted, or completely interdicted, which clearly confirm the above. EDA inspectors have verified that signed and dated informed consent forms were available for each participant in ongoing clinical trials and that they were signed prior to the initiation of trial activities.

3) How many personal medical records of inpatients participating in clinical trials were checked and whether the inspectors found in these files any information about the clinical trial (it should be recalled that the psychiatrist, a member of the delegation, did not find any);

Subject of the BDA review according to its competence, only the documents and data on clinical trials is only the general documentation on trials and personal medical documentation of patients, only as participants in relevant clinical trials. All other medical records and their medical history are outside the scope of the Good Clinical Practice review that the BDA has applied.

4) It was established that the inpatients participating in the trials received compensation for travel expenses (please remember that a number of patients stated to the delegation that they periodically received BGN 20 each), and if so, what travel expenses were compensated to those patients who did not have to travel anywhere as they stayed in the hospital all the time.

Reimbursement for travel expenses was provided for in only one of the protocols of the seven trials examined, namely: *"Assessment of the bioequivalence of two medicinal products containing aripiprazole: Aripiprazole LAI powder and solvent for suspension for injection with prolonged release for intramuscular administration, 400 mg, Greece (Test), against ABILIFY MAINTENA® (aripiprazole) for suspension for injection with prolonged release for intramuscular use, 400 mg, USA (Reference). Multicentre, multinational, open-label, randomized, multiple-dose, cross-over, two-Period, pharmacokinetic trial in patients with schizophrenia"*, protocol code CPA21001 and sponsor Pharmathen S.A., Greece with principal investigator Dr Kalin Grozdev.

As was already stated in our Report with your Inc. No. 04-14-26/28.04.2023, according to the test protocol, each participant should receive compensation of BGN 100 per main visit for travel expenses. The same information is available in the informed consent form. In this regard, an explanation has been requested from the principal investigator regarding the requirements and the method of realization of the compensation. As proof of the fact that BGN 100 was paid to the respective participants, the principal investigator, Dr Grozdev, showed the inspectors notes, with data on the participant and the trial, with available fields for signature and a field to be filled in by hand for the amount provided.

Due to the lack of evidence for a compensatory mechanism, i.e. failure to submit supporting documents for travel expenses incurred by the participants, as a result of the inspection a major discrepancy was found in the conduct of the clinical trial in the particular centre.

In conclusion, it should be stated that the issues raised and the discrepancies found, as a result of the inspection of the above-mentioned clinical trial, led to a timely response by the sponsor of the trial to remove the participants from the trial as a result of the termination of their participation, and the closure of the research centre State Psychiatric Hospital-Tserova Korii as a clinical trial centre.

Appendices:

1. Positive Opinion for conducting a clinical trial "A phase 2, randomized, double-blind, placebo-controlled test to evaluate the efficacy, safety, and tolerability of two fixed doses (10 mg and 30 mg once daily) of CVL-231 in participants with schizophrenia experiencing an acute exacerbation of psychosis" - No. EKKI/CT-0991/26.10.2022
2. Positive Opinion for conducting a clinical trial "A 52-Week, Open-Label Phase 2 Test to Evaluate the Long-Term Safety and Tolerability of CVL-231 in Adult Participants with Schizophrenia" No. EKKI/CT-0990/26.10.2022
3. Positive Opinion for conducting a clinical trial "An open-label, multicentre test to evaluate the safety and tolerability of Lumateperone as adjunctive therapy in the treatment of patients with major depressive disorder" - No. EKKI/CT-1241/23.12.2021
4. Positive Opinion for conducting a clinical trial "Assessment of the bioequivalence of two medicinal products containing aripiprazole: Aripiprazole LAI powder and solvent for prolonged-release injection suspension for intramuscular application, 400 mg, Greece (Test) vs. ABILIFY MAINTENA® (Aripiprazole) prolonged-release injection suspension for intramuscular application, 400 mg, USA (Reference) - multicentre, multinational, open-label, randomized, multiple-dose, crosswise over two periods pharmacokinetic test in patients with schizophrenia" - No. EKKI/CT-0201/09.03.2022
5. Positive Opinion for conducting a clinical trial "A randomized, double-blind, placebo-controlled, parallel-group trial of Lumateperone for seizure prevention in patients with schizophrenia" - No. EKKI/CT-1100/24.11.2021
6. Positive Opinion for conducting a clinical trial "An open-label, multicentre test to evaluate the safety and tolerability of Lumateperone as adjunctive therapy in the treatment of patients with major depressive disorder" - No. EKKI/CT-1074/18.11.2021
7. Positive Opinion for conducting a clinical trial "A multicentre, randomized, double-blind, placebo-controlled study to evaluate the efficacy and safety of iloperidone administered for 4 weeks in the treatment of patients with acute manic episodes associated with bipolar type 1 disorder" - No. EKKI/CT-1151/09.12.2020.

Sincerely,

<Signature illegible>

<Round seal: Bulgarian Executive Drug Agency, REPUBLIC OF BULGARIA >

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