

The supply of plasma-derived medicinal products in the future of Europe

Second edition

23-24
April 2024
Rome, Italy

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NAZIONALE
SANGUE

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Ministero della Salute

THE ITALIAN EXPERIENCE ON PDMPs CONTINGENCY

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National Blood Centre, Italy

Disclosure

I hereby declare that I have neither financial nor non-financial relationships related to any of the products or services described, reviewed, evaluated or compared in this presentation.



Agenda

- **The Italian Blood System**
- **The Italian PDMPs System**
- **The global context and the effects of the pandemic**
- **Demand for drivers, 2019 - 2023**
- **IG national production and distribution, 2019 - 2023**



The Italian Blood System



Healthcare governance in Italy

Federalist framework since 2001

Healthcare (HC) delivering is by law delegated to the 21 Regions

6 Autonomous Regions and Provinces with additional autonomy/privileges
(Aosta Valley, Friuli Venezia Giulia, AP Trento, AP Bolzano, Sicily, Sardinia)

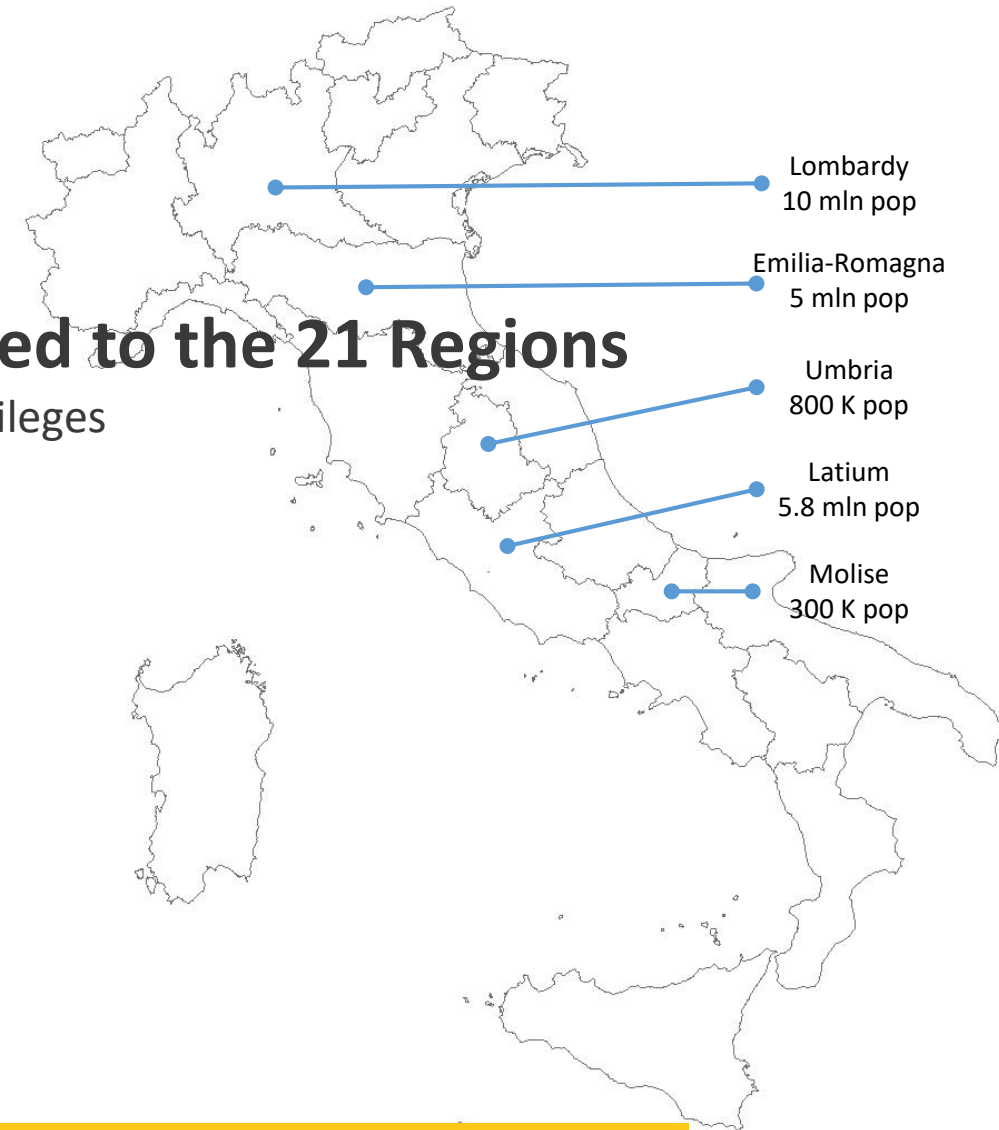
Ministry of Health

Responsible for:

- general healthcare legislation
- transposing EU provisions
- defining “basic healthcare levels” (BHCL)
- control of BHCL application in the regions
- control of regional budget balance
- general public health regulation

Any law / regulation must be preliminarily formally “shared” with regions (State-Regions agreements)

Ministry of Economy strongly conditions the HC national budget (108-110 billion €)

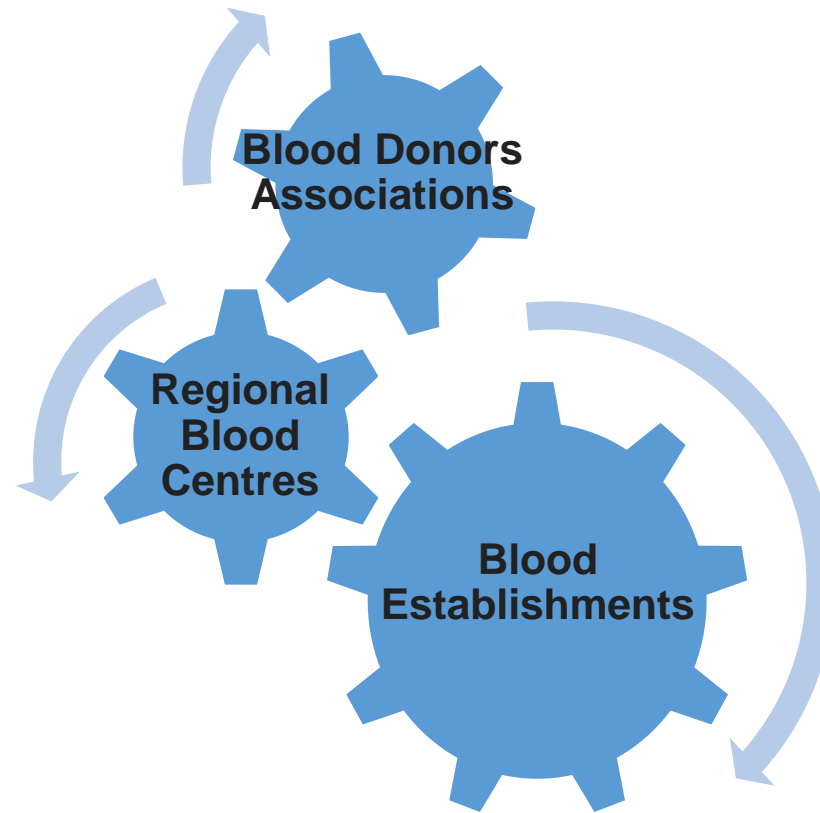


The Italian Blood System - Law October 21, 2005

Regional Blood Centres:

In each of the 21 regions, a Regional Blood Centre is established by law. The regional Blood Centres coordinate the related local networks of Blood Establishments and Blood Collection Units, complying with national regulation and self-sufficiency, quality and safety plans

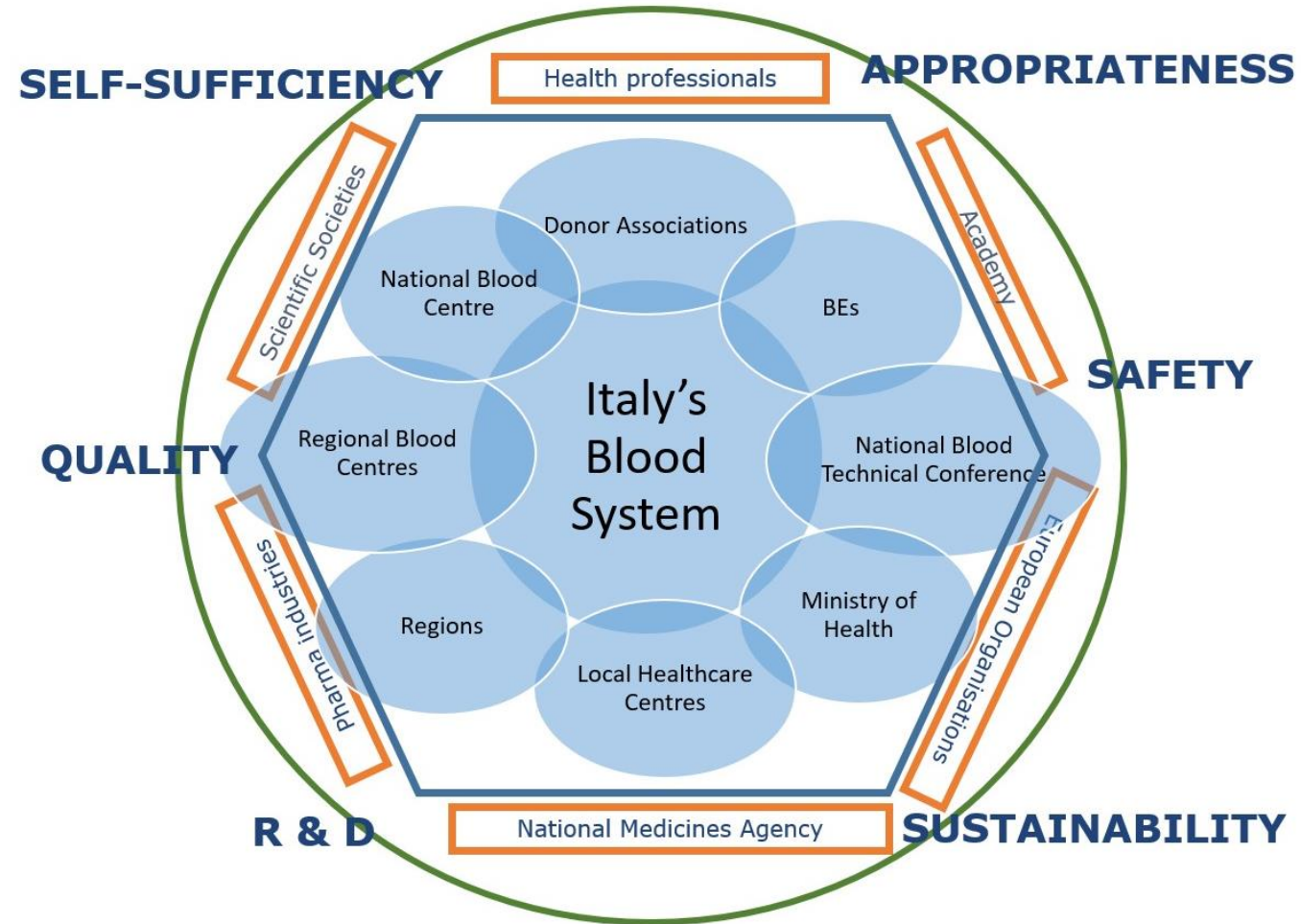
Blood Establishments: in addition to performing blood and blood component collection, processing, testing, storage and distribution, most Blood Establishments also work as hospital blood banks



Blood Donors Associations: there are four main blood donors organisations (AVIS, FIDAS, FRATRES, CRI) that are highly involved in the blood donor management. By law, they can run Blood Collection Units upon the release of specific regional authorization and accreditation, under the technical control of both Blood Establishments and Regional Blood Centers.



Stakeholders and Strategic Objectives



The Italian Blood System - Founding principles

- **Voluntary, anonymous, non-remunerated blood donation** is recognized as an essential activity for the National Health Service.
- The management of the transfusion process is unitary and “indivisible” and is **subject to specific authorisation/accreditation that complies with European regulations.**
- The management of the Italian Blood System is implemented through an exclusively public governance scheme: **BEs are exclusively public and hospital-based.**
- **Human blood is not a source of profit.** The costs incurred for the production and distribution of blood and blood products, including hematopoietic stem cells, are not chargeable in any form to the recipient.



The Italian Blood System and PDMPs

Law no. 219 October 21, 2005

Founding Principles

Art. 1
National Self-sufficiency

Art. 2
VNRB donation
PDMPs production is part of Transfusion medicine activities

Art. 5
Transfusion medicine activities (including the PDMPs production) are BHCLs

Art. 15 (PDMPs production)

4 Ministerial Decrees
April 12, 2012
December 5, 2022
December 19, 2022

Ministerial Decree
in update
December 5, 2014

Art. 16 (import-export)

State-Regions Agreement
February 7, 2013

Ministerial Decree
December 2, 2016

Instruments

State-Regions Agreements
~~October 20, 2015~~
June 17, 2021

State-Regions Agreement
~~March 14, 2016~~
July 8, 2021

Lgs.D
261/2007

Art. 26

Ministerial Decree
December 2, 2016
Plasma and PDMPs National Plan 2017 - 2021

National self-sufficiency of PDMPs

“[...] to provide patients, in a systematic and sustainable way, with the prompt and continuous availability of a defined set of PDMPs with the highest level of quality and safety and in compliance with the existing regulatory framework, which meets appropriate clinical needs through the national collection of plasma based on voluntary and not remunerated donations with the contribution of PDMPs shares acquired on the market.”



National self-sufficiency of PDMPs 2.0

In the recent years the capability “[...] to provide patients, in a systematic and sustainable way, with the prompt and continuous availability of a defined set of PDMPs [...]” has been significantly constrained by the demand/supply dynamics of the PDMPs global market. Thus,



Strategic independence

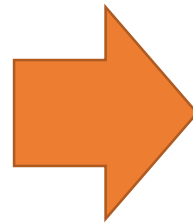


the capability of National Health Systems to make the procurement/supply of PDMPs autonomous from the dynamics of the global market



The annual National self-sufficiency programme

Self-sufficiency of blood and blood products, **including PDMPs** is a national *supra-regional* strategic goal, i.e. independent of the regionalised organisation of health-care delivery.



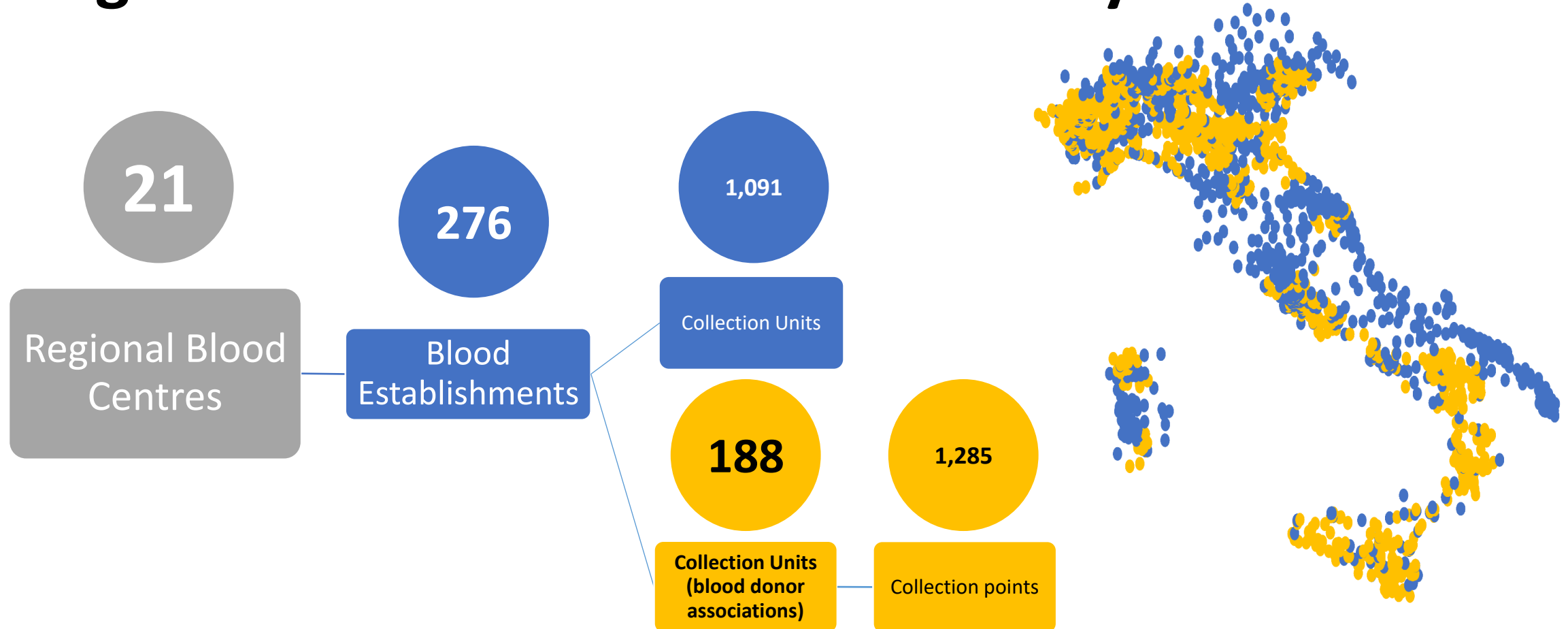
Every year, the Minister of Health, on the basis of the indications provided by the National Blood Center in accordance with Regions, annually defines the national self-sufficiency program, which identifies:

- the historical consumption,
- the real needs,
- the production levels required,
- the resources,
- the criteria for financing the system,
- the tariffs references for the compensation between the regions,
- the levels of import and export that may be needed.

Since 2008, several annual National self-sufficiency programmes have been published and became Law







Organisation of the collection in Italy



Data sources: BEs Information System (Sistema informativo dei Servizi TRAsfusionali) – Last access 12/04/2024

Toll fractionation System-Interregional Agreements

Four interregional Agreements:

-  NAIP
(New Interregional Agreement for Plasma-Derived Medicinal Products)
-  Accordo LPS
(Lombardy, Piedmont, Sardinia Agreement)
-  RIPP
(Plasma/Plasma-Derived Interregional Group)
-  Pla.Net
(Plasma Network)

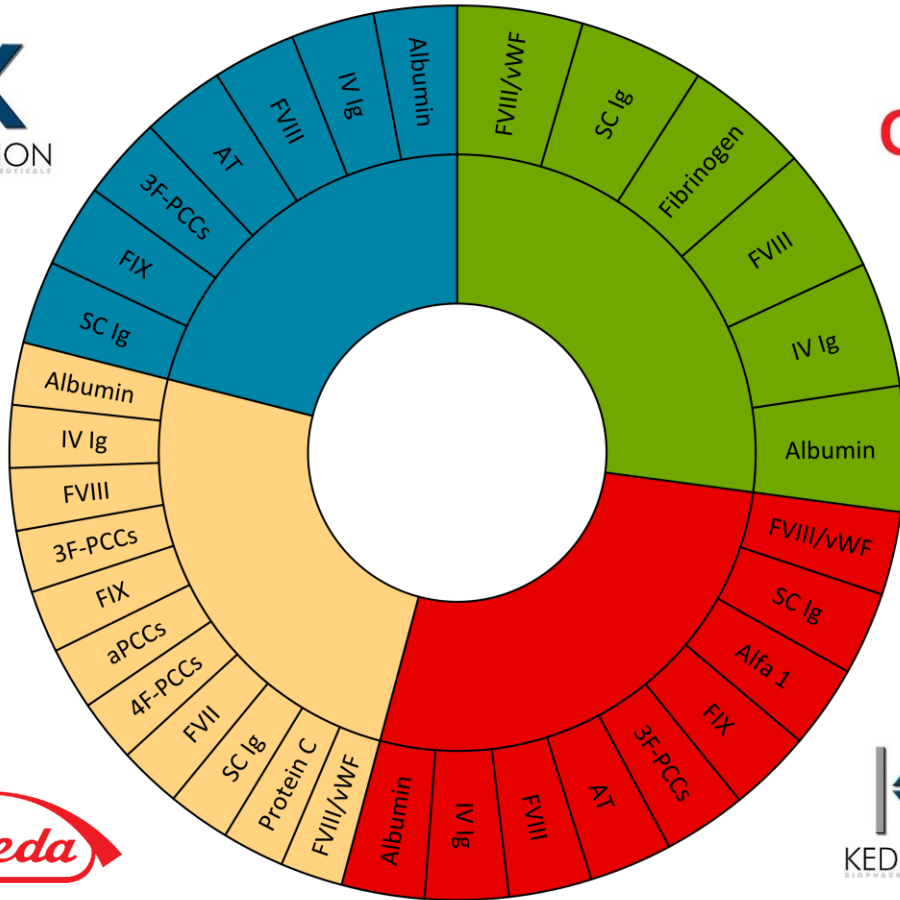
CSL Behring
(New Interregional Agreement for Plasma-Derived Medicinal Products)



Toll fractionation System-Interregional Agreements



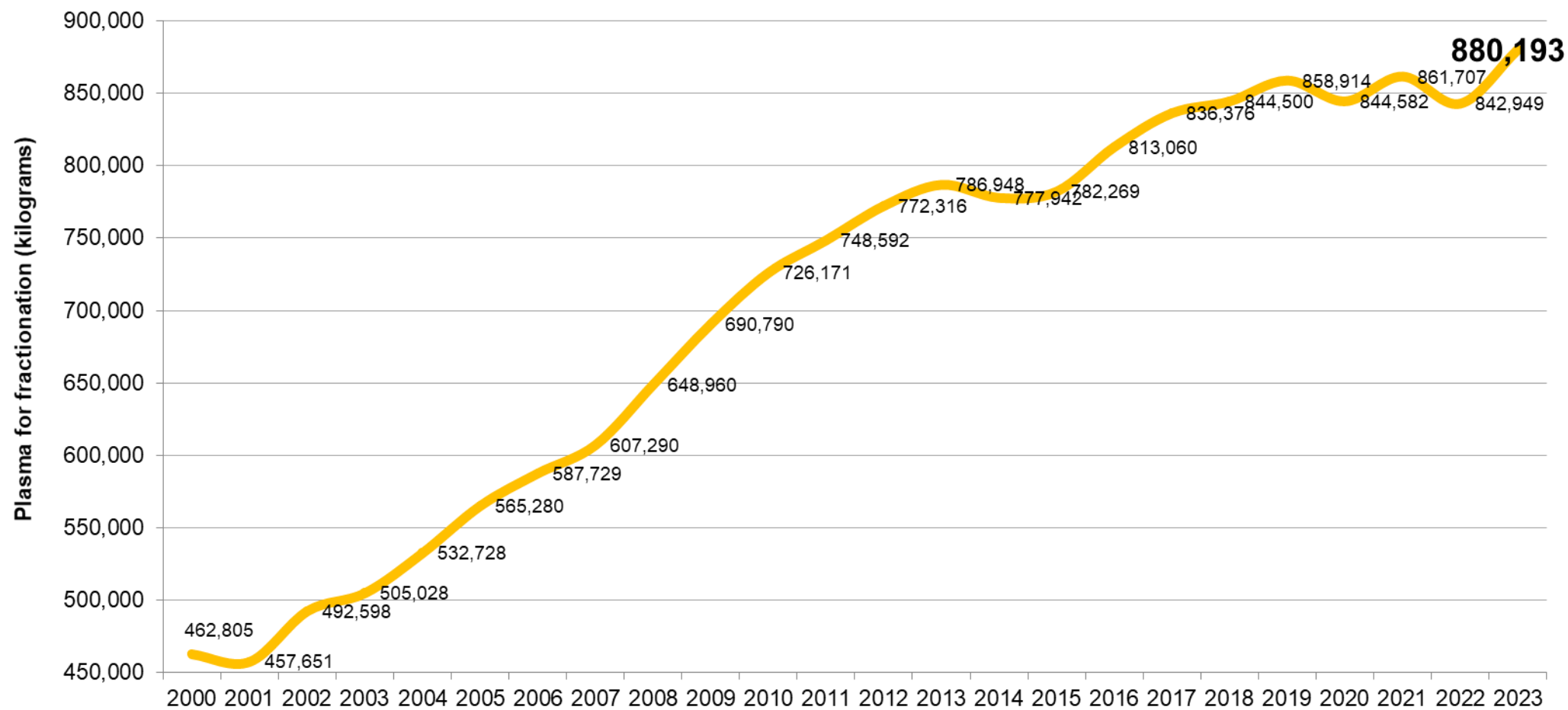
CSL Behring



Plasma for fractionation in Italy - Year 2023



Plasma for fractionation, 2000 - 2023

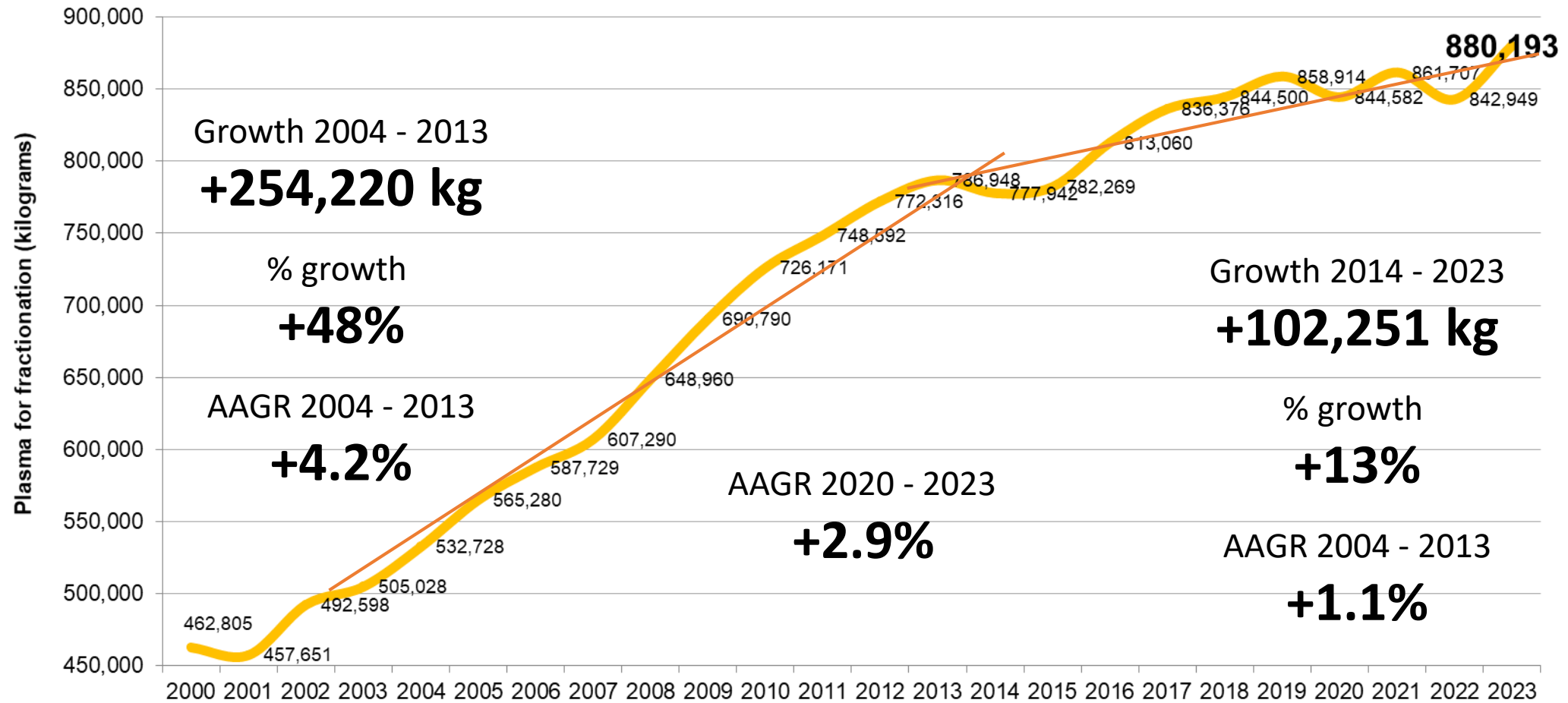


Data sources: - Adapted by the Italian National Blood Centre on data from Fractionation industries. January 2024

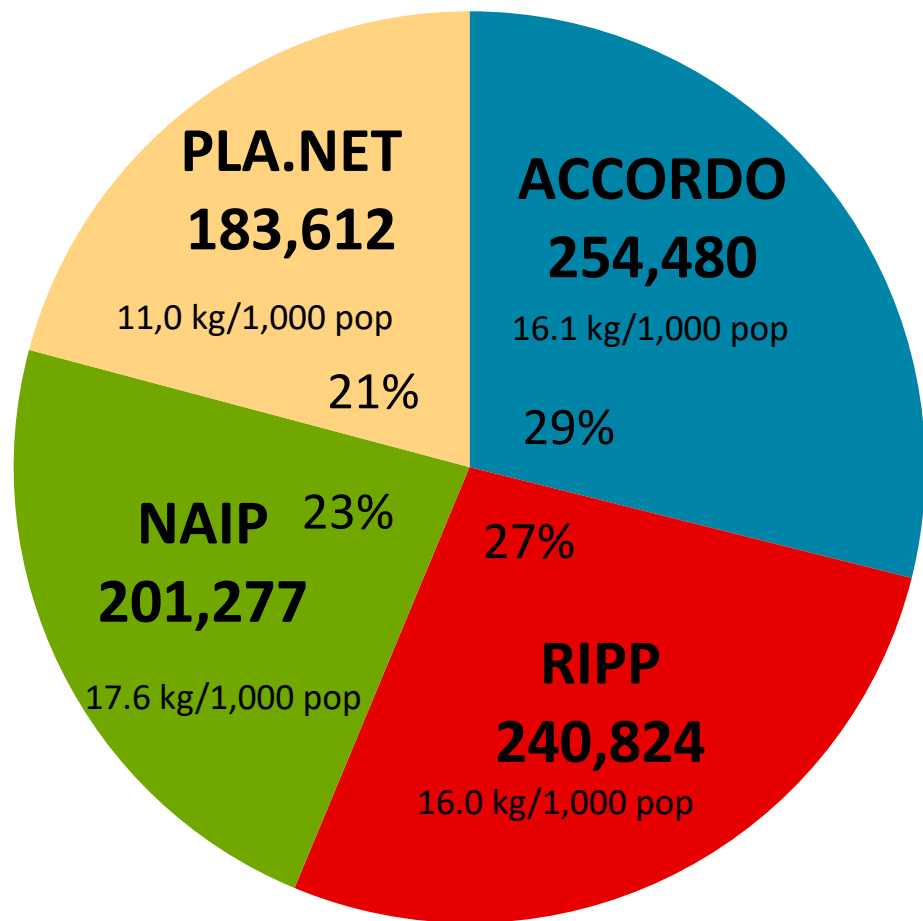
THE SUPPLY OF PLASMA-DERIVED MEDICINAL PRODUCTS IN THE FUTURE OF EUROPE – Rome, 23-24 APRIL 2024



Plasma for fractionation, 2000 - 2023



Plasma for fractionation 2023



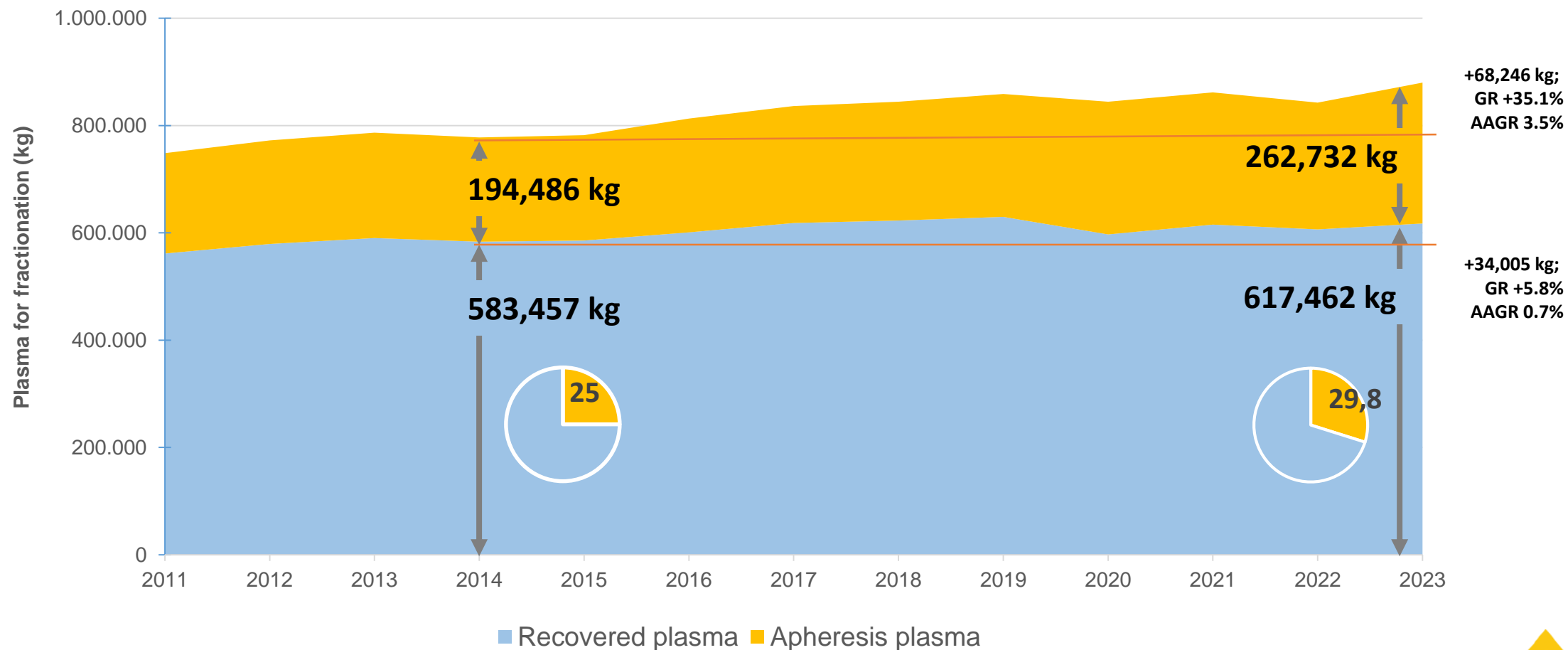
ITALY
880,193 kg
14.9 kg /1,000 pop



Data sources: Adapted by the Italian National Blood Centre on data from Fractionation industries. January 2024



Plasma for fractionation 2023 by category

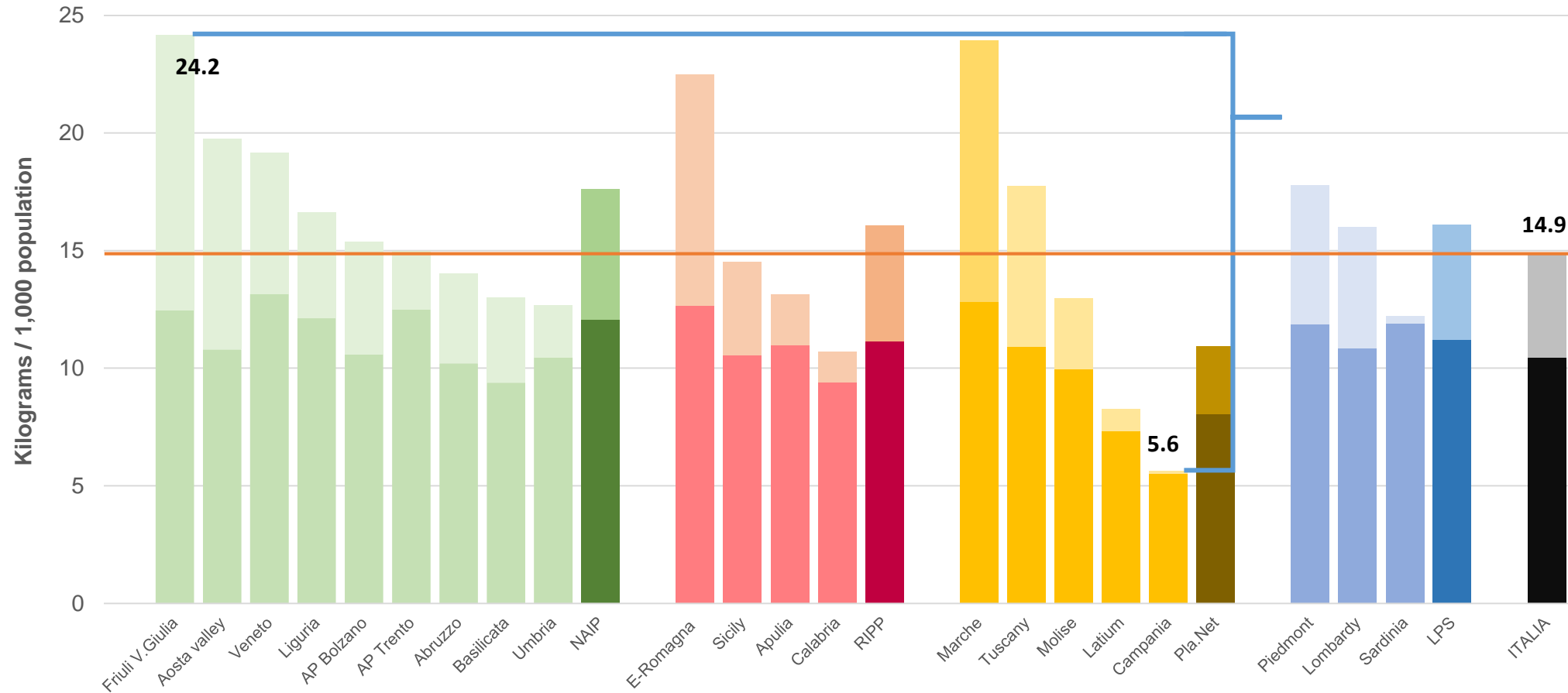


Data sources: Adapted by the Italian National Blood Centre on data from Fractionation industries. January 2024

THE SUPPLY OF PLASMA-DERIVED MEDICINAL PRODUCTS IN THE FUTURE OF EUROPE – Rome, 23-24 APRIL 2024



Plasma for fractionation by Regions and AAPP, Agreements, Category - 2023 (kg / 1,000 pop)



Data sources: Adapted by the Italian National Blood Centre on data from Fractionation industries. January 2024

THE SUPPLY OF PLASMA-DERIVED MEDICINAL PRODUCTS IN THE FUTURE OF EUROPE – Rome, 23-24 APRIL 2024

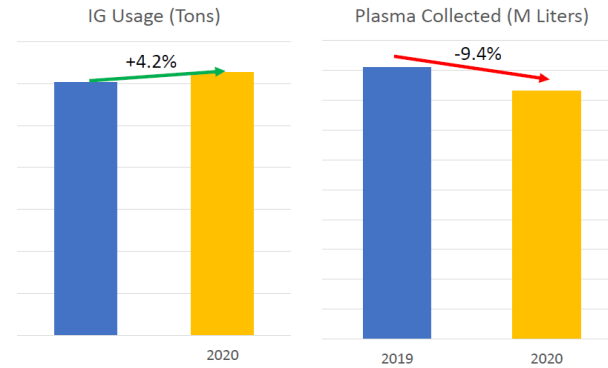


The global context and the effects of the pandemic



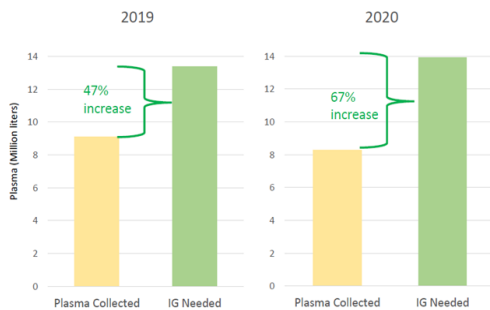
European IG use vs Plasma collection

European IG Usage vs. Plasma Collection in 2019 vs. 2020



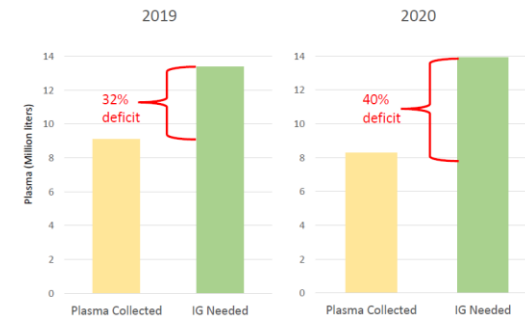
As a result of the drop in collections, due to the pandemic and the continued rise in IG demand, the imbalance of collections and IG product need grew in 2020.

Increase in Collections needed in 2019 and 2020 to meet needs of Patients in Europe



Increase in plasma collections required to meet the IG needs of all patients:
 2019: 4.3 million liters
 2020: 5.6 million liters

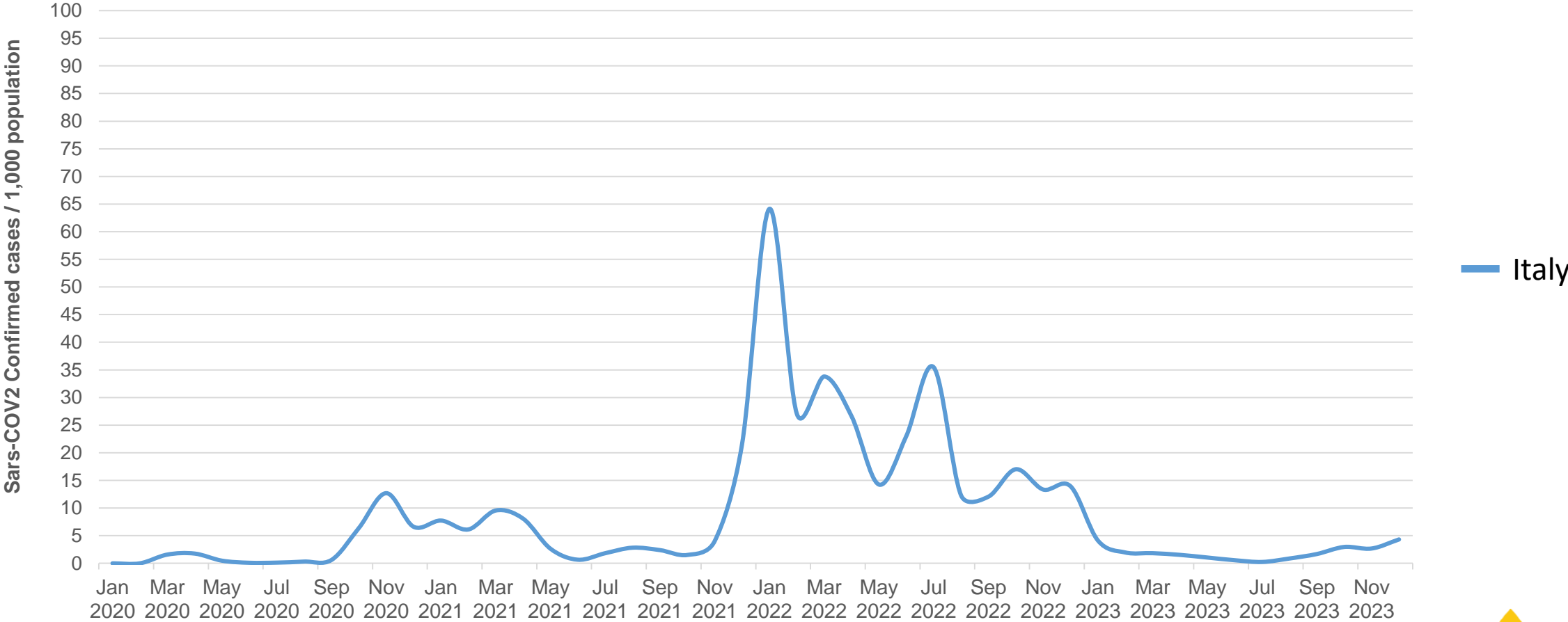
2019 and 2020 Imbalance of Plasma Collections and Need for IG in Europe



The self-sufficiency of Europe, dropped 8 percentage points from 2019 to 2020.



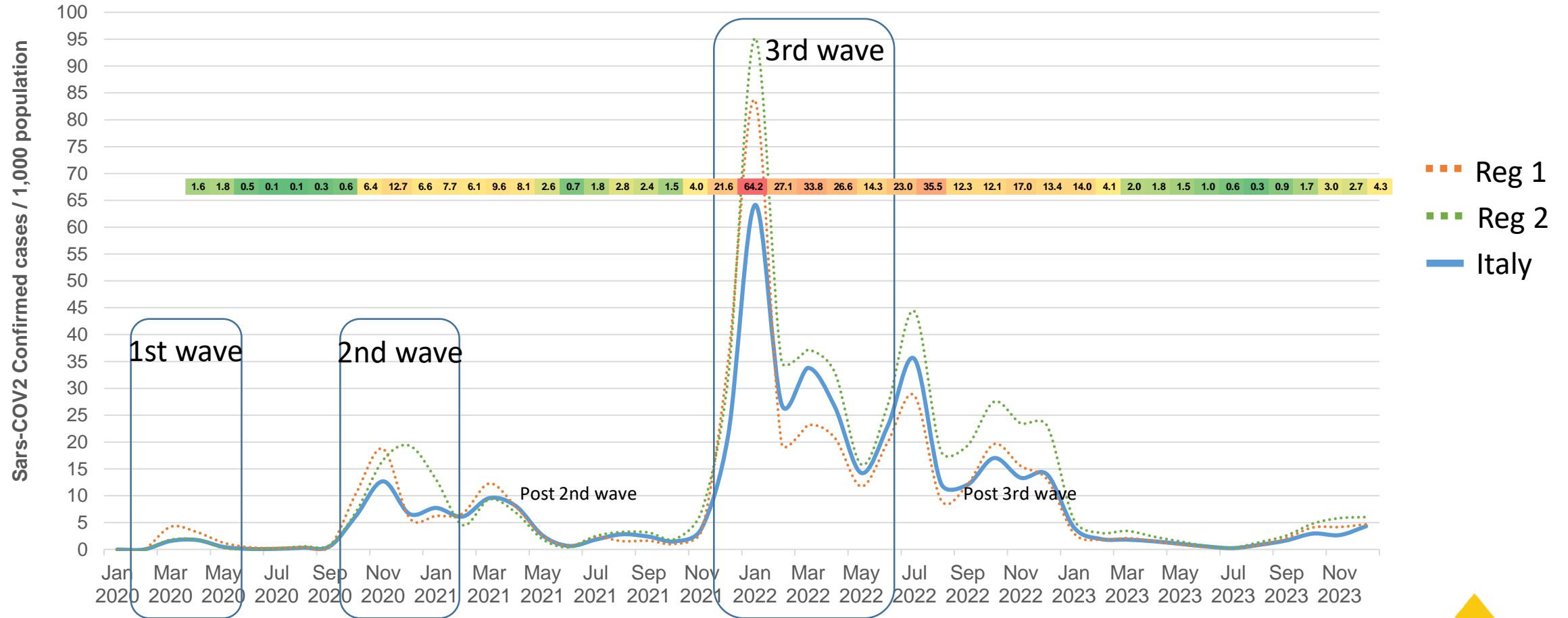
The Sars Cov-2 pandemic in Italy



Data sources: Adapted by the Italian National Blood Centre on data from Weekly Covid-19 Bulletins, Italian Ministry of Health; Demo.ISTAT, Italian Institute of Statistics.



The Sars Cov-2 pandemic in Italy

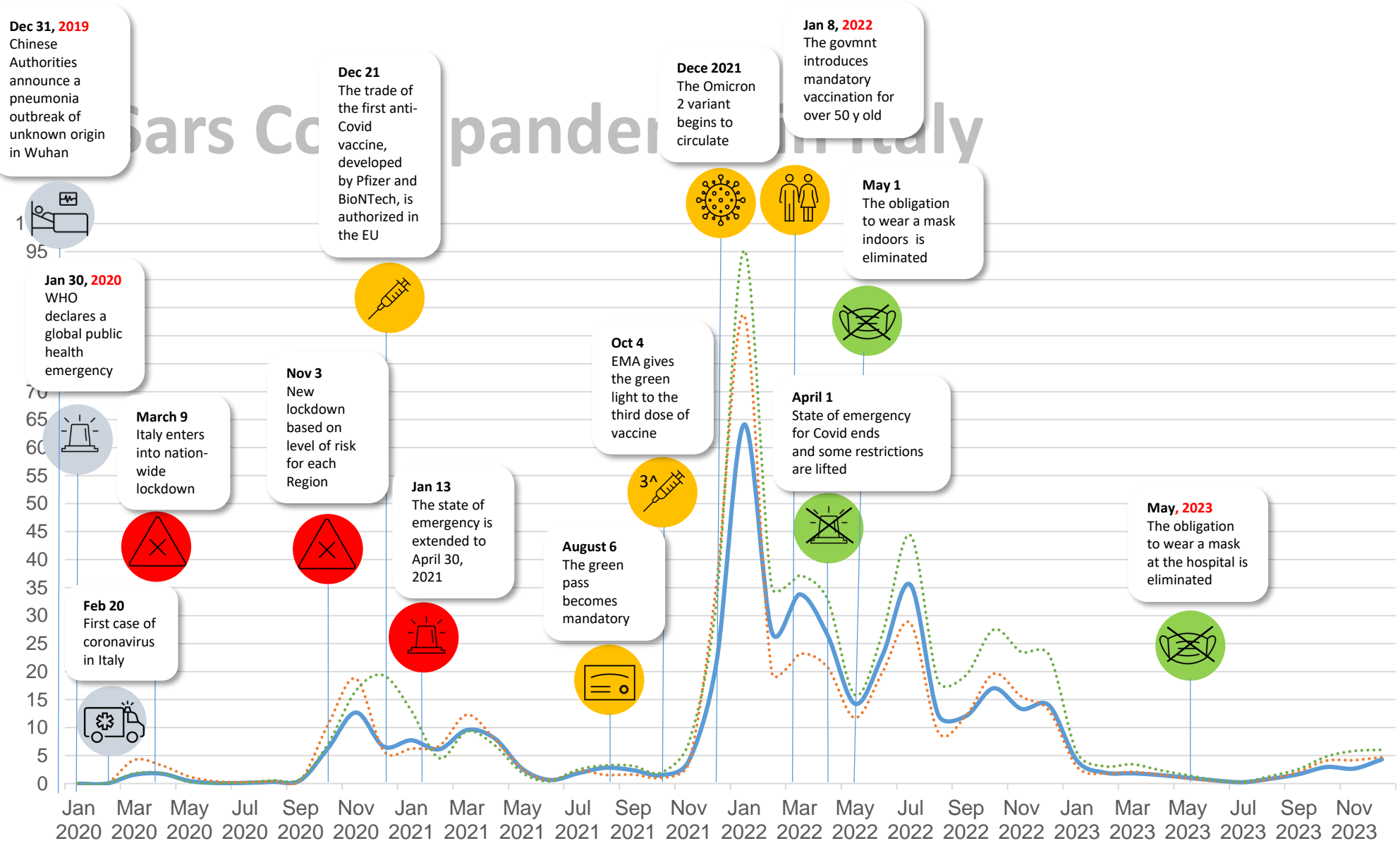


Data sources: Adapted by the Italian National Blood Centre on data from Weekly Covid-19 Bulletins, Italian Ministry of Health; Demo.ISTAT, Italian Institute of Statistics.



Sars CoV2 pandemic in Italy

Sars-COV2 Confirmed cases / 1,000 population

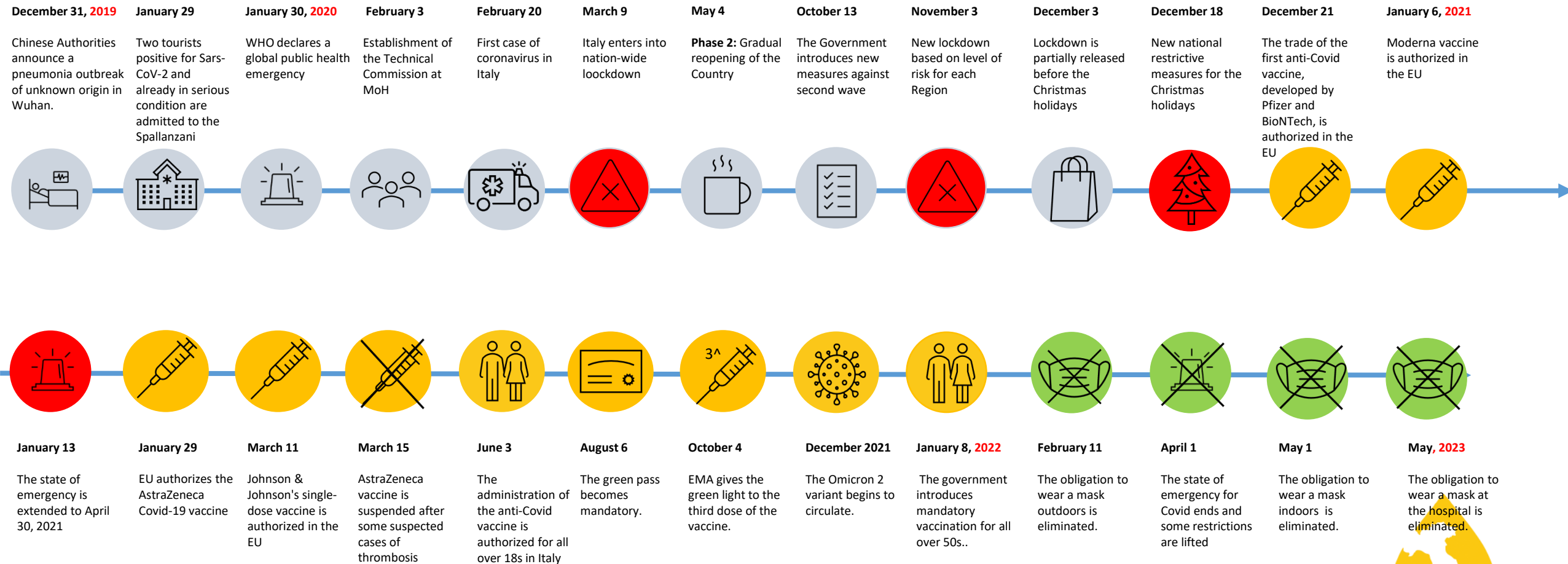
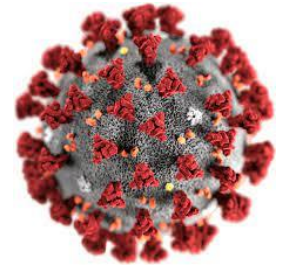


Reg 1
Reg 2
Italy

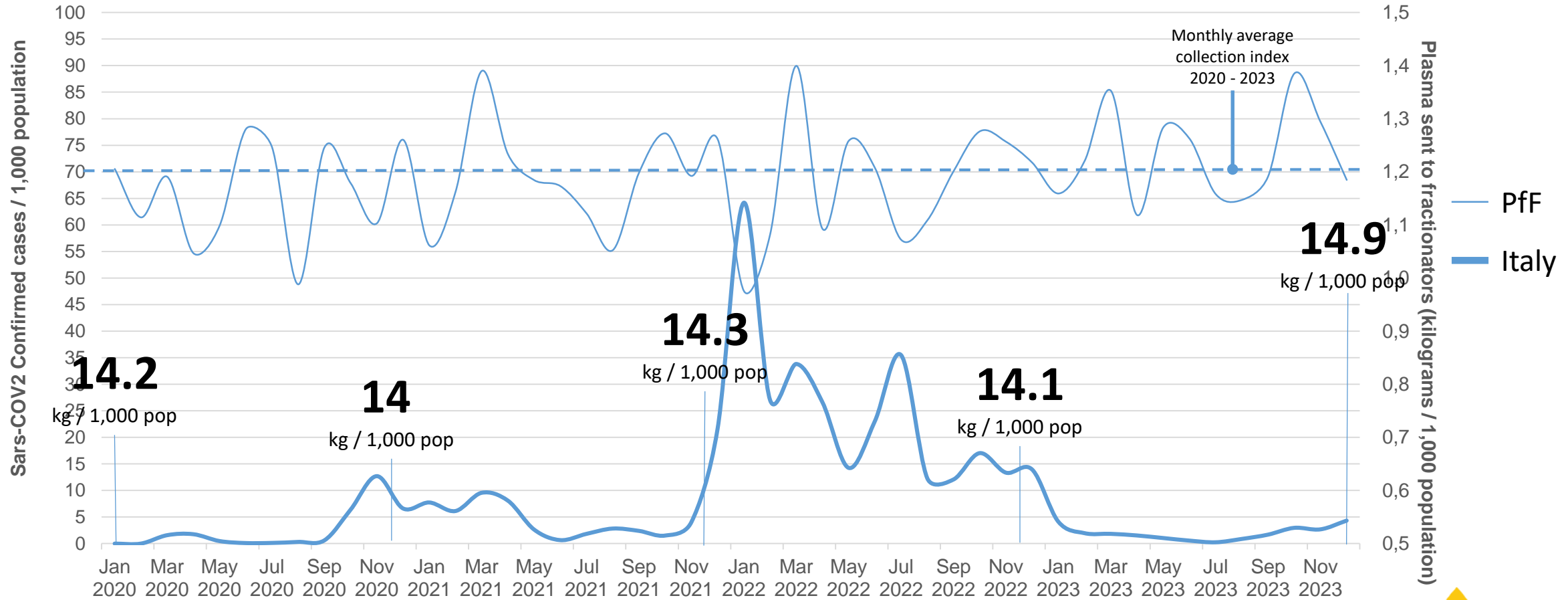
Data sources: Adapted by the Italian National Blood Centre on data from Weekly Covid-19 Bulletins, Italian Ministry of Health; Demo.ISTAT, Italian Institute of Statistics.



Timeline of the Sars Cov-2 pandemic in Italy



The Sars Cov-2 pandemic in Italy & collection

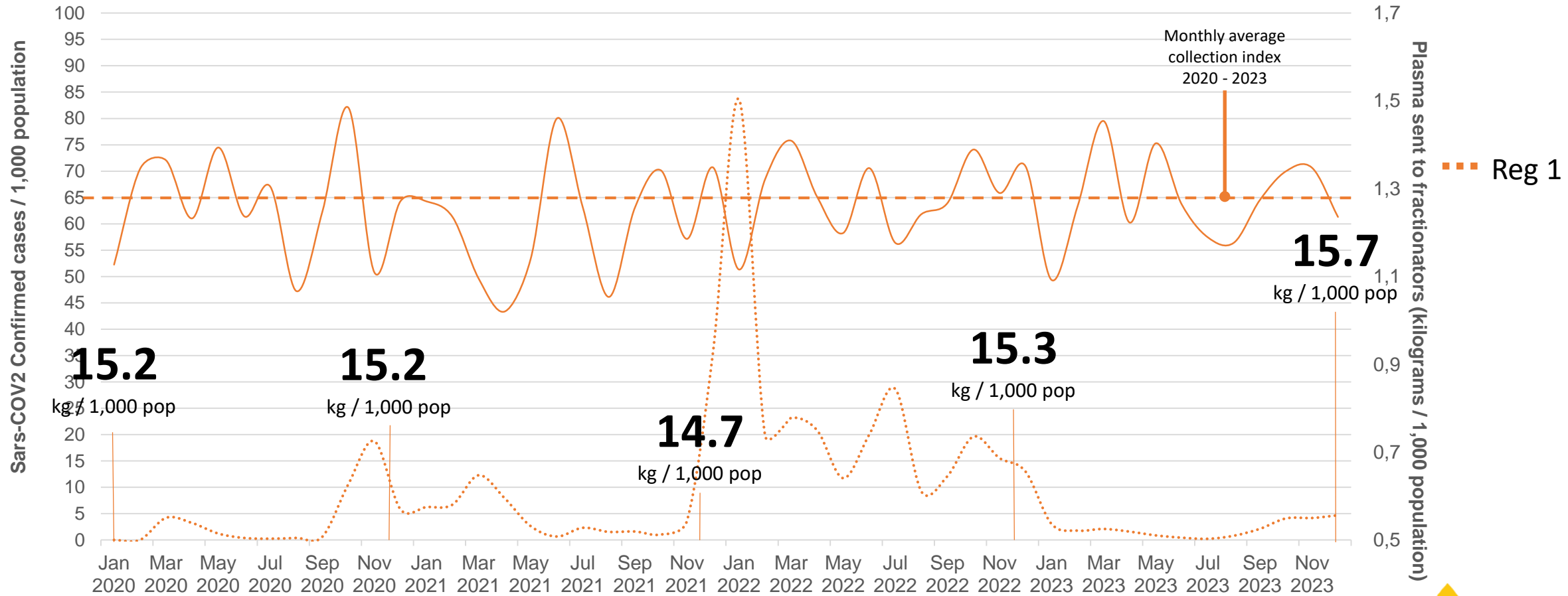


PfF: Plasma for Fractionation

Data sources: Adapted by the Italian National Blood Centre on data from Fractionation industries. January 2024

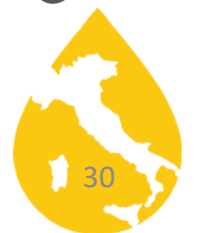


The Sars Cov-2 pandemic in Italy & collection

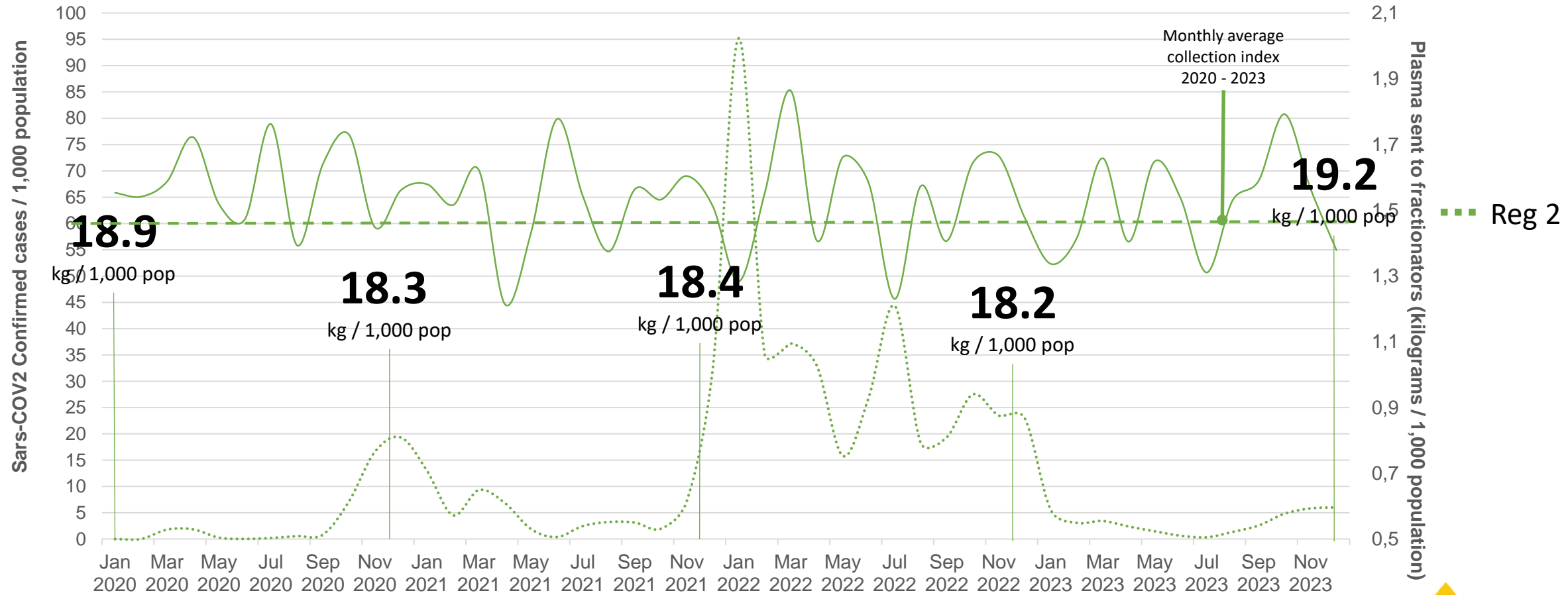


PfF: Plasma for Fractionation

Data sources: Adapted by the Italian National Blood Centre on data from Fractionation industries. January 2024



The Sars Cov-2 pandemic in Italy & collection



PfF: Plasma for Fractionation

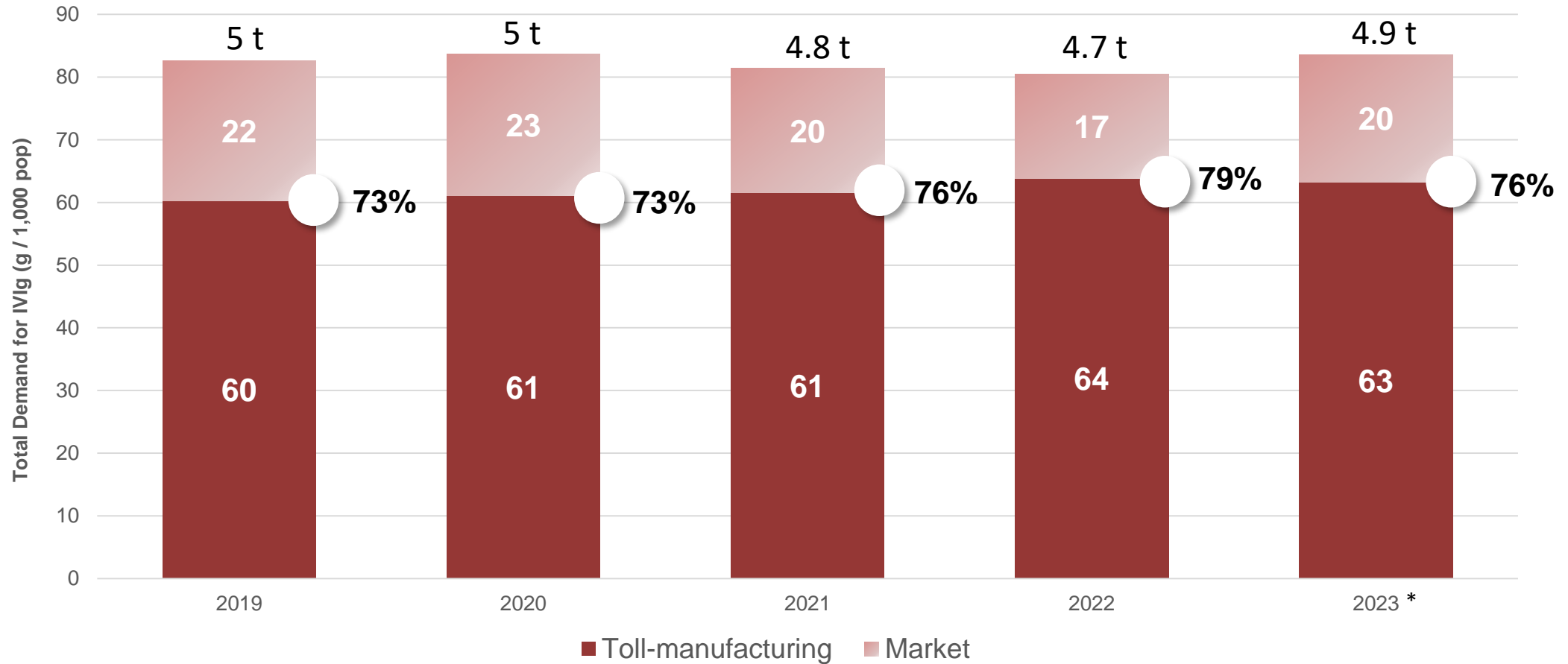
Data sources: Adapted by the Italian National Blood Centre on data from Fractionation industries. January 2024



Demand for drivers, 2019 - 2023



IVIg in Italy, 2019 - 2023



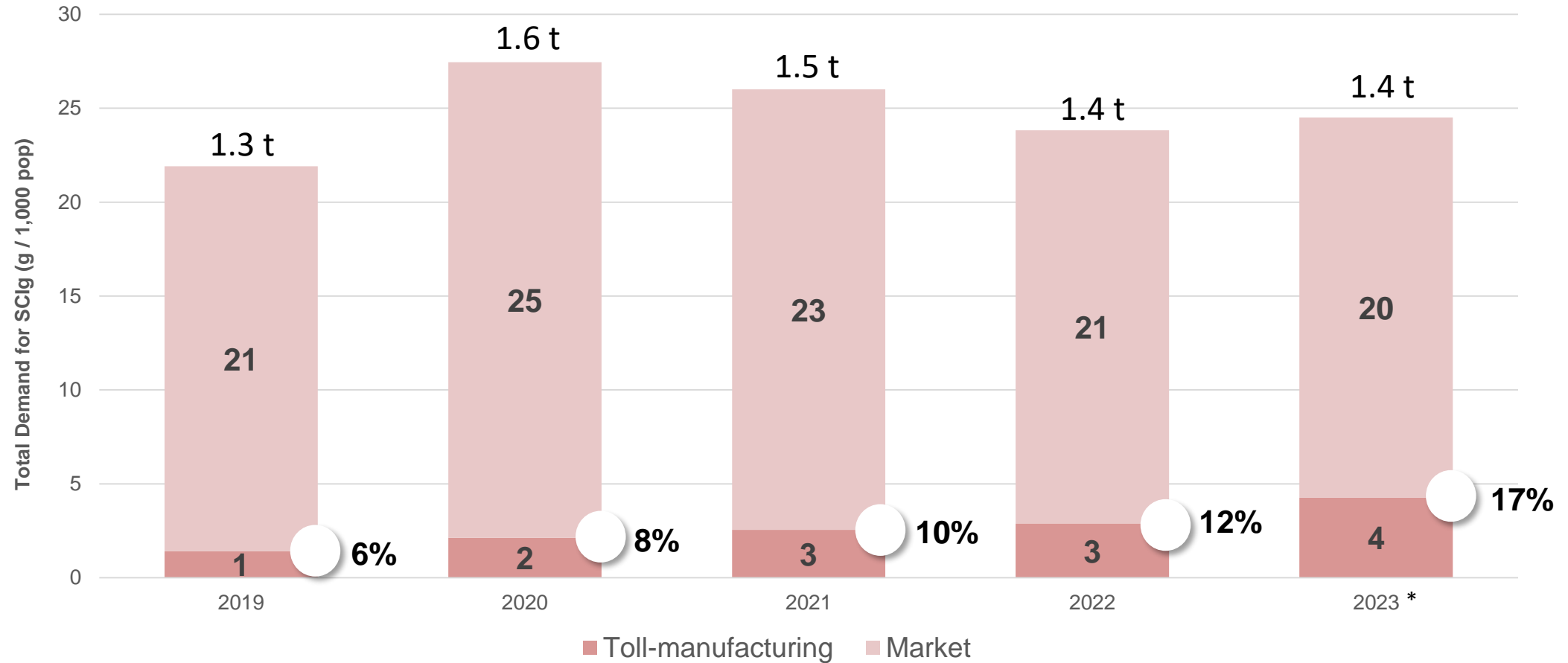
Data sources: - Adapted by the CNS on data from the Traceability information flow-Italian Ministry of Health and Demo.ISTAT- Italian Institute of Statistics

* Preliminary data

The value does not include *High titre IVIg*



SCIg in Italy, 2019 - 2023

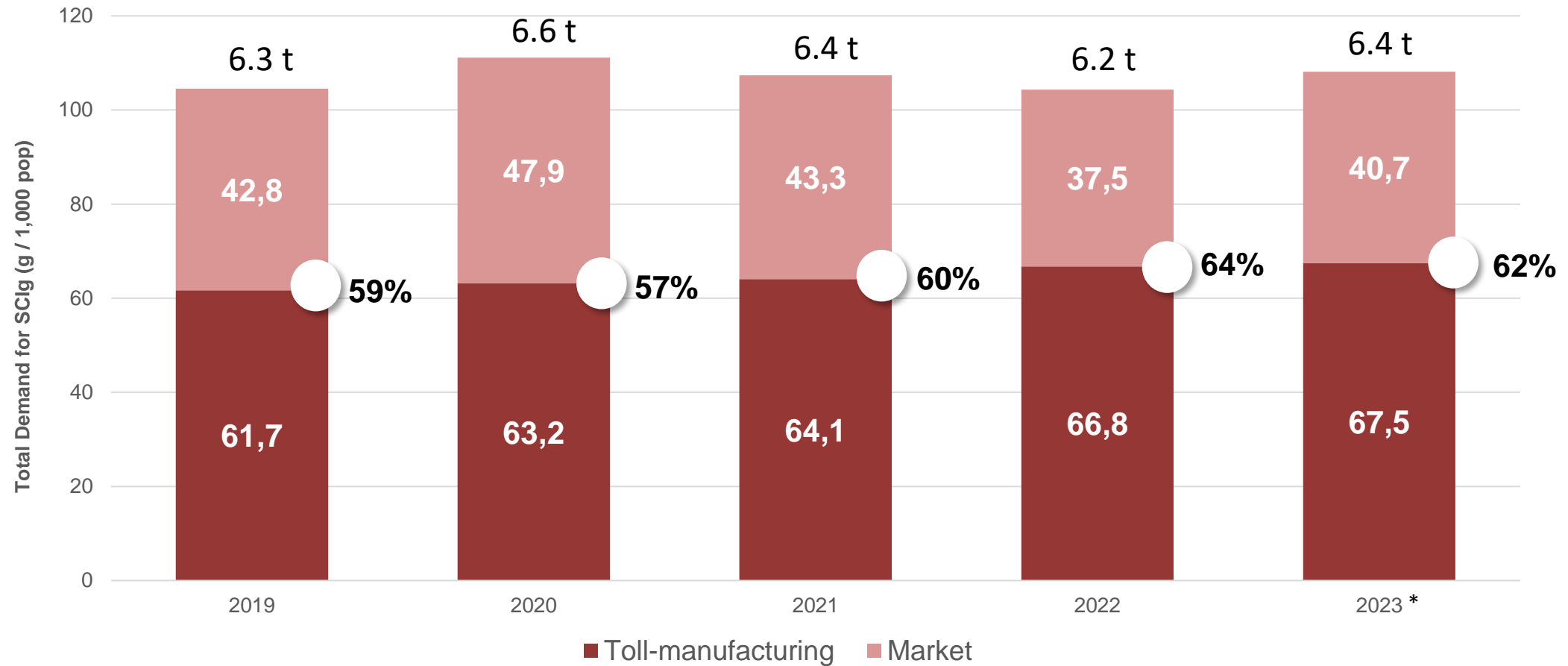


Data sources: - Adapted by the CNS on data from the Traceability information flow-Italian Ministry of Health and Demo.ISTAT- Italian Institute of Statistics

* Preliminary data



IG (IVIg+SCIg) in Italy, 2019 - 2023



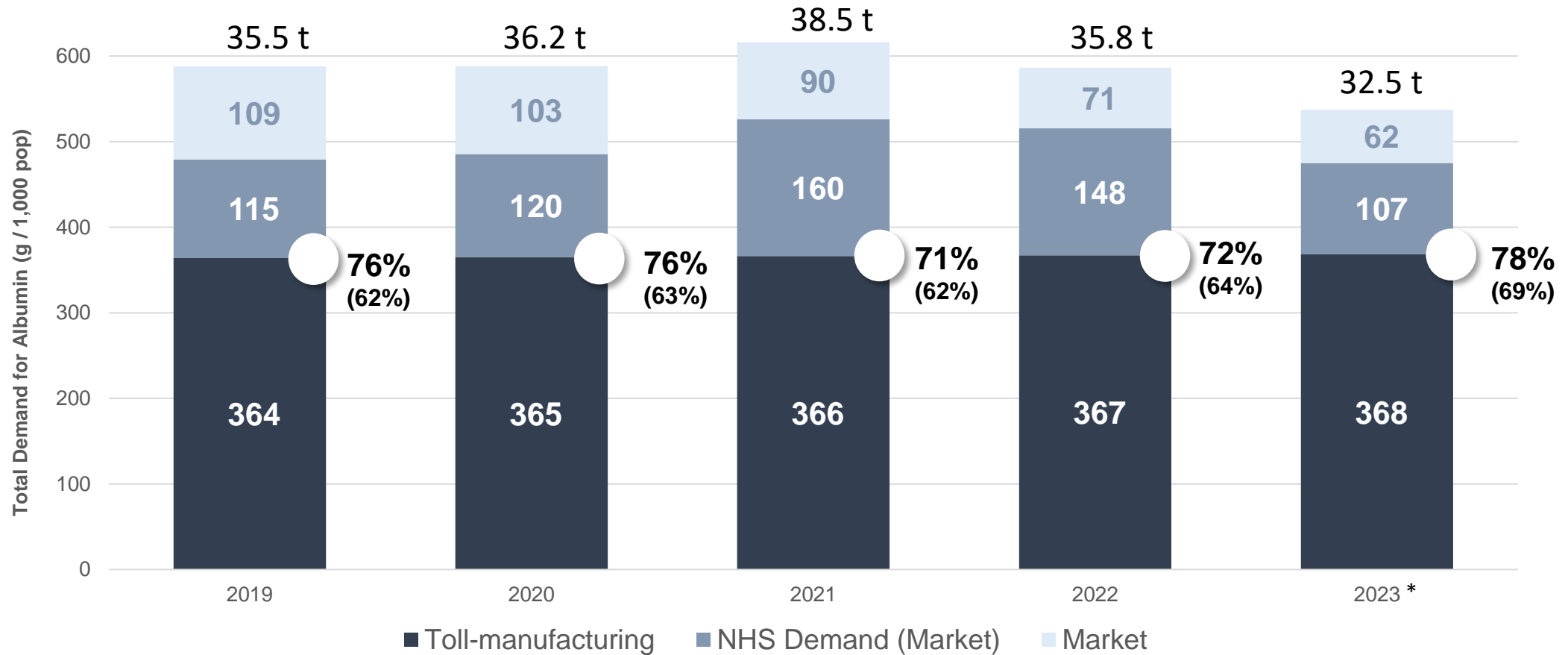
Data sources: - Adapted by the CNS on data from the Traceability information flow-Italian Ministry of Health and Demo.ISTAT- Italian Institute of Statistics

* Preliminary data

The value does not include *High titre IVIg*



Albumin in Italy, 2019 - 2023



Data sources: - Adapted by the CNS on data from the Traceability information flow-Italian Ministry of Health and Demo.ISTAT- Italian Institute of Statistics

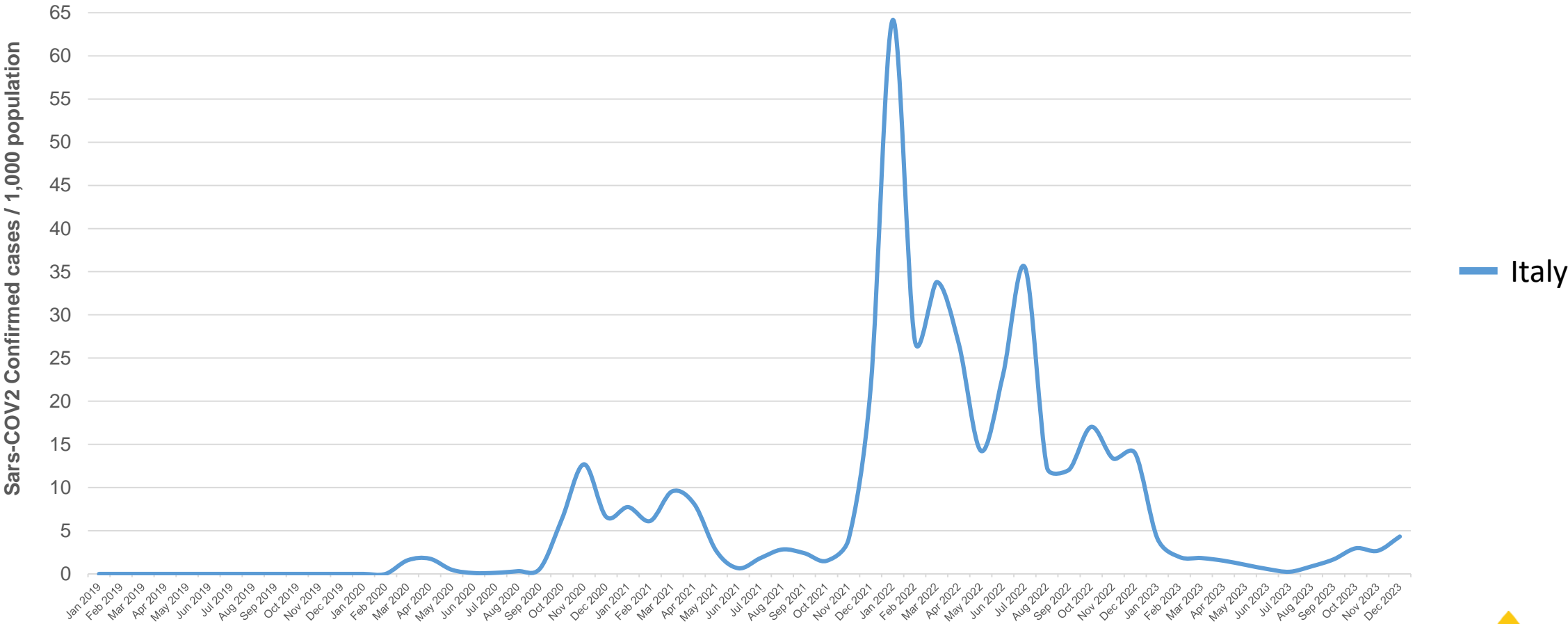
* Preliminary data



IG distribution, 2019 - 2023



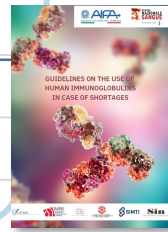
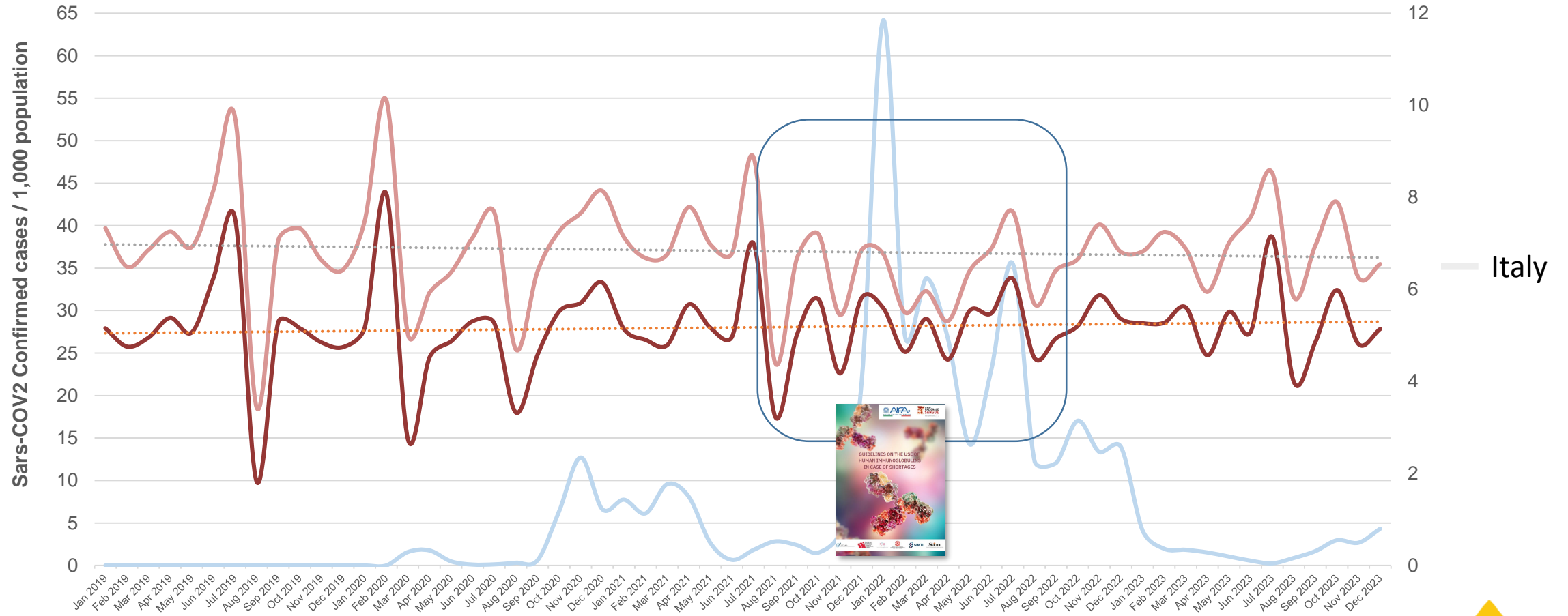
The Sars Cov-2 pandemic in Italy and IG



Data sources: Adapted by the Italian National Blood Centre on data from Weekly Covid-19 Bulletins, Italian Ministry of Health; Demo.ISTAT, Italian Institute of Statistics.



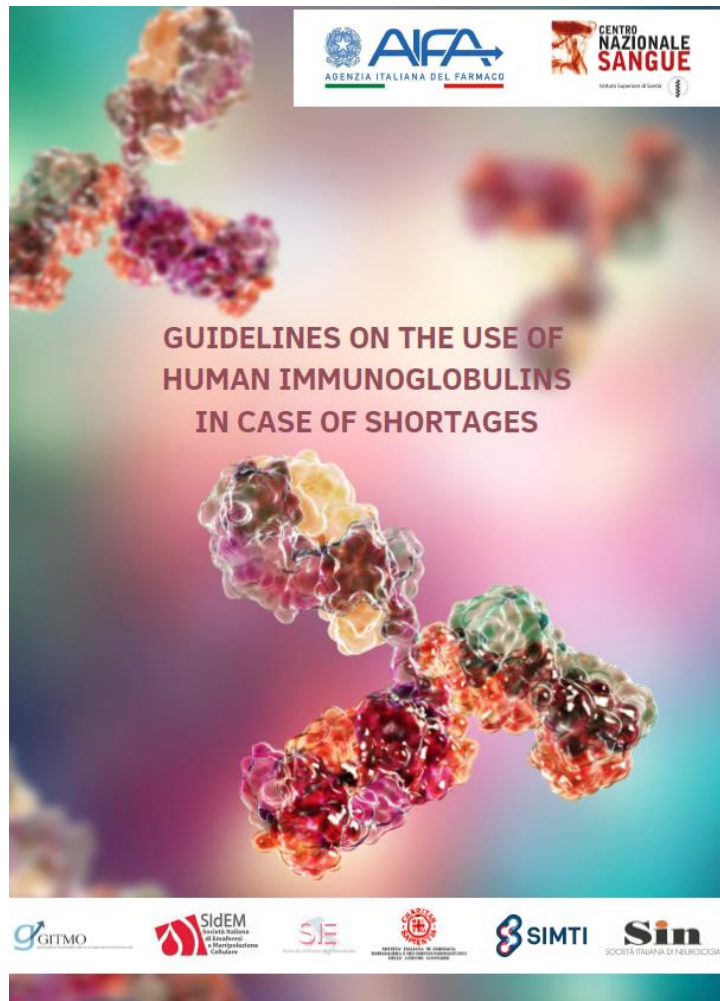
The Sars Cov-2 pandemic in Italy and IG



Data sources: Adapted by the Italian National Blood Centre on data from Weekly Covid-19 Bulletins, Italian Ministry of Health; Demo.ISTAT, Italian Institute of Statistics.



Guidelines for the use of IGs in case of shortages



“GUIDELINES ON THE USE OF HUMAN IMMUNOGLOBULINS IN CASE OF SHORTAGES”

<https://www.centronazionale sangue.it/wp-content/uploads/2022/02/Documento-uso-IG-in-condizioni-di-carezza.pdf>

<https://www.aifa.gov.it/-/documento-indirizzo-aifa-cns-uso-immunoglobuline-umane-condizioni-carezza>

The "**GUIDELINES ON THE USE OF HUMAN IMMUNOGLOBULINS IN CASE OF SHORTAGES**" is the result of a multidisciplinary work conducted by CNS and AIFA with the contribution of the Italian Society of Hemapheresis and Cellular Manipulation (SidEM), Italian Society of Transfusion Medicine and Immunohematology (SIMTI), Italian Society of Hematology (SIE), Italian Society of Neurology (SIN), Italian Society of Hospital Pharmacy and Pharmaceutical Services of Health Authorities (SIFO) and Italian Group of bone marrow and hematopoietic stem cell transplantation (GITMO).

Guidelines for the use of IGs in case of shortages

Inventory level	Description and activities
Green	<p>IG supply/inventory meets demand.</p> <ul style="list-style-type: none"> Follow jurisdictional best practice recommendations for use of IG (indications, optimal use guides, modality of administration, and doses). Use the lowest IG dose for the shortest duration required to achieve the desired outcome. For ongoing therapy, ensure the achievement of measurable clinical outcomes; IG should not be continued in patients with no demonstrable benefit. Prior to starting Ig treatment, consider use of all other safe, effective, and accessible alternative therapies. Where use is indicated, confirm that use aligns with the patient's goals of care. Use a dose calculator based on adjusted body weight, and track Ig levels to adjust dose, as appropriate.
Green Advisory Phase	<p>Ig supply/inventory levels are reduced or there are signs that short-term demand may outstrip capacity. Reduce use by 10 to 20%:</p> <ul style="list-style-type: none"> Continue to follow all the actions outlined in Green phase. Round down IG treatment doses and frequency. Re-assess all patients that are already on treatment to find the minimal effective dose and optimize the treatment for each individual. Review stocking practices and maintain the minimum inventory level required. Reduce the refill volume for patients on home infusion products Consider the use of alternative therapies. Consider increasing availability of alternative therapies Initiate actions to prepare for the potential escalation to Amber and Red phase by: <ul style="list-style-type: none"> Identifying patients that can be switched to SCIG (in the event of an IVIG shortage) or IVIG (in the event of an SCIG shortage), or other alternative therapies. Initiating local and provincial processes to support an adjudication process in the event of a red phase advisory.
Amber	<p>IG supply/inventory levels are low for a short or prolonged period. Reduce use by 20 to 50%:</p> <ul style="list-style-type: none"> Continue to follow all the actions outlined in Green phase and Green Advisory phase. Limit Ig use to clinical circumstances when there are: <ul style="list-style-type: none"> No viable alternatives; and/or the condition is life-threatening or there is a risk for irreversible disability as identified in the table below. Use the lowest IG dose for the shortest duration required to achieve the desired outcome. Implement screening of all IG orders within the hospital transfusion service/blood bank.
Red	<p>There is a critical and prolonged Ig shortage. Reduce use by over 50%:</p> <ul style="list-style-type: none"> Limit Ig use to clinical circumstances when there are: <ul style="list-style-type: none"> No viable alternatives; and/or

LEGEND



IG supply/inventory levels are low for a short or prolonged period. **Reduce use by 20 to 50%:**

- Continue to follow all the actions outlined in Green phase and Green Advisory phase.
 - Limit Ig use to clinical circumstances when there are:
 - No viable alternatives; **and/or**
 - the condition is life-threatening or there is a risk for irreversible disability as identified in the table below.
 - Use the lowest IG dose for the shortest duration required to achieve the desired outcome.

Implement screening of all IG orders within the hospital transfusion service/blood bank.

There is a critical and prolonged Ig shortage. **Reduce use by over 50%:**

- Limit Ig use to clinical circumstances when there are:
 - No viable alternatives; **and/or**
 - the condition is life-threatening or there is a risk for irreversible disability as identified in the table below.
- Have each case and dose approved by a formally established peer committee as per local jurisdictional guidance.

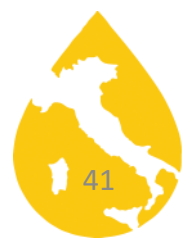
File a written copy of the decision in the patient's medical record and send another copy to Transfusion Medicine Services (blood bank).

CONDITION	CRITERIA FOR ENSURING APPROPRIATE AND PRIORITY USE OF IGS IN CASE OF SHORTAGES
Bullous dermatitis (e.g., pemphigus vulgaris, bullous pemphigoid)	<ul style="list-style-type: none"> Not permitted for use, apart from exceptional cases when Do not use
Pyoderma gangrenosum	
Acquired coagulation factor inhibitors	
Allogeneic haematopoietic stem cell transplant	
Autoimmune haemolytic anaemia (AIHA)	<ul style="list-style-type: none"> Preferential use Should be based on the expert opinion of the physician, depending on the severity and frequency of infections and known to be associated
Scleromyxedema	
Autoimmune neutropenia	
Stevens-Johnson syndrome and toxic epidermal necrolysis	
Catastrophic antiphospholipid syndrome	
Fetal and neonatal alloimmune thrombocytopenia (FNAT)	

CONDITION	CRITERIA FOR ENSURING APPROPRIATE AND PRIORITY USE OF IGS IN CASE OF SHORTAGES
Dermatomyositis	<ul style="list-style-type: none"> In cases of severe intolerance to other
Eosinophilic granulomatosis with polyangiitis (Churg Strauss syndrome)	<ul style="list-style-type: none"> In cases of severe intolerance to other
Juvenile dermatomyositis	<ul style="list-style-type: none"> In cases of severe intolerance to other
Kawasaki disease	<ul style="list-style-type: none"> First line therapy Following the initial phase if there is no long
Macrophage activation syndrome (MAS)	<ul style="list-style-type: none"> In cases of severe intolerance to other
Polymyositis	<ul style="list-style-type: none"> In cases of severe intolerance to other

CONDITION	CRITERIA FOR ENSURING APPROPRIATE AND PRIORITY USE OF IGS IN CONDITIONS OF SHORTAGES
Enterovirus meningitis	<ul style="list-style-type: none"> In severe cases in immunocompromised patients
Infectious mononucleosis (such as EBV)	
Infected myelitis	<ul style="list-style-type: none"> In cases of severe disease and failure, contraindication or intolerance to other therapeutic options¹
Linezolid	<ul style="list-style-type: none"> In cases of severe disease and failure, contraindication or intolerance to other therapeutic options¹ Consider steroids and/or plasma exchange whenever possible Initial and maintenance treatment in cases of failure, contraindication or intolerance to other forms of immunosuppressive therapy²
	<ul style="list-style-type: none"> In cases of vision-threatening severe disease with failure, contraindications or intolerance to other therapeutic options

CONDITION	CRITERIA FOR ENSURING APPROPRIATE AND PRIORITY USE OF IGS IN CASE OF SHORTAGES
Heart, lungs, liver, kidneys, pancreas (humoral rejection or pre-transplant HLA/ABO desensitization)	<ul style="list-style-type: none"> May be used as part of combination therapy with immunosuppressive therapy and/or plasmapheresis in selected cases. As part of combination therapy with immunosuppressive therapy and/or plasmapheresis, evaluated on a case-by-case basis by a peer committee For post-transplant treatment only, not new initiation of pre-transplantation desensitization protocol Consult with transplant team required regarding potential delay in initiation of new transplants



Working group for IGs shortages - est. Sept. 2020

Composed by:

- Italian Ministry of Health
- National Blood Centre
- Italian Medicines Agency
- Voluntary donor associations
- Patient associations
- Fractionators

Aim:

- Periodic monitoring meetings
- Opportunity for discussion between the stakeholders of the system.
- Production of guidelines for the use of IGs in case of shortages.



ESI - Emergency Support Instruments



EUROPEAN COMMISSION
DIRECTORATE-GENERAL FOR HEALTH AND FOOD SAFETY

Health systems, medical products and innovation
Medical products: quality, safety, innovation

Brussels
SANTE.DD.GI.B.4/MA

PPPA-ECI-CCP-2020 LIST OF BENEFICIARIES *

Project N.	Type ¹	Country	Beneficiaries
1	Single	Belgium	Belgische Rode Kruis
2	Single	Bulgaria	Regional Center of Transfusion Hematology Pleven
3	Joint	Croatia	Hrvatski Zavod Za Transfuzijsku Medicinu
		Croatia	Clinical Hospital Center Rijeka
		Croatia	University Hospital Split
		Croatia	University Hospital Osijek
		Croatia	General Hospital Zadar
		Croatia	General Hospital Dubrovnik
		Croatia	General Hospital Varaždin
4	Single	Denmark	Blood and Tissue Center, Central Denmark Region, Denmark
5	Single	Denmark	Syddansk Transfusionsvæsen og Vævscenter
6	Single	Finland	Finnish Red Cross Blood Service
7	Single	France	Etablissement français du sang
8	Joint	Germany	DRK-Blutspendedienst Baden-Württemberg-Hessen Ggmbh
		Germany	Universitätsklinikum Hamburg Eppendorf
		Germany	Medical centre University of Freiburg
		Germany	Department of transfusion medicine Städtisches Klinikum Karlsruhe
		Germany	Stuttgard City Hospital
9	Joint	Germany	DRK-Blutspendedienst NSTOB, DRK Blood Transfusion Center NSTOB
		Germany	Hannover Medical School
		Germany	Abteilung Transfusionsmedizin der Universitätsmedizin Göttingen
		Germany	University Hospital of Halle/Saale Transfusion Medicine
		Germany	Blutspendezentrale Südharz Klinikum Nordhausen
10	Joint	Germany	Department of Transfusion Medicine, Cellular Therapeutics and Hemostaseology (ATMZH)
		Germany	Universitätsklinikum Augsburg, Institut für transfusion medicine and hemostaseology
11	Joint	Germany	University Hospital of Cologne
		Germany	Institute for Laboratory und Transfusion Medicine, Heart and Diabetes Center North Rhine Westfalia
		Germany	University Hospital Essen Institute for Transfusion Medicine

Country	Beneficiaries
Italy	ASST Sette Laghi
Italy	Servizi Aziendali di Immunologia e Trasfusionale Azienda Sanitaria dell'Alto Adige
Italy	Servizi di Immunologia e Trasfusione Ospedale S. Chiara di Trento
Italy	SIMT/CPVE AOU CDSS Torino – Capofila
Italy	DIMT Padova
Italy	U.O.C. S.I.M.T. ASL Frosinone
Italy	Blood establishment transfusion service – AORNA. Cardarelli, Napoli and SRC Campania – Regione Campania
Italy	Servizio Trasfusionale di Reggio Calabria
Italy	I2113 - UOC Medicina Trasfusionale Azienda Ospedaliera Papardo - Messina
Italy	Servizi di Immunologia e Medicina Trasfusionale - Ospedale maggiore "C.A. Pizzardi" - Bologna
Italy	U.O. Medicina Trasfusionale - IRCCS Ospedale Policlinico San Martino Genova
Italy	Azienda Ospedaliera Universitaria Policlinico Di Bari
Italy	S.C. di Immunologia e Medicina Trasfusionale - Azienda USL Valle d'Aosta
Italy	Dipartimento trasfusionale Area Vasta Udinese
Poland	Regionalne Centrum Krwiodawstwa i Krwiolecznictwa w Kalisz
Poland	Regionalne Centrum Krwiodawstwa i Krwiolecznictwa w Łodzi
Poland	Regionalnego Centrum Krwiodawstwa i Krwiolecznictwa w Raiborzu
Poland	Regionalne Centrum Krwiodawstwa i Krwiolecznictwa w Warszawie
Poland	Regionalne Centrum Krwiodawstwa i Krwiolecznictwa w Wrocławiu
Poland	RCKiK w Lublinie
Poland	Regionalne Centrum Krwiodawstwa i Krwiolecznictwa w Radomiu
Poland	Regional Center of Blood Donation and Treatment In Cracow
Portugal	Centro de Sangue e Transplantação do Porto
Portugal	Centro de Sangue e Transplantação de Lisboa
Portugal	Centro de Sangue e Transplantação de Coimbra
Romania	Institute of Transfusion Hematology "CT Nicolau" Bucharest
Slovenia	Zavod Republike Slovenije za transfuzijsko medicino
Spain	Red Andaluza de Medicina Transfusional, Tejidos y Células
Spain	Centro de Transfusión de Extremadura
Spain	Centro de Transfusión de la Comunidad de Madrid
Spain	Centro de transfusión de las fuerzas armadas
Spain	Centre de Transfusió de la Comunitat Valenciana
Spain	Instituto Canario de Hemodonación y Hemoterapia (ICHH)
Spain	Centro de Transfusión de Ciudad Real
Spain	Centro de Transfusión de Albacete-Cuenca
Spain	Centro de Transfusión de Toledo-Guadalajara
Spain	Centro Vasco de transfusión y Tejidos
Spain	Banc de Sang i Teixits de Catalunya
Spain	Banco de Sangre y Tejidos de Aragón
Spain	Centro Comunitario de Sangre y Tejidos de Asturias
Spain	Banc de Sang i Teixits de les Illes Balears
Spain	Banco de Sangre y Tejidos de Navarra
Spain	Banco de Sangre y Tejidos de Cantabria
Spain	Centro de Transfusión de la Rioja
Spain	Axencia Galega de Sangue, Órganos e Tecidos

The general objective of these grants is to facilitate urgent and efficient increases in blood establishment capacity for collection, storage and testing of CCP for the abovementioned purposes. It is to be achieved through investment in equipment and other associated needs so that such collection and storage is not detrimental to the amount of plasma collected for other medical needs.




ESI - Emergency Support Instruments

Types of activities for which to use the financing:

- **Investment in equipment for the collection of CCP** including:
 - o Plasmapheresis machines;
 - o Donor beds and bedside tables;
 - o Collection sets and other disposables for CCP collection;
 - **Investment in equipment for the storage of CCP** including: freezer rooms and/or stand-alone freezers;
 - **Recovery of costs related to the testing and characterisation of CCP**, including tests of the levels of antibodies.
- Training activities** related to the use of the equipment, and the activities mentioned above;
- **Organisational alignment to make optimal use of the equipment** mentioned above in the overall structure and processes of the blood establishment.



ESI - Emergency Support Instruments

 **European Commission - Press release** 

COVID-19: Commission supports blood services to increase COVID-19 convalescent plasma collection

Brussels, 11 January 2021

- Action financed through the **Emergency Support Instrument**, for a total of **€36 million**
- In 14 Member States and the UK (over 150 blood establishments in total).
- Purchase of plasmapheresis machines and associated equipment, including collection kits, storage equipment, laboratory testing and characterization of plasma and organizational changes within blood centers.

2.2. Programma nazionale plasma e medicinali plasmaderivati (MPD)

Come già accennato, nel 2021 si è conclusa la vigenza del Programma Nazionale Plasma e MPD 2016-2020 che, come primo programma nazionale in materia, ha rappresentato una tappa fondamentale nell'ambito dell'autosufficienza nazionale di medicinali emoderivati ottenuti dalla lavorazione del plasma nazionale in conto-lavoro. Nel corso del 2022 il Sistema trasfusionale italiano procederà tanto alla riformulazione degli obiettivi strategici qualitativi e quantitativi del Sistema quanto al ripensamento di strumenti dispositivi che ne agevolino un opportuno raggiungimento e che valorizzino al meglio il mutato quadro normativo europeo, anche in considerazione del cospicuo finanziamento di oltre 7 MLN di euro pervenuto al Sistema trasfusionale italiano nel corso del 2021 nell'ambito del progetto ESI (finanziato dalla Commissione europea), finalizzato a garantire la costante raccolta di plasma per frazionamento industriale, anche in presenza del fenomeno pandemico. Tali strumenti dovranno essere inclusi nel nuovo Programma che, a partire dai risultati raggiunti, disponga il SSN al conseguimento di più elevati livelli di autosufficienza di plasma e MPD e lo renda in grado di garantire il soddisfacimento di

SARS Cov-2 pandemic effect

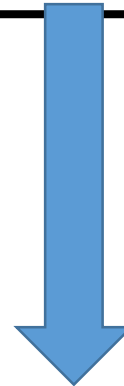
Difficulties for donors to reach blood centers due to the pandemic.



Decrease in US plasma collection (-20%)



Many diagnostic-therapeutic activities have undergone reductions and restrictions, aimed at saving resources to be invested in the health sectors most involved in the management of the emergency



Risk for maintaining a sustainable and quality supply for patients, also in consideration of the constant increase in national demand for Immunoglobulins recorded in recent years.



Measures to mitigate the effects of the pandemic

- Increase plasma collection
- Intensive monitoring of collection, production, distribution, stocks
- Continuous interaction with all stakeholders
- Maximise the appropriateness of clinical-therapeutic use
- Make immunoglobulin production economically viable
- Access to treatment by priority criteria
- Replace the use of IV administered immunoglobulins with SC administered ones
- Close partnership with prescribers (lengthen the adm. intervals or decrease dosages)
- Set up working groups to share strategies



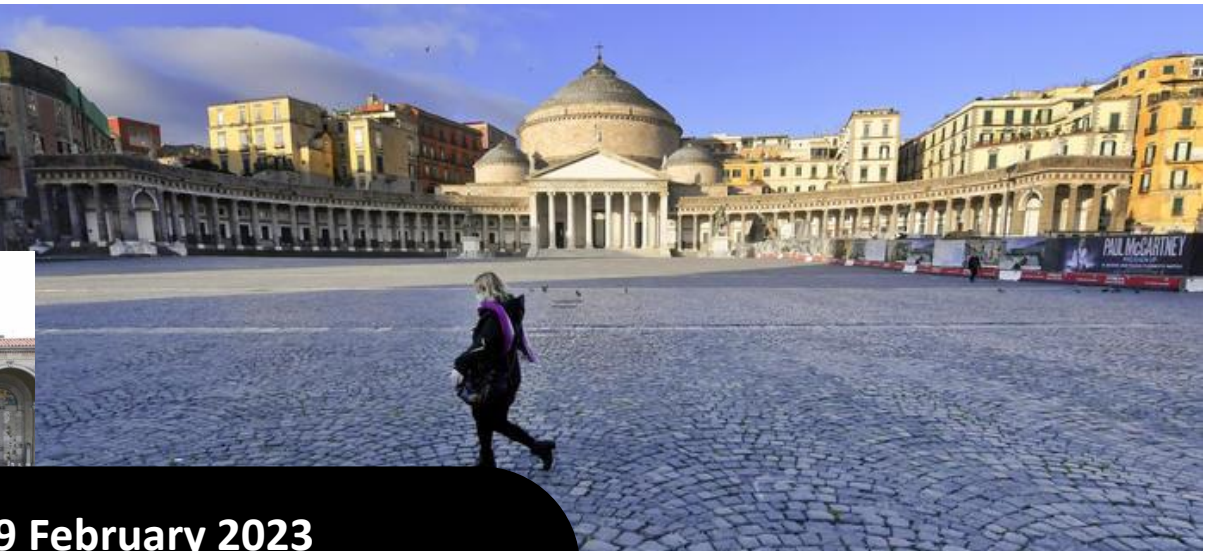
<https://www.centronazionalesangue.it/rapporti-tecnici/>



SELF-ADVERTISING



**Unlimited thanks to
all health professionals
involved**



26,716,934 positive cases as of 9 February 2023
130,468 deaths (ISS figures as of 5 Oct 2021)

These data make Italy the 8th country in the world and the 3rd in Europe in terms of total number of cases, the 8th country in the world and the 3rd in Europe in terms of absolute number of deaths, the 41st country in the world in terms of total cases in relation to population and the 22nd country in terms of deaths in relation to population

**Grazie
per la vostra
attenzione**



Thank you

AIP
All blood and plasma donors
All Directors of Regional Blood Centres
Claudia Biffoli
Silvio Brusaferrò
Chiara Brutti
Livia Cannata
Cristiana Chelucci
CIDP
John Coltrane
Karen Cristiano
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Rossana Psaila
Simonetta Pupella
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SIFO
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