

***TECHNICAL ARRANGEMENT  
between  
the Ministry of Health of the Italian Republic  
and  
the Ministry of Health and Social Affairs of the Republic of Albania  
for scientific collaboration  
in the field of congenital bleeding disorders***

The Ministry of Health of the Italian Republic and the Ministry of Health and Social Affairs of the Republic of Albania, hereinafter referred to as "the Parties",

taking into consideration the Memorandum of Cooperation in the field of health and medical sciences between the Ministry of Health of the Italian Republic and the Ministry of Health of the Republic of Albania signed in Tirana on November 19, 2007, and the Memorandum of Understanding between the Italian National Institute of Health (ISS) and the Institute of Public Health of Albania (IPH) signed, for ISS, on July 19, 2017, and, for the IPH, on April 5, 2018, aimed to foster collaboration in various areas of public health;

in view of the friendly relations established between the Parties that have laid grounds for mutual trust; -

taking into account the European Union legislation and recommendations in the field of rare diseases and Cross-Border Healthcare that Italy as Member State is compliant with;

taking also into account the Council of Europe's, European Committee on Blood Transfusion (CD-P-TS) Resolution, CM/Res(2017)43 on Principles concerning haemophilia therapies [replacing Resolution CM/Res(2015)3] that calls on Governments to take into account specific principles for the treatment and care for patients suffering from haemophilia, such as the creation of haemophilia care systems based on multidisciplinary approaches, the prophylaxis for severe haemophilia, and the new levels of International Units (I.U.) per capita as annual coagulation Factor VIII (FVIII) and Factor IX (FIX) utilization;

in pursuance of the Italian legislation which allows the exportation of plasma-derived medicinal products (PDMPs), originated by Italian plasma, made available by Italian Regions and exceeding the need of the Italian population, in the context of international agreements or projects,

including the option of non-income generating cost recovery and humanitarian exportation;

having regard to the Italian State-Regions Agreement Rep. atti n. 37/CSR of February 7, 2013, for the promotion and implementation of cooperation agreements for the export of plasma-derived products for humanitarian purposes, which envisages the training of human resources, as well as support for the design and implementation of health care networks for patients with haemophilia and other congenital bleeding disorders (CBDs) as activities aimed at guaranteeing the rational and ethical use of PDMPs originated by Italian plasma. In particular, the same ASR states that the Italian Ministry of Health has assigned such activities to the Italian National Blood Centre (CNS) "[...] *in collaboration with the interested Regions and Autonomous Provinces, with the technical-scientific assistance of qualified experts in the field and the synergy with professional organisations and associations operating in Italy and taking into account the multilateral and bilateral collaboration programs [...]*";

having consideration that some Italian Regions are already making available FVIII, FIX and high-level training to Albania; -

have entered into the following understanding:

## **Article 1**

### **Objective**

This Arrangement is aimed to establish cooperation between the Parties with the goals of:

1. Contributing to the improvement of the quality of haemophilia services in the Republic of Albania.
2. Promoting an ethical and good use of PDMPs made available by Italian Regions to Albania.
3. Reinforcing the scientific and technical collaboration in the field.

In particular, the donation of PDMPs from Italian Regions will be able to increase the level of (I.U.) per capita of general population in Albania, enabling the implementation of prophylaxis especially in children with severe haemophilia and the reduction of the number of annual bleeding rate in patients with CBDs.

## **Article 2**

### **Commitments of the Parties**

Within the framework of the Technical Arrangement, the Ministry of Health and Social Affairs of the Republic of Albania is committed to:

1. Provide periodic and detailed reporting on the use of PDMPs made available by Italian Regions.
2. Establishing and developing a national haemophilia centre network aimed at improving the quality of care and the access to specialised services.
3. Establishing and developing a national haemophilia programme aimed at improving the quality of care and the access to a sustainable supply of clotting factor concentrates, including the option to partially reimburse to the Italian Regions the manufacturing costs on the basis of a cost recovery principle.
4. Implementing an electronic medical record (EMR) and establishment of a national registry of CBDs, supporting the clinical management and the health care planning of these diseases.
5. Defining and implementing protocols and clinical pathways for the management of patients with CBDs.
6. Implementing collaboration scientific research projects in the related field.

Within the framework of the present Technical Arrangement and as stated in the premise, the Ministry of Health of the Italian Republic availing itself of the CNS, and of the ISS, in collaboration with the interested Regions and Autonomous Provinces, and with the technical-scientific assistance of qualified experts and the synergy with professional organisations and associations, is committed to:

1. Developing a medium and long-term supply program of PDMPs made available by Italian Regions.
2. Providing technical assistance and support for the design and implementation of services/networks for CBDs.
3. Providing training, technical and capacity building support.

The exchange of information will not concern personal data. If necessary, any personal data will be aggregated to make them anonymous.

In order to implement any forms of cooperation provided for in this Agreement, the exchange of individual personal data, if necessary, will be governed by a specific subsequent Agreement signed by the Parties. Pending the conclusion of such specific Agreement, only initiatives that do not involve the transfer of personal data may be carried out, except in cases where such transfers are permitted without adequate safeguards under the legislation of the Parties.

### **Article 3**

#### **Monitoring**

The Parties are committed to report each other the ongoing activities carried out in the context of the present Technical Arrangement at least on an annual basis.

### **Article 4**

#### **Laws in force**

The present Technical Arrangement will be implemented in full compliance with the respective national legislations and in conformity with applicable international law, including, as for the Italian Party, the obligations arising from Italy's membership of the European Union.

This Technical Arrangement does not constitute an international agreement which may lead to rights and obligations under international law.

### **Article 5**

#### **Terms, Conditions and Costs**

The terms and conditions of each activity under the present Technical Arrangement will be negotiated by the Parties.

The activities set forth in this Technical Arrangement will be implemented by the Parties within the limits of their ordinary budget availability, without any additional costs for the State budgets of the Italian Republic and the Republic of Albania. Travel and accommodation expenses will be covered by the Parties within their respective obligations.

## **Article 6**

### **Divergences**

Any divergence in the interpretation and implementation of this Technical Arrangement will be settled amicably through direct consultation or negotiations between the Parties.

## **Article 7**

### **Effectiveness**

The present Technical Arrangement takes effect on the date of signature. It will remain effective for a period of five (5) years and will automatically be extended for additional periods of successive five (5) years, unless either Party notifies the other Party of its intention to terminate it, at least six (6) months in advance of its expiry date.

The present Technical Arrangement may be amended in writing, by mutual consent of the Parties.

Signed at Rome, on November 12nd 2021, in two originals, each in the Italian, Albanian and English languages, all texts equally being authentic. In case of divergence of interpretation, the text in English will prevail.

**For the Ministry of Health  
of the Italian Republic**

*Roberto Speranza*

**For the Ministry of Health and  
Social Affairs  
of the Republic of Albania**

*Ogerta Manastirliu*