



**CENTRO
NAZIONALE
SANGUE**



National plasma strategies in Europe: Italy & Malta

Fabio Candura, PhD

(L Cannata, A Palmieri, L Teofili)

Italian National Blood Centre

National Institute of Health, Rome

Timeline

23.12.2009
Memorandum
of
Understanding
signed between
the Italian MoH
and the Ministry
of Social Policies
of Malta

04.01.2024
The National
Blood
Transfusion
Service (NBTS)
of Malta
formally reaches
out the Italian
National Blood
Centre (CNS) to
establish
cooperation
between the
two countries in
the specific area
of transfusion
activities
(provision of
blood in cases of
national
emergency,
possibility of
fractionating
Maltese plasma)

10.04.2024
The Ministry of
Health is
informed about
Malta's request
to sign a
Technical
Agreement (TA)

Definition of the
terms and
contents of the
TA

Technical
agreement
drafted in both
languages
(EN-IT)

04.06.2025
CNS and
Maltese
ministry of
Social Policies
representatives
request and
obtain ministers'
authorisation
for the
delegated
signature

09.06.2025
The technical
agreement is
signed in
Valletta, Malta

Technical Agreement

European framework

The initiatives for a strong European Health Union should work in favour of European self-sufficiency, in particular as regards the supply of critical SoHO and the ability to minimise the risk of shortages. The lessons learned and the resulting measures taken at Union level should serve as a reference for the prevention, detection and resolution of future health crises.

- **SUPPLY PROJECT** (Strengthening voluntary non-remunerated plasma collection capacity in Europe – GA 101056988): the project main objective was not only to increase the collection of plasma from voluntary non-remunerated donors throughout Europe but also to strengthen cooperation between European countries especially in times of emergency.

Technical Agreement

European framework

The initiatives for a strong European Health Union should work in favour of European self-sufficiency, in particular as regards the supply of critical SoHO and the ability to minimise the risk of shortages. The lessons learned and the resulting measures taken at Union level should serve as a reference for the prevention, detection and resolution of future health crises.

- **SoHO REGULATION (EU) 2024/1938:**

Whereas 69): The exchange of SoHO between Member States is necessary for ensuring optimal patient access and sufficiency of supply, particularly in the case of local crises or shortages.

Art. 62: Member States shall, within their territories and in collaboration with SoHO national authorities, SoHO competent authorities and SoHO entities, each within their respective competence, consider all reasonable efforts for achieving a sufficient, adequate and resilient supply of critical SoHO with a view to appropriately meet recipients' needs, and to contribute to European self-sufficiency.

Technical Agreement

Contents

Scope:

- Strengthen the cooperation between the two countries in the field of transfusion activities;
- Promote the ethical and appropriate use of plasma in order to avoid wastage of raw material itself to be used for the production of life-saving plasma-derived medicinal products.

Italy will facilitate the transfusional support to the Maltese population in case of emergency contingencies:

- Supplying and/or processing and testing blood and blood components of Malta in case of emergency situations;
- Processing plasma in collected in Maltese territory in conformity with the Italian legislation on import and export of blood and blood products.

Technical Agreement

Contents

Activities:

- Establishment of an operational plan suitable for outlining the actions to be taken and the actors involved in case of emergency related to provision of blood and blood products in the Maltese territory.

Technical Agreement

Contents

Operational agreement (ongoing) between Maltese and Italian relevant Competent Authorities and/or their organisational entities (Regional Blood Centre and blood establishments) to ensure:

- the continuity of a sufficient supply of blood and blood components to the Maltese Islands,
- the availability of an alternative supply channel for blood and blood components in case of emergency or crisis.



Thank you

