La domanda di immunoglobuline in italia

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Centro nazionale sangue
Istituto Superiore di Sanità, Roma

Bologna – 16 ottobre 2025

Agenda

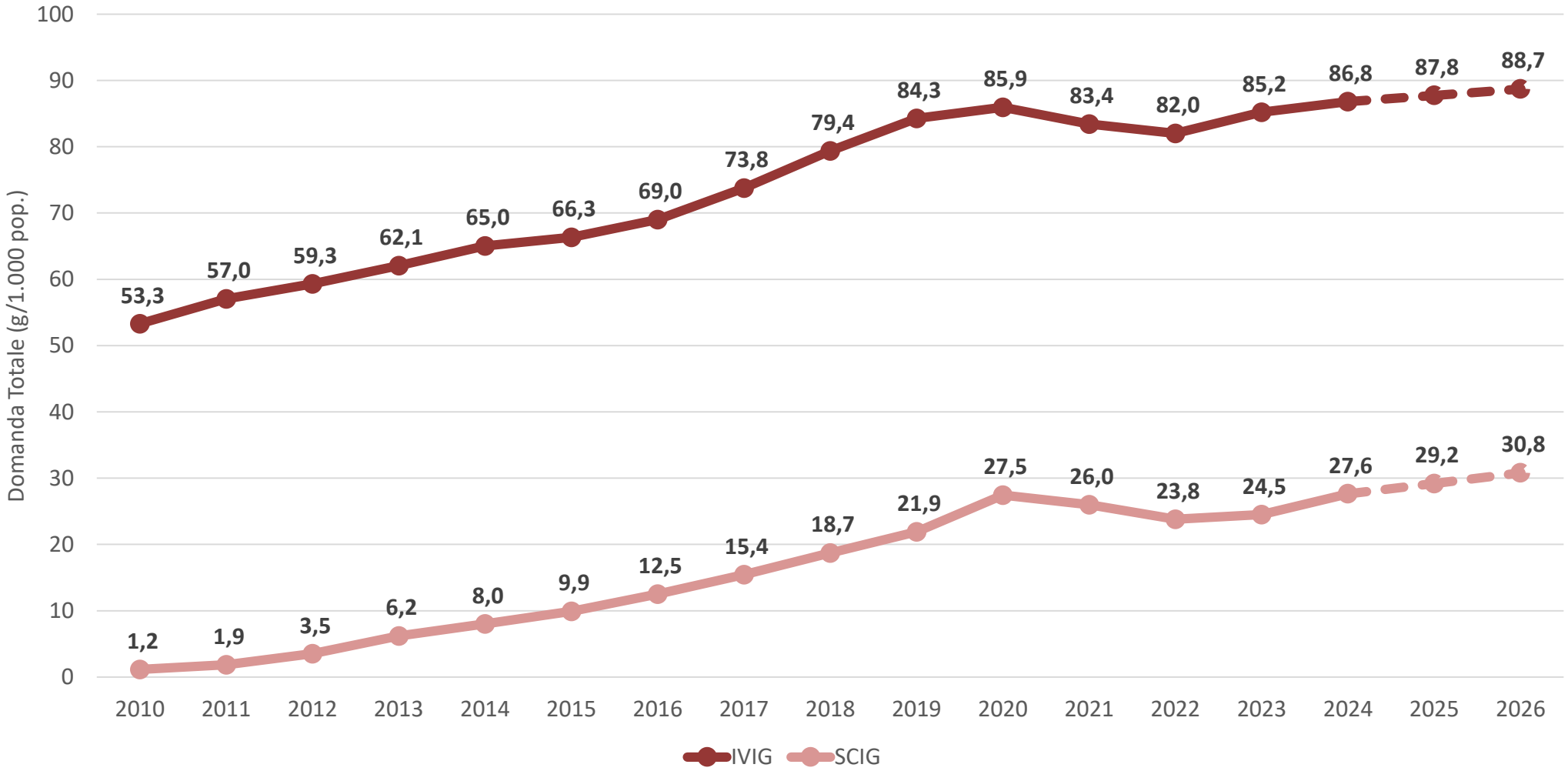
Immunoglobuline umane polivalenti: domanda e autosufficienza

Immunoglobuline specifiche

Immunoglobuline anti-D

Immunoglobuline umane polivalenti

Domanda nazionale di immunoglobuline polivalenti – Trend 2010 - 2026



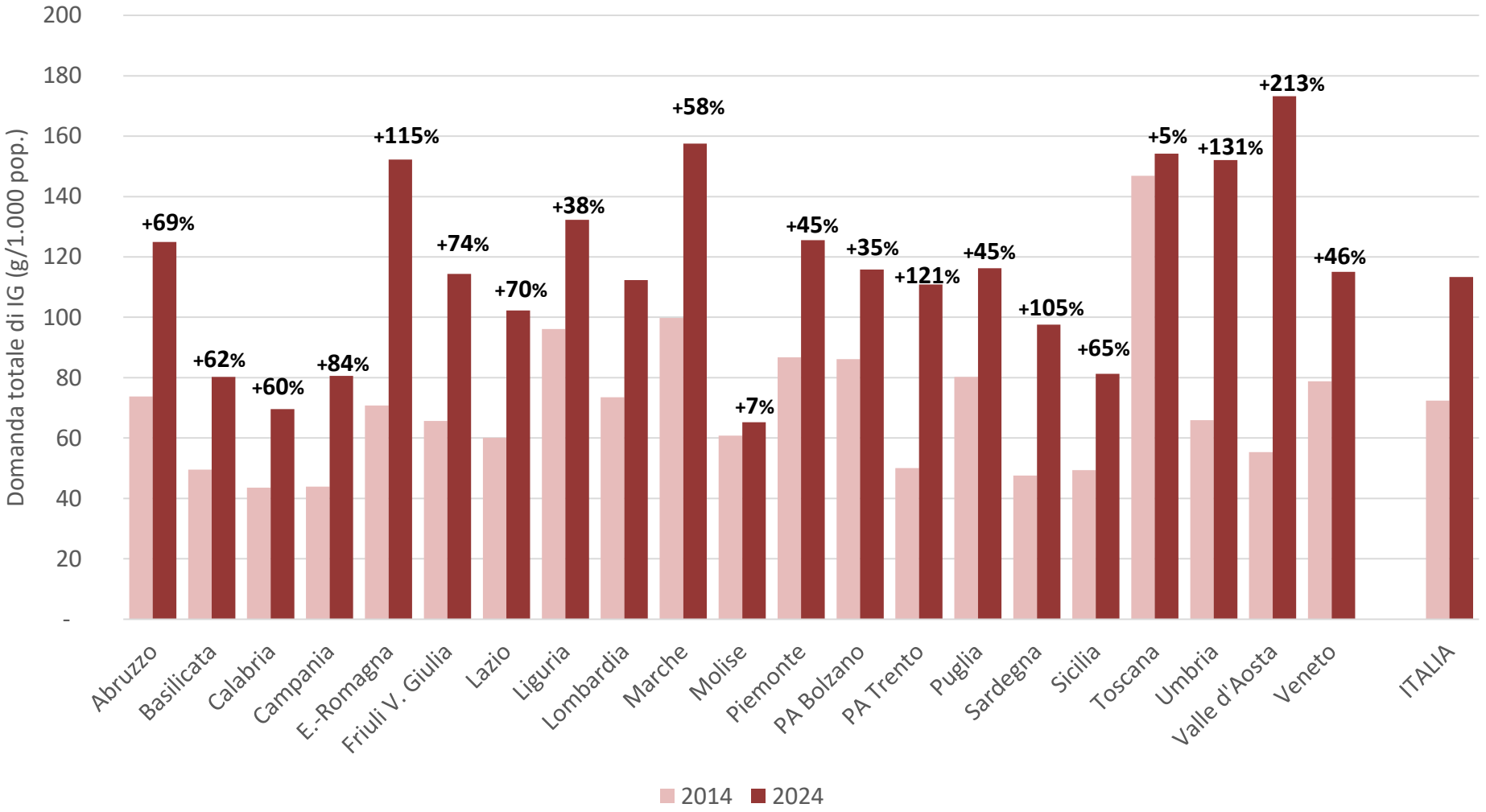
Δ% media IVIG: +0,59% negli ultimi 5 anni

Δ% media SCIG: +5,03% negli ultimi 5 anni

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

Dati Preliminari

Domanda regionale di IG (IV+SC) – 2024 vs 2014



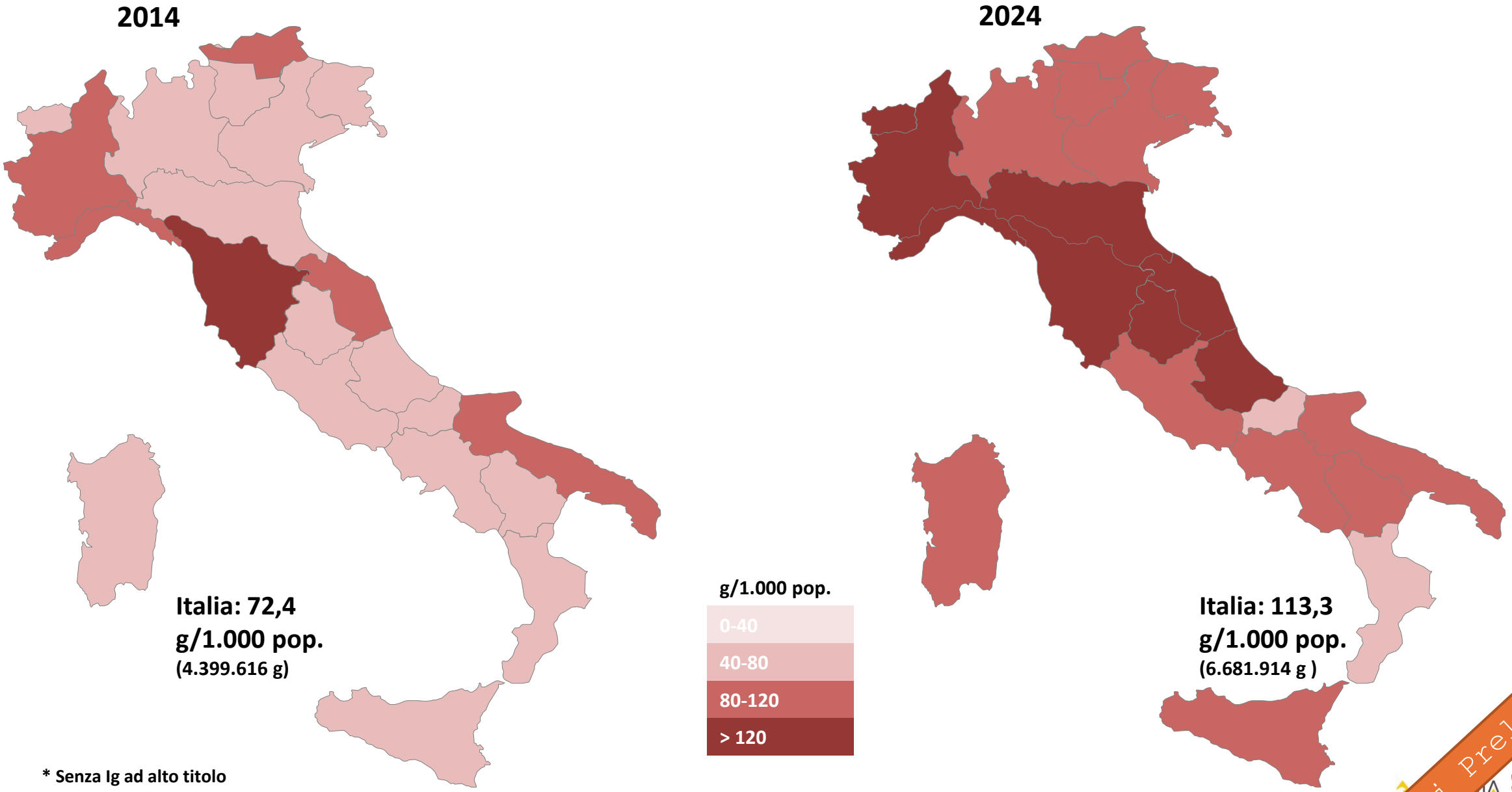
Δ% 2024 vs 2014= +57%

Δ% media annua= +4,7%

Dati Preliminari

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

Domanda nazionale di IG TOTALI (IV+SC)* – 2024 vs 2014

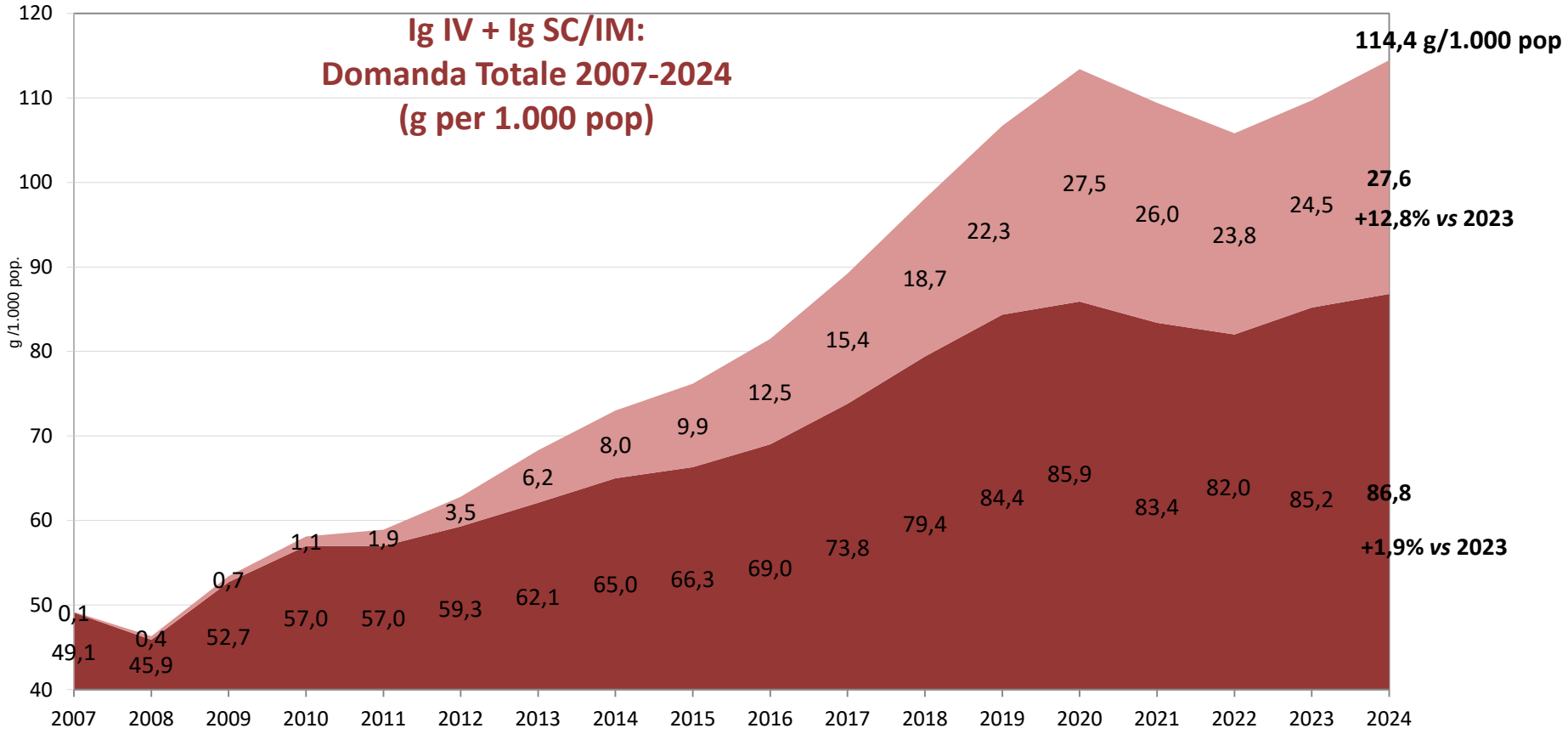


* Senza Ig ad alto titolo

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

Dati Preliminari

Domanda nazionale di immunoglobuline polivalenti – Anno 2024



SCIg 1.630.126 g

IVIg 5.118.962 g
di cui **67.174** g
di Ig ad alto titolo
di IgM

Ig TOT 6.749.088 g
(114,4 g/1.000 pop)

Ig IV Variazione annuale media domanda (2014 - 2024): ≈ + 3,0 %

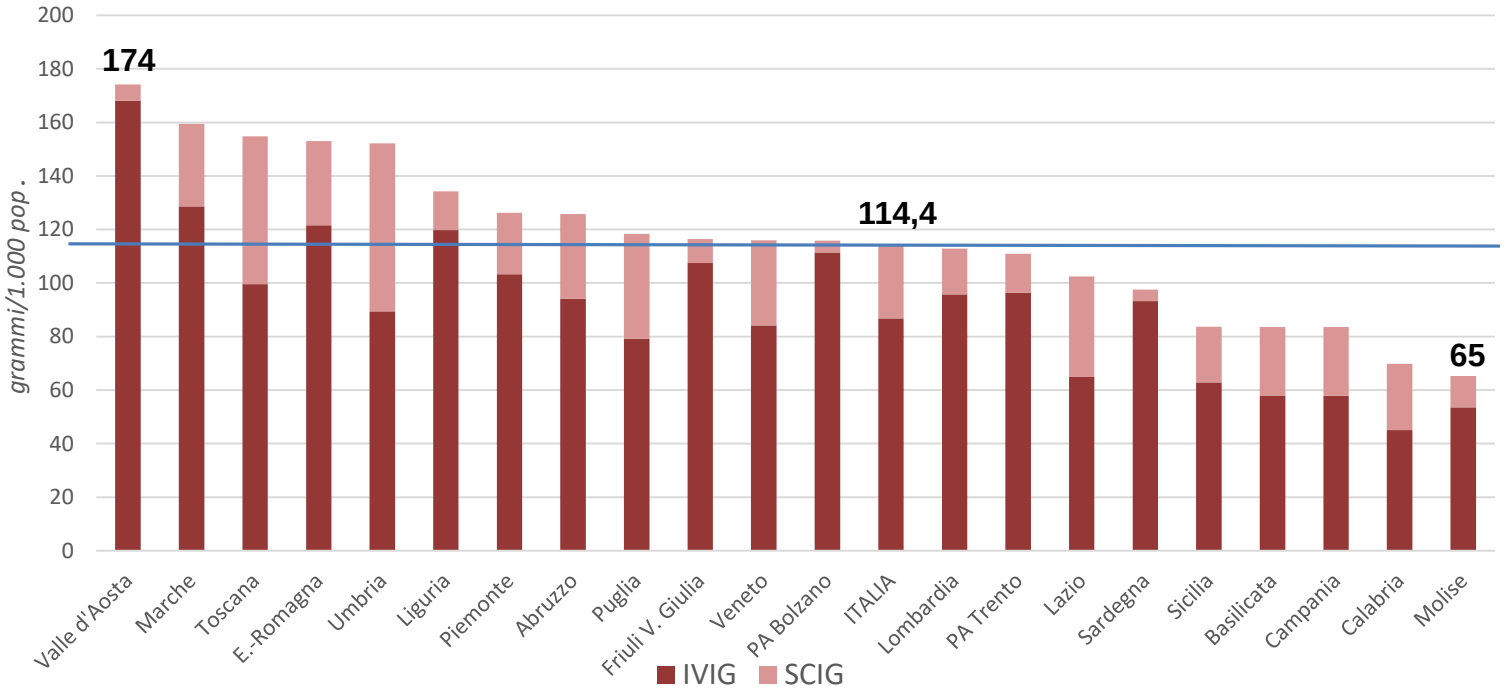
Ig SC Variazione annuale media domanda (2014 - 2024): ≈ +13,9%

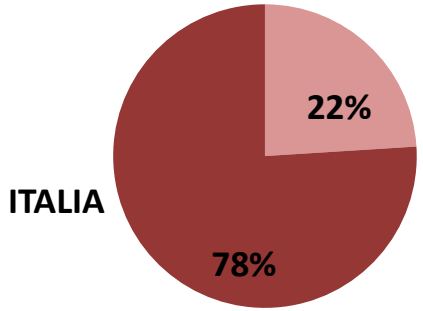
Ig TOT Variazione annuale media domanda (2014 - 2024): ≈ +4,7%

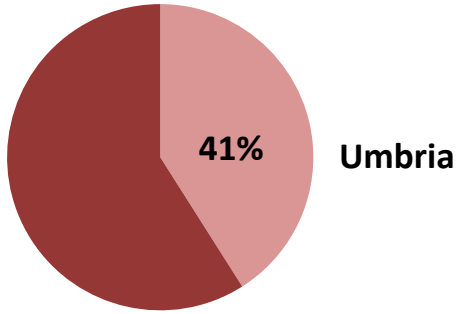
Dati Preliminari

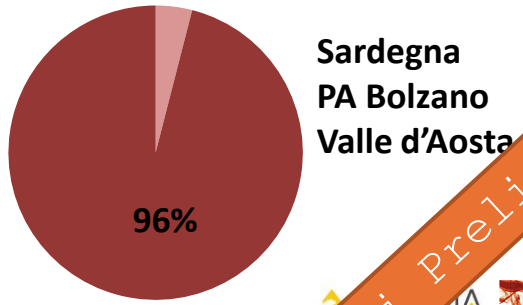
Data sources: - Adapted by the CNS on data from the Traceability information flow-Italian Ministry of Health and Demo.ISTAT- Italian Institute of Statistics

Domanda nazionale/regionale di immunoglobuline polivalenti – Anno 2024









Ig IV (g/1.000 pop) **max Valle d'Aosta (168 g), min Calabria (45 g)**

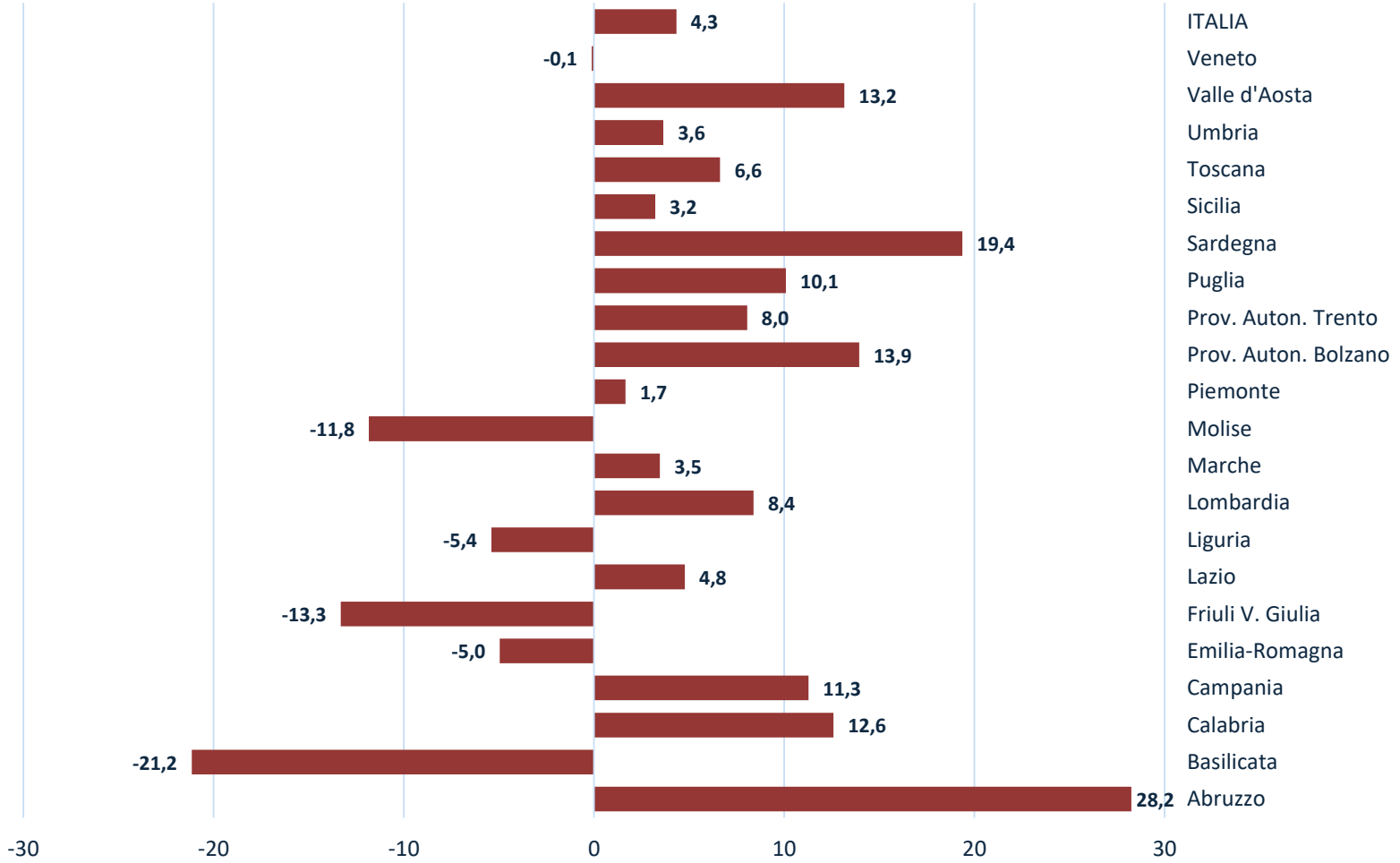
Ig SC (g/1.000 pop) **max Umbria (63 g), min Sardegna, PA Bolzano (4 g)**

Ig TOT (g/1.000 pop) **max Valle d'Aosta (174 g), min Molise (65 g)**

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

Dati Preliminari

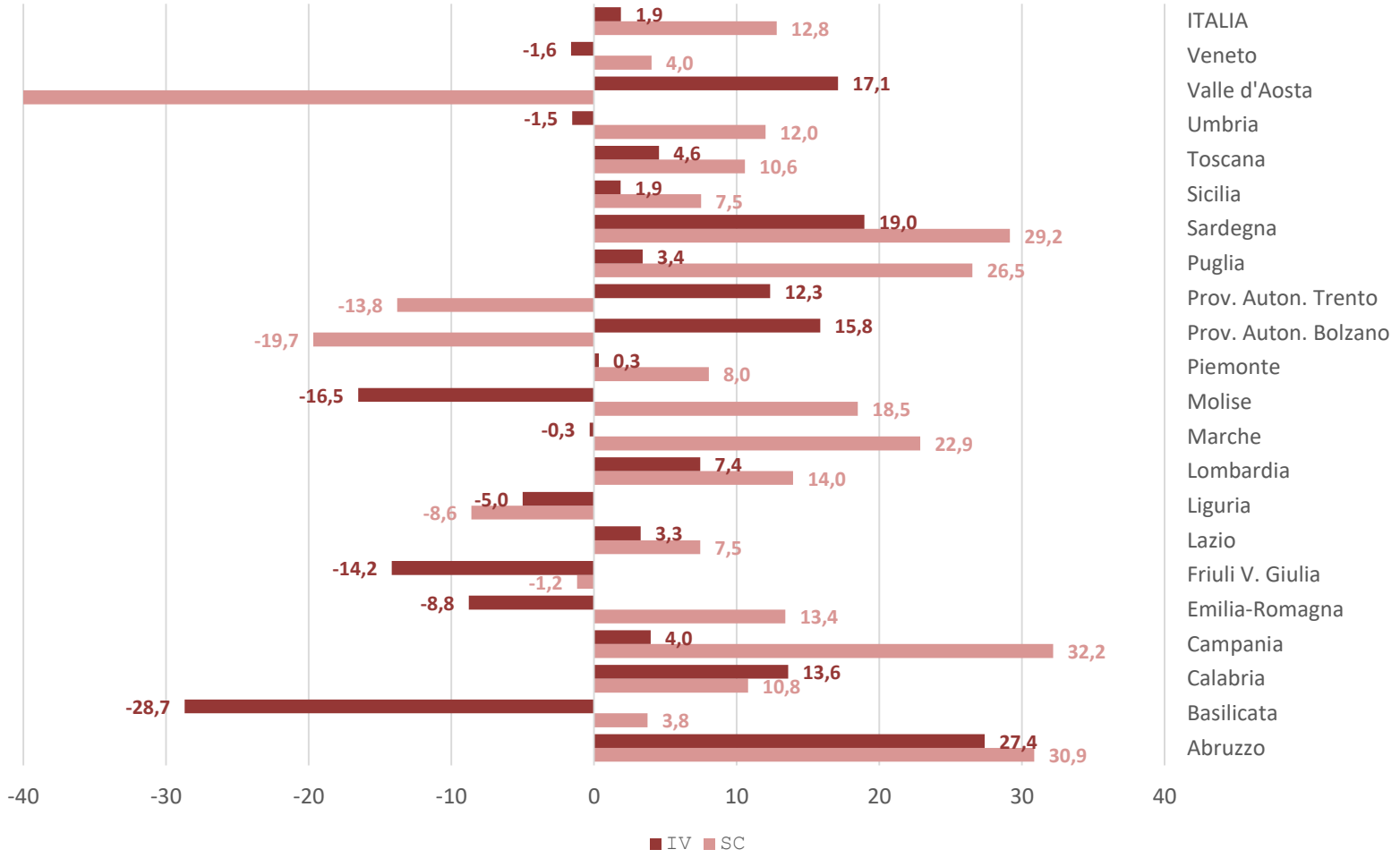
Variazione % della domanda regionale e nazionale di IG TOTALI Anno 2024 vs 2023



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

ati Preliminar

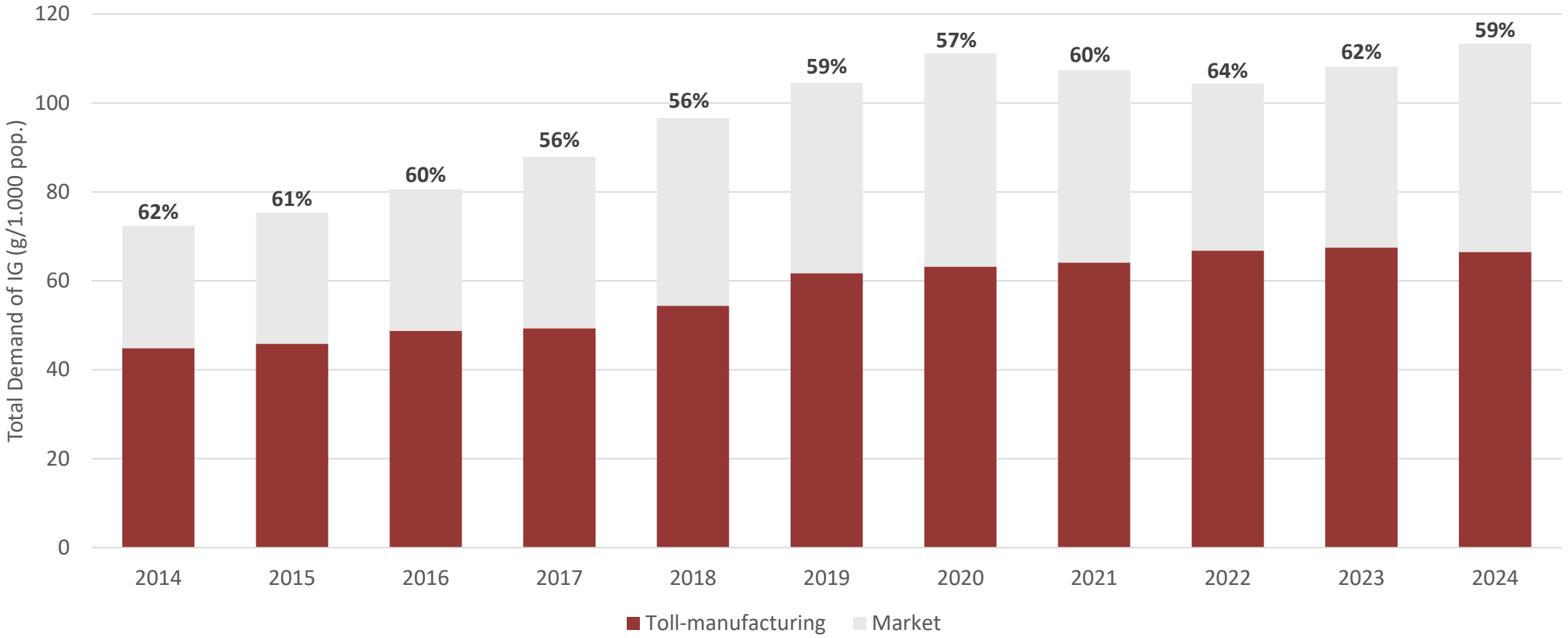
Variazione % della domanda regionale e nazionale di IVIg e SCIg
Anno 2024 vs 2023



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

ati Preliminar

Autosufficienza IG Totali – Anni 2014 - 2024

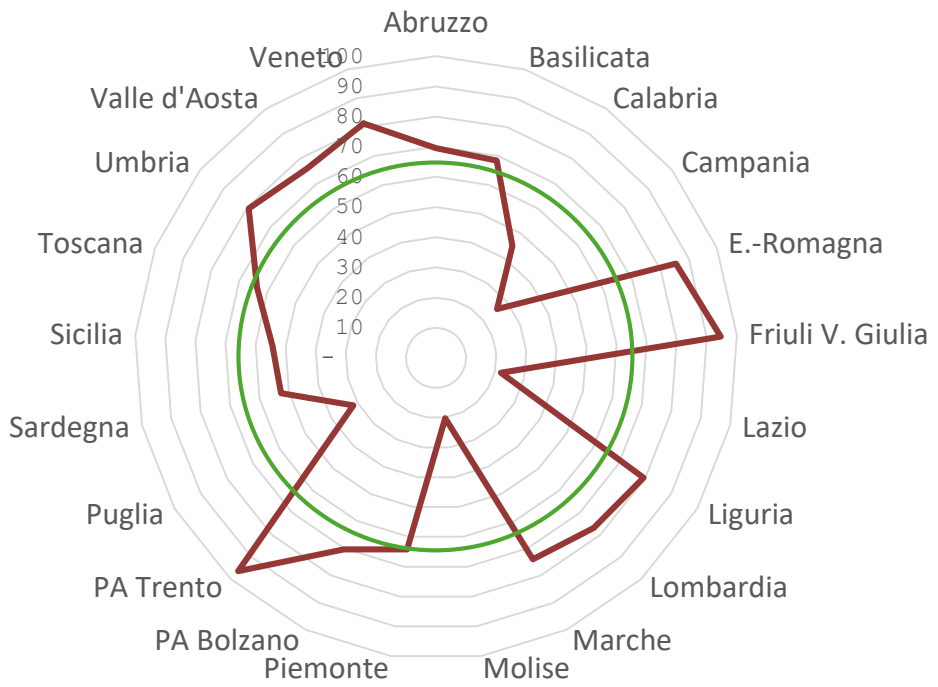


Data sources: - Adapted by the CNS on data from the Traceability information flow-Italian Ministry of Health and Demo.ISTAT- Italian Institute of Statistics

Dati Preliminari

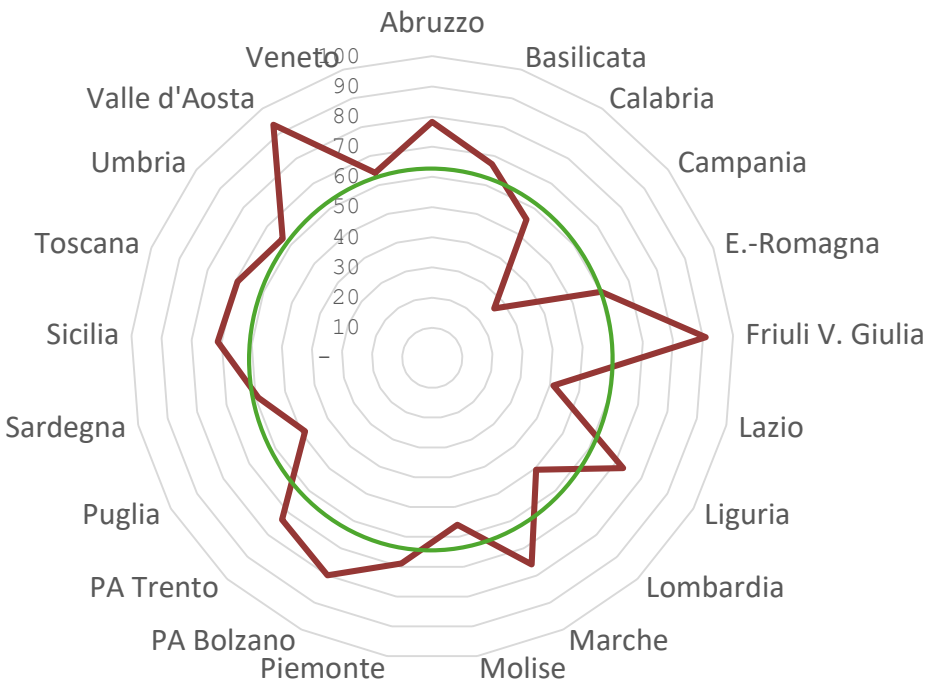
Autosufficienza regionale di IG – 2024 vs 2014

2014



ITALIA: 62%

2024



ITALIA: 59%

Dati Preliminari

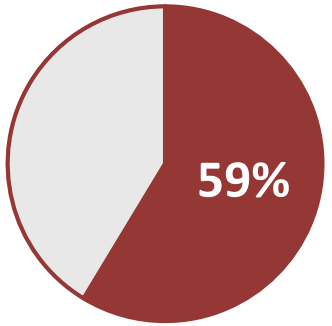
Data sources: - Adapted by the CNS on data from the Traceability information flow-Italian Ministry of Health

Domanda nazionale e interregionale di immunoglobuline polivalenti – Anno 2024

Accordo	D_TOT*	CL	D_SSN*	% Autosufficienza su D_TOT
NAIP	1.369.734	977.466	1.365.058	71
RIPP	1.648.083	976.615	1.589.728	59
PlaNet	1.852.318	938.560	1.765.037	51
LPS	1.811.778	1.026.760	1.633.163	57
ITALIA	**6.681.914**	**3.919.401**	**6.352.986**	**59**

% Autosufficienza* Italia, 2024

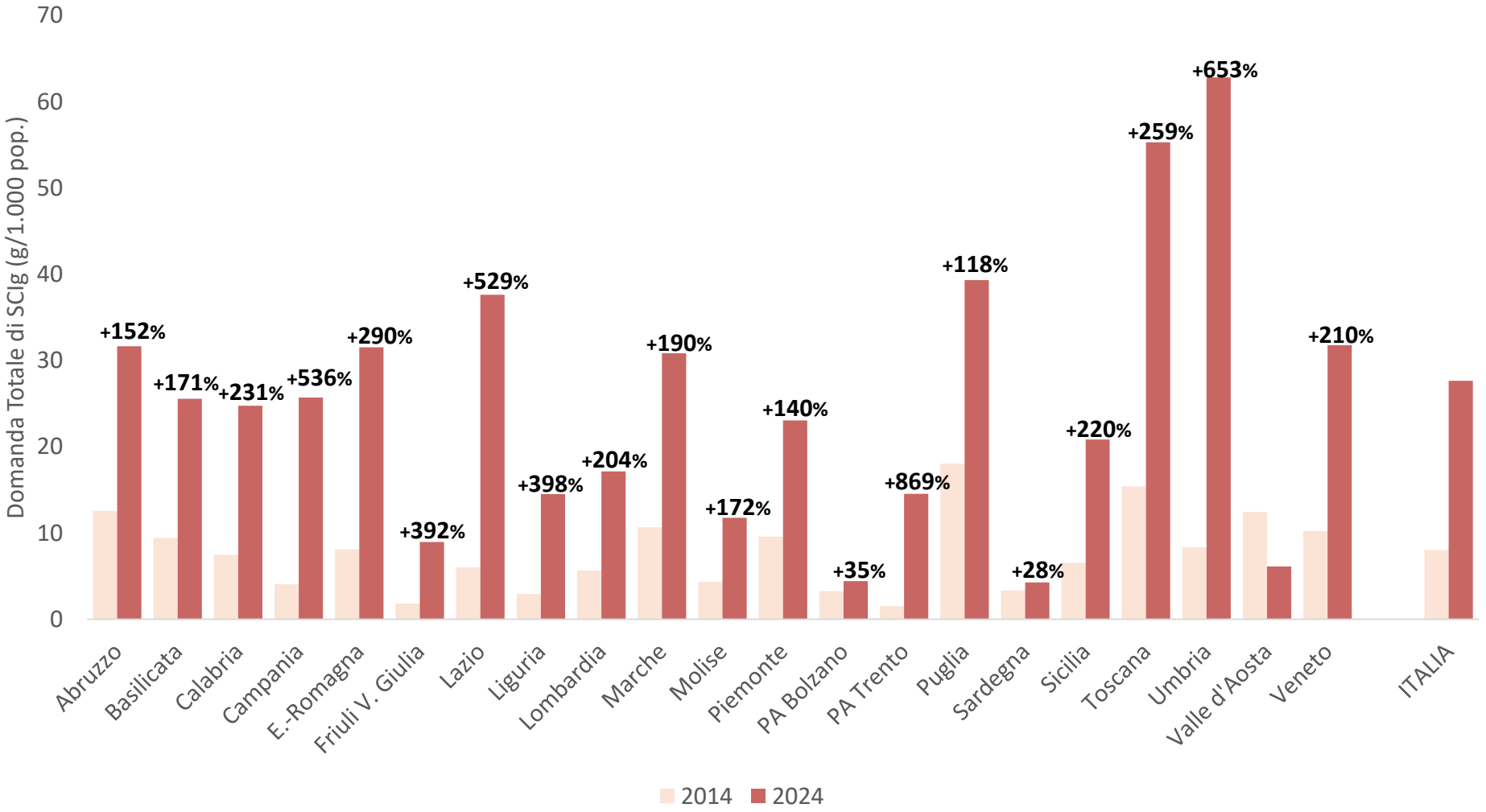
*Il valore non include "*High titre IVIg*"



Dati Preliminari

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

Domanda regionale di SCIg – 2024 vs 2014



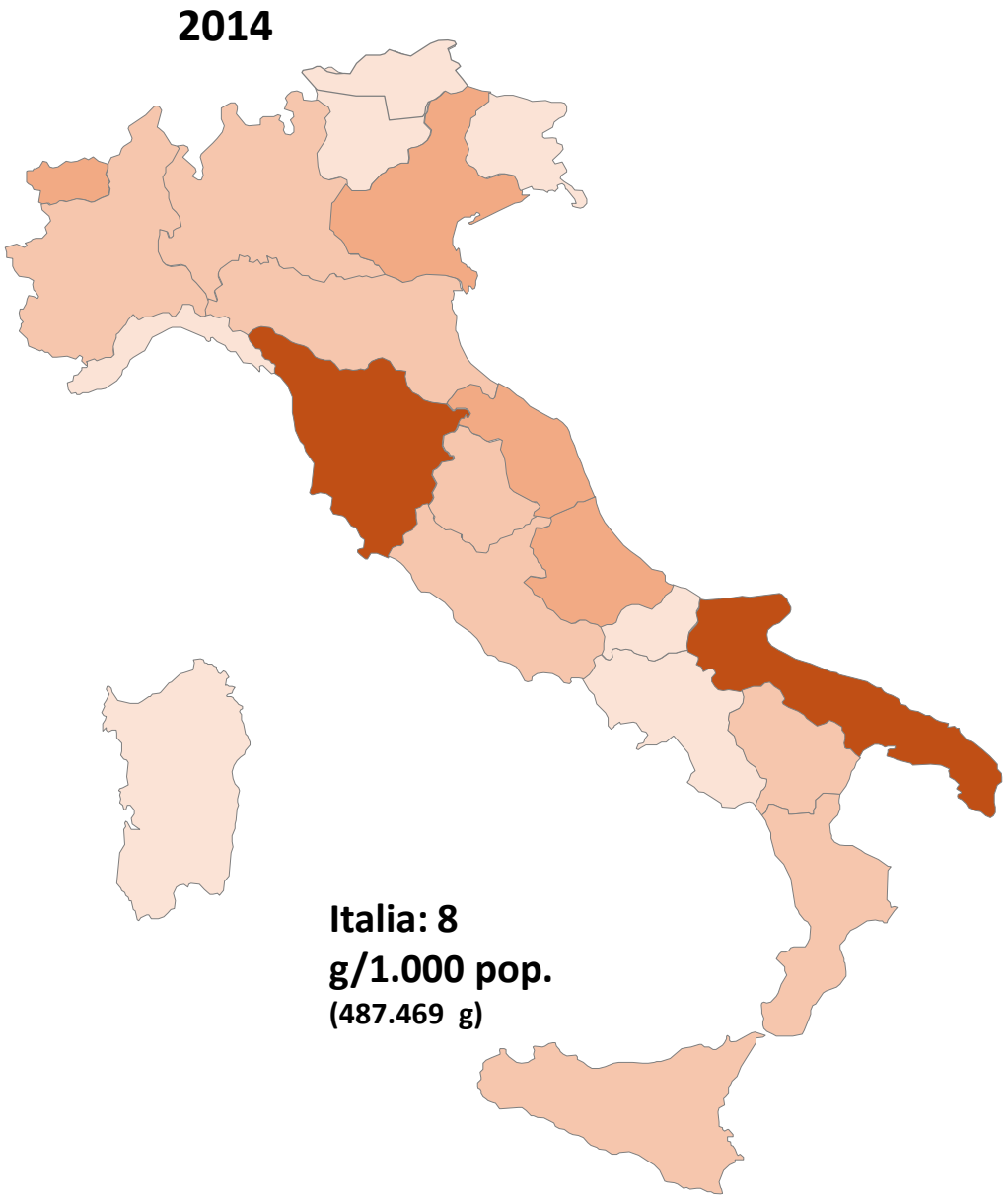
Δ% 2024 vs 2014= +245%

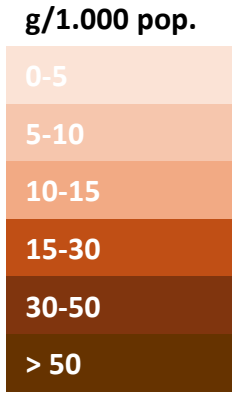
Δ% media annua= +13,9%

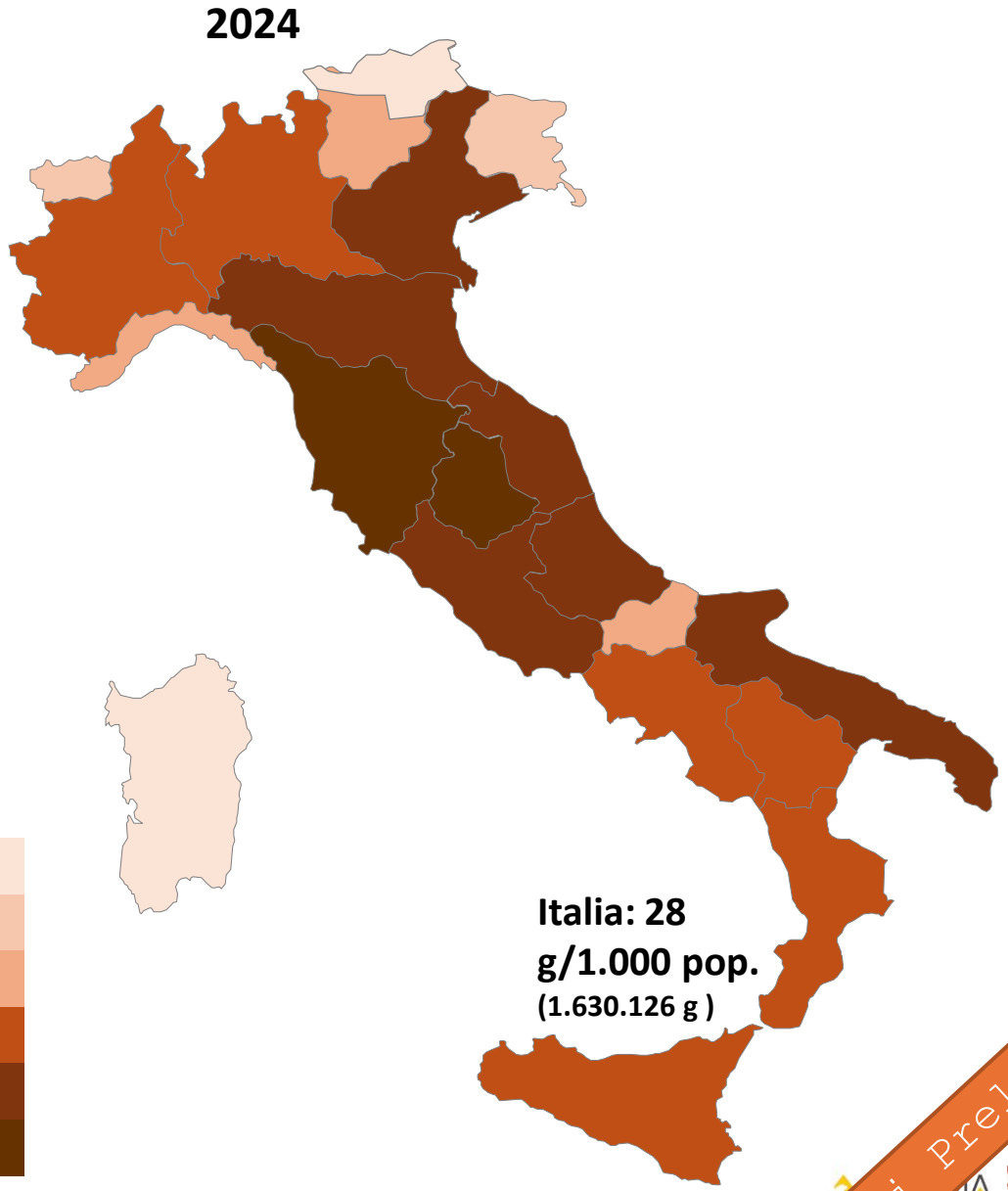
Data sources: - Adapted by the CNS on data from the Traceability information flow-Italian Ministry of Health and Demo.ISTAT- Italian Institute of Statistics

Dati Preliminari

Domanda nazionale di SCIg – 2024 vs 2014



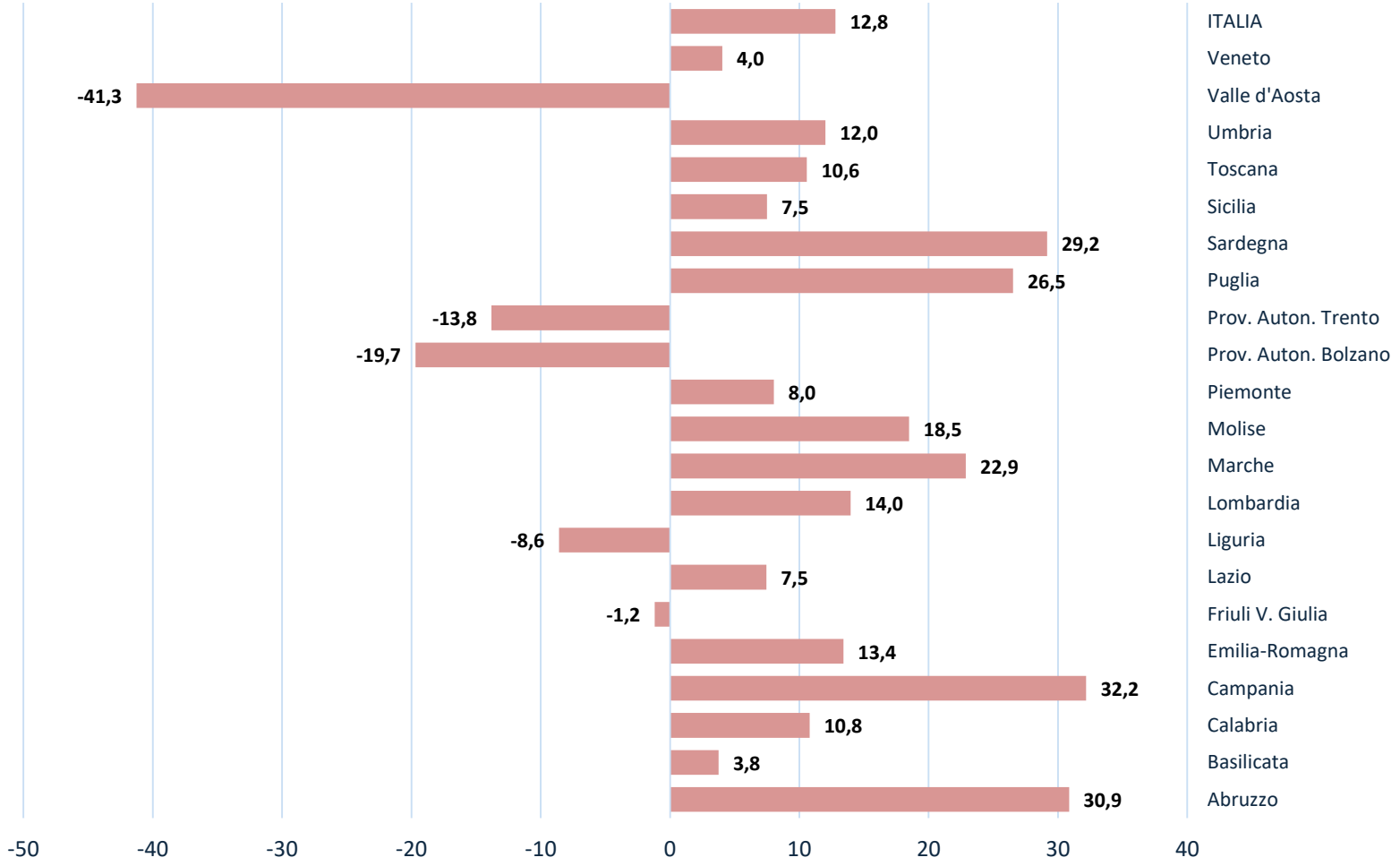




Dati Preliminar

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

Variazione % della domanda regionale e nazionale di SCIg
Anno 2024 vs 2023

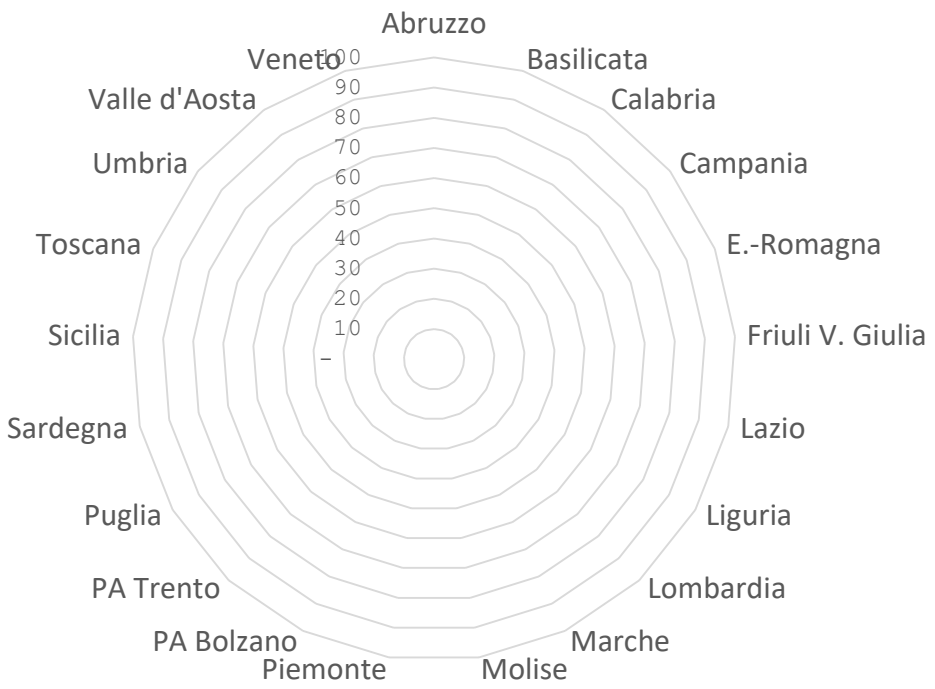


Data sources: - Adapted by the CNS on data from the Traceability information flow-Italian Ministry of Health and Demo.ISTAT- Italian Institute of Statistics

Dati Preliminari

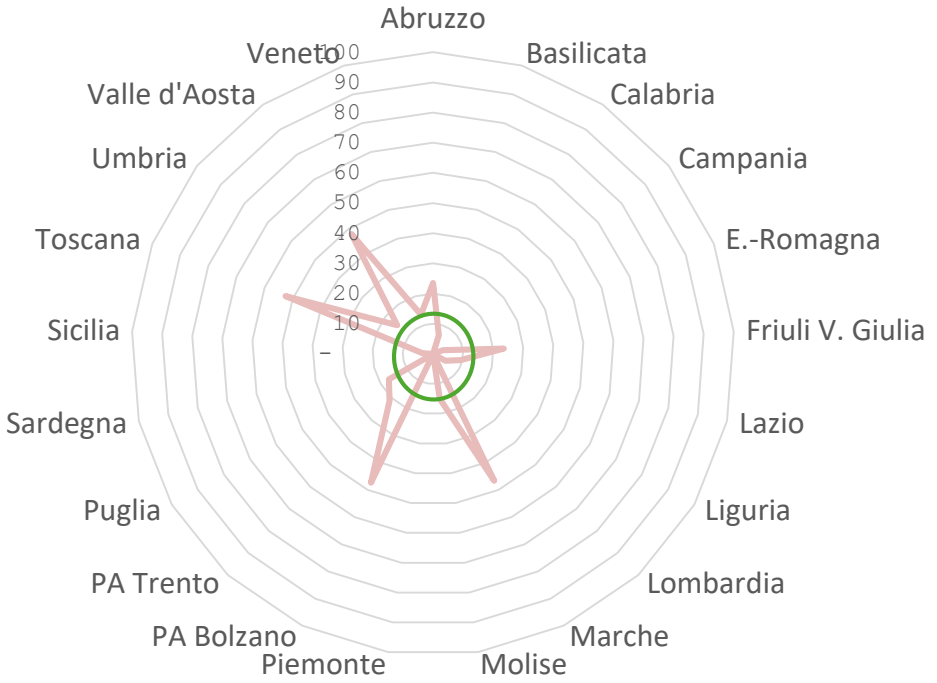
Autosufficienza regionale di SCIg – 2024 vs 2014

2014



ITALIA: 0%

2024

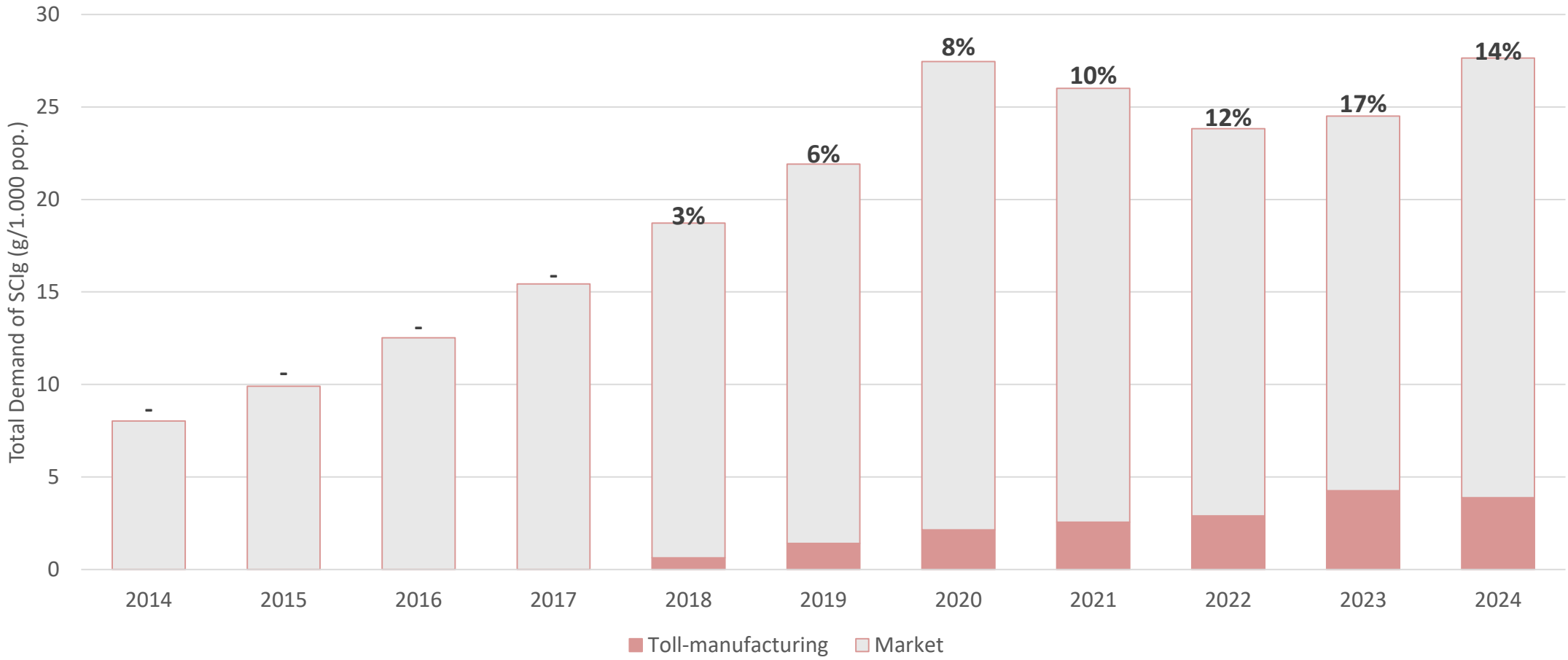


ITALIA: 14%

Dati Preliminari

Data sources: - Adapted by the CNS on data from the Traceability information flow-Italian Ministry of Health

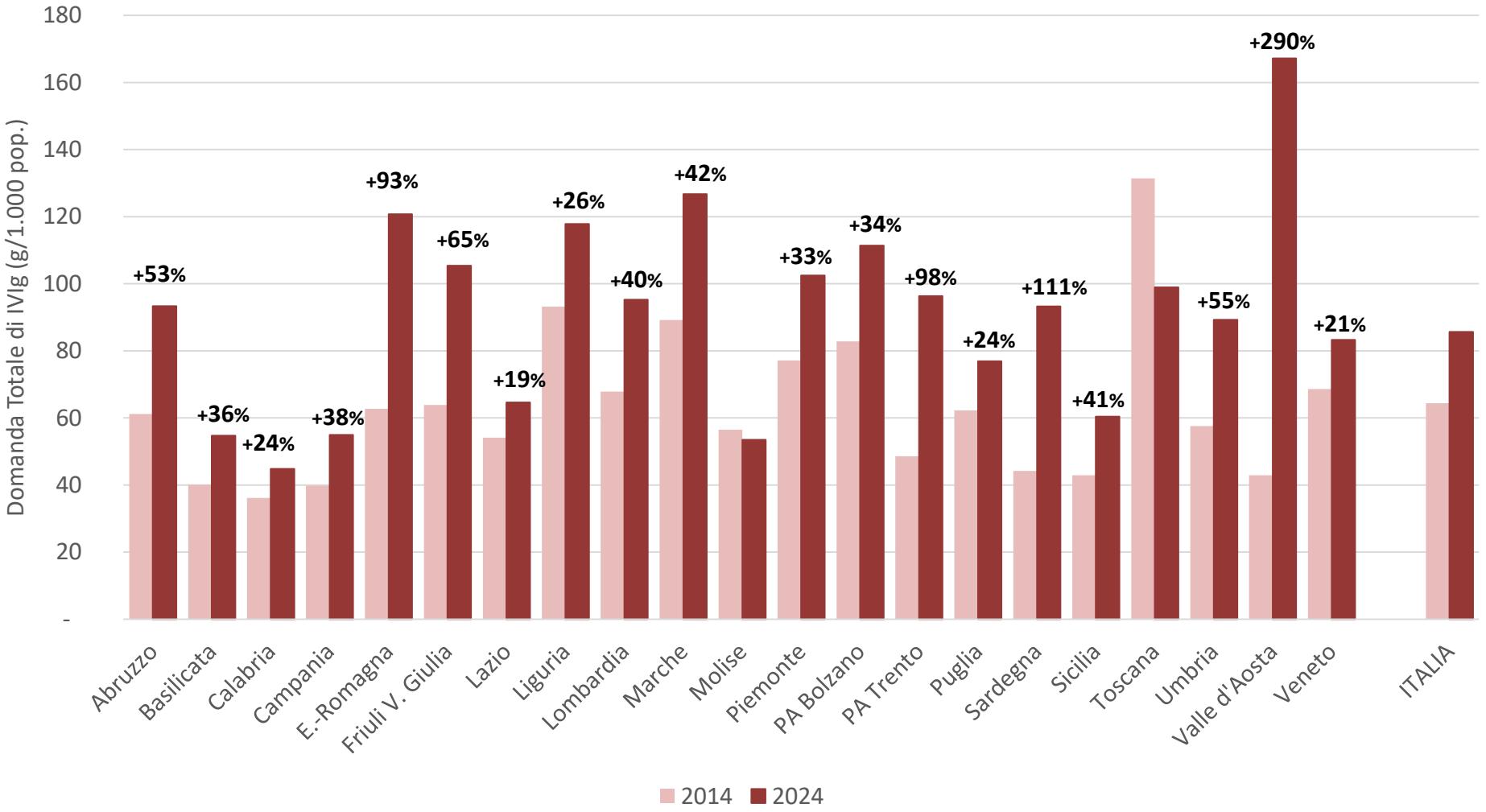
Autosufficienza SCIg – Anni 2014 - 2024



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

Dati Preliminari

Domanda regionale di IVIg* – 2024 vs 2014



Δ% 2024 vs 2014= +33%

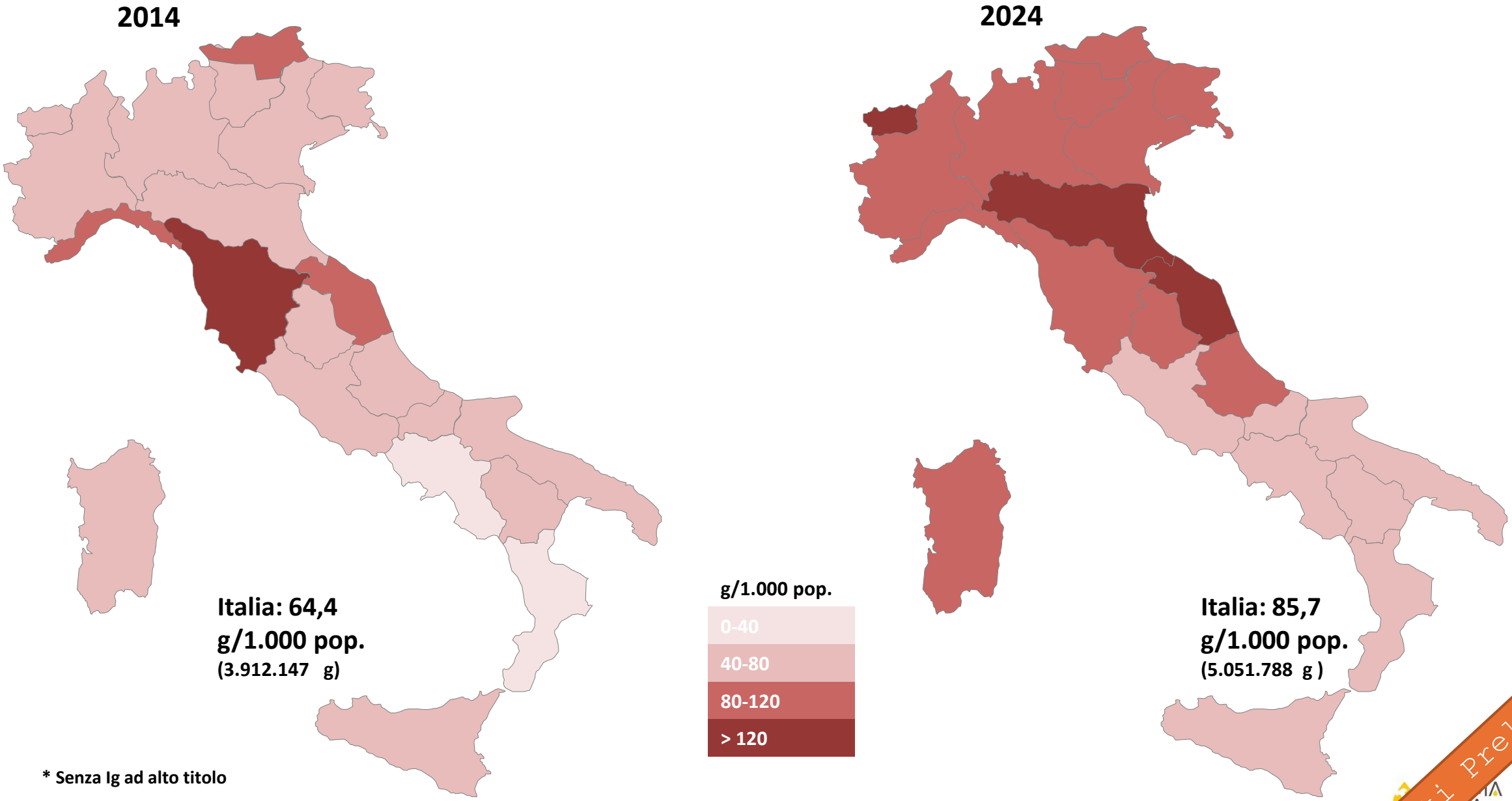
Δ% media annua= +2,95%

*** Senza Ig ad alto titolo**

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

Dati Preliminari

Domanda nazionale di IVIg* – 2024 vs 2014

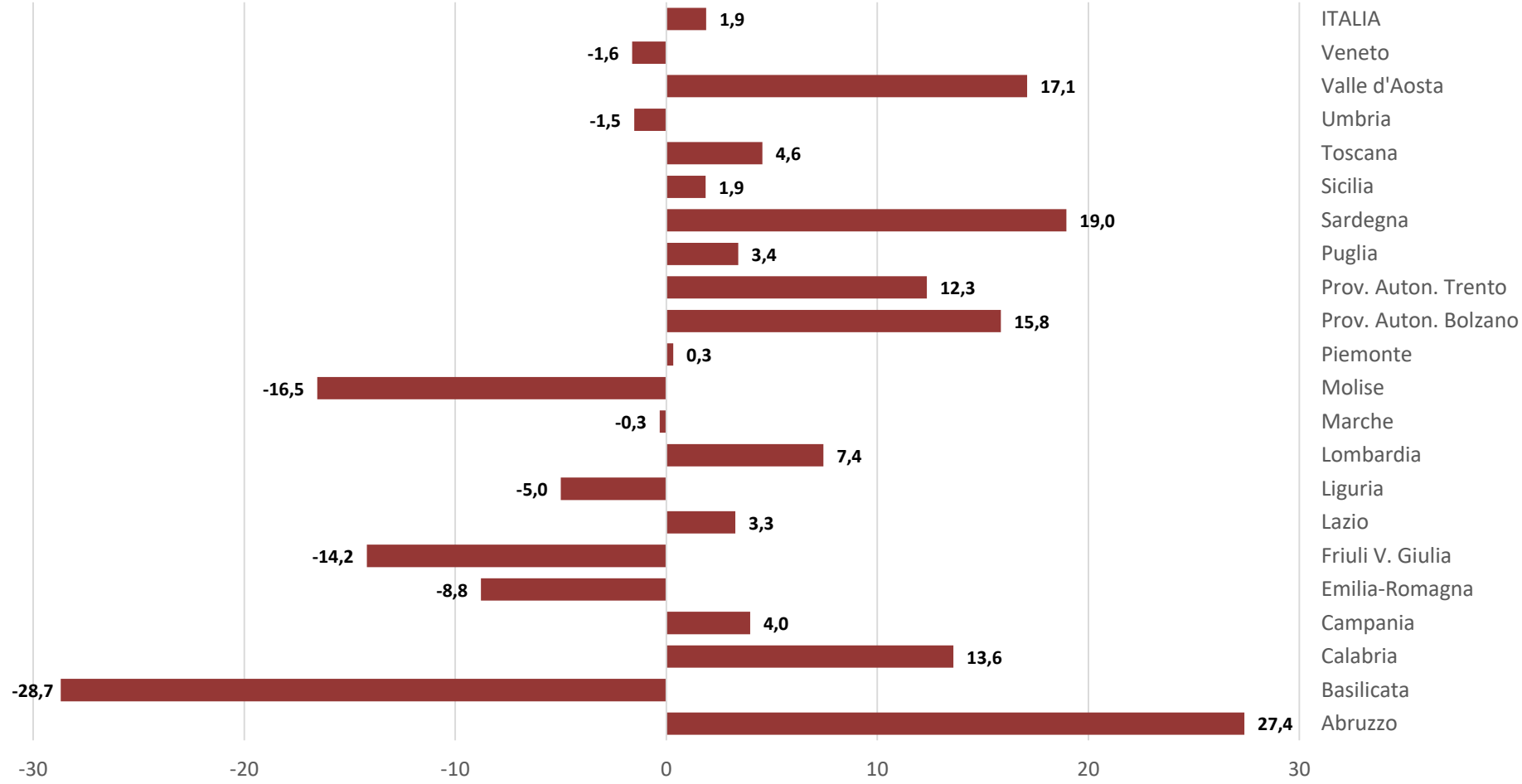


* Senza Ig ad alto titolo

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

Dati Preliminari

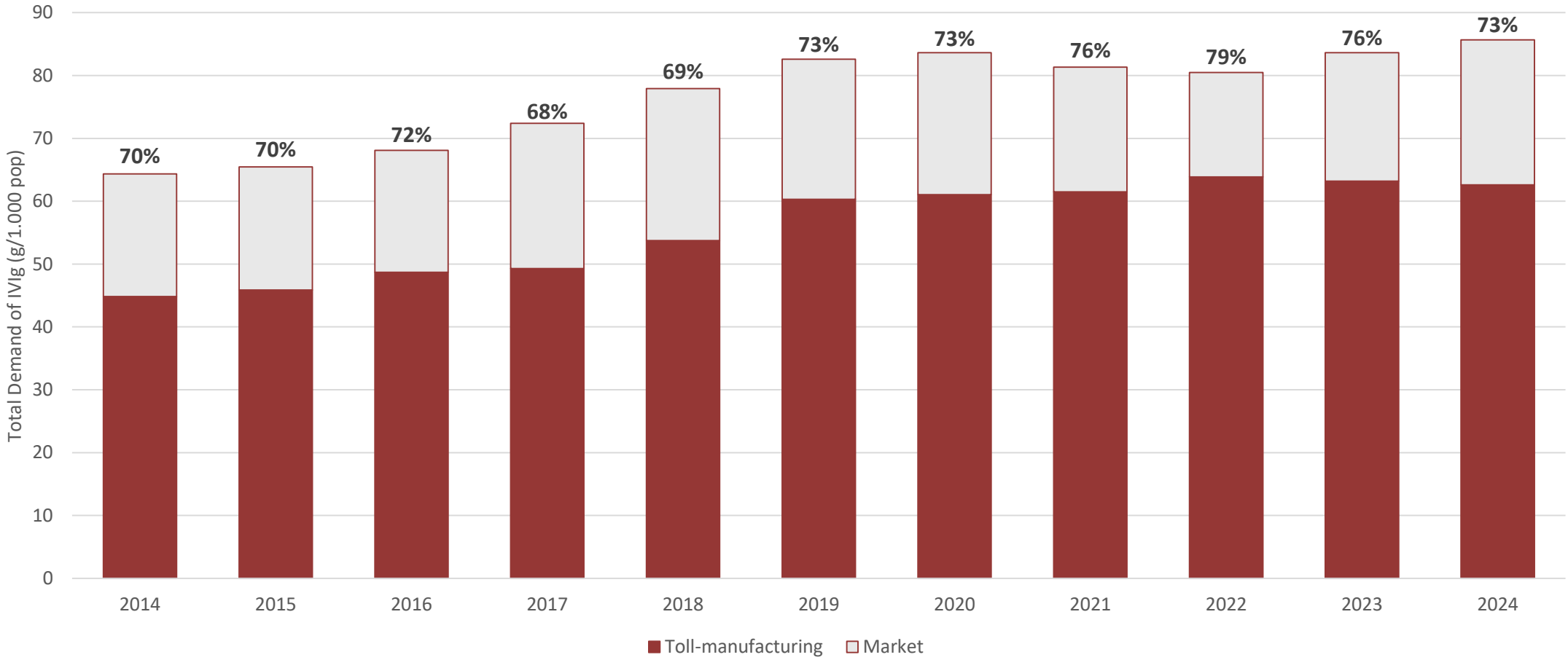
Variazione % della domanda regionale e nazionale di IVIg
Anno 2024 vs 2023



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

Dati Preliminari

Autosufficienza IVIg – Anni 2014 - 2024

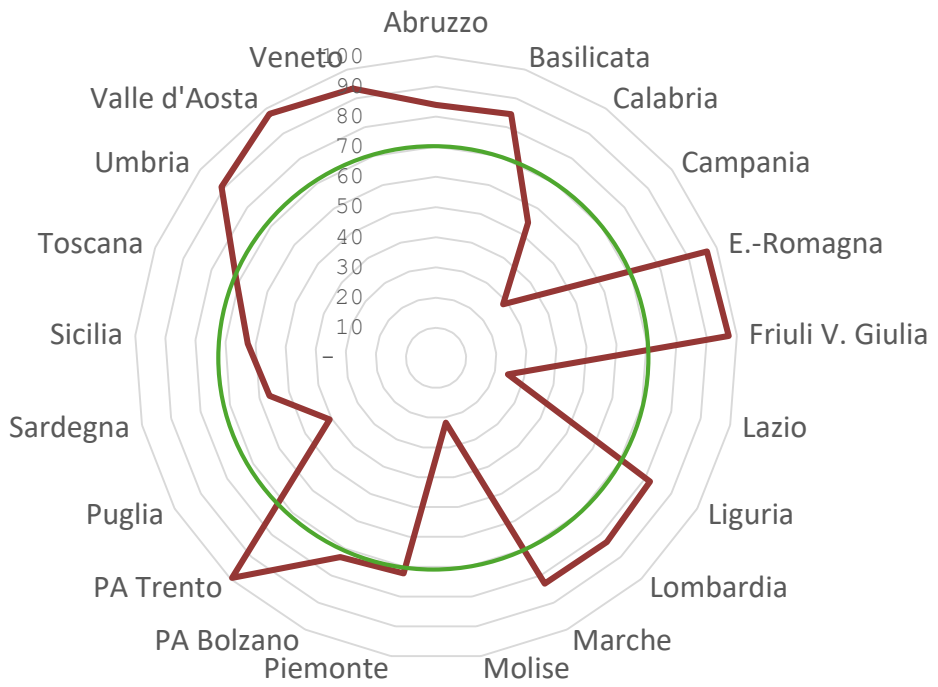


Data sources: - Adapted by the CNS on data from the Traceability information flow-Italian Ministry of Health and Demo.ISTAT- Italian Institute of Statistics

Dati Preliminari

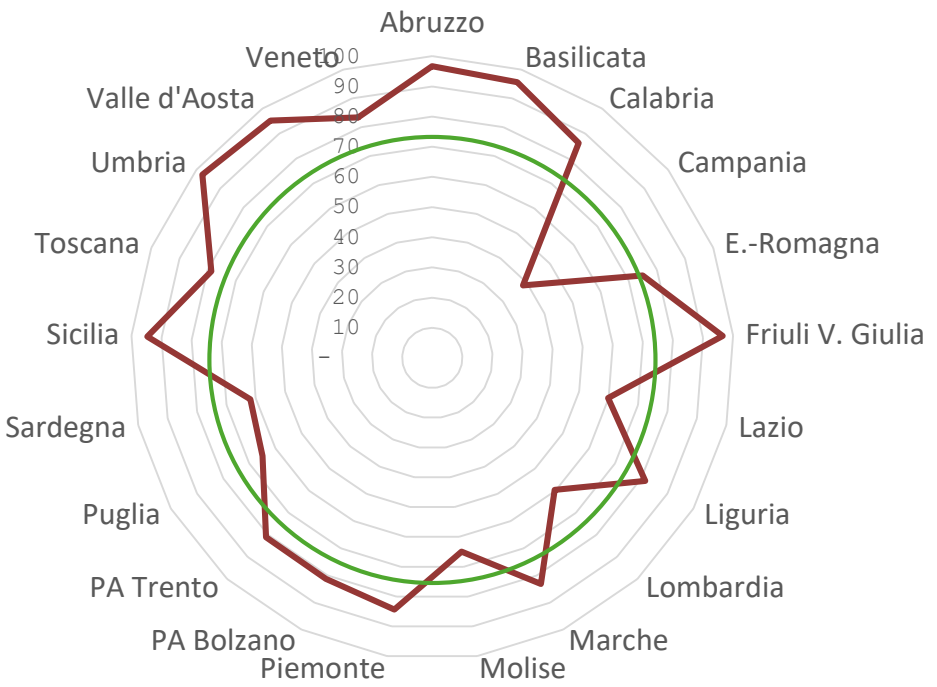
Autosufficienza regionale di IVIg* – 2024 vs 2014

2014



ITALIA: 70%

2024



ITALIA: 73%

*** Senza Ig ad alto titolo**

Data sources: - Adapted by the CNS on data from the Traceability information flow-Italian Ministry of Health

Dati Preliminari

Obiettivi del Programma Nazionale di autosufficienza 2025

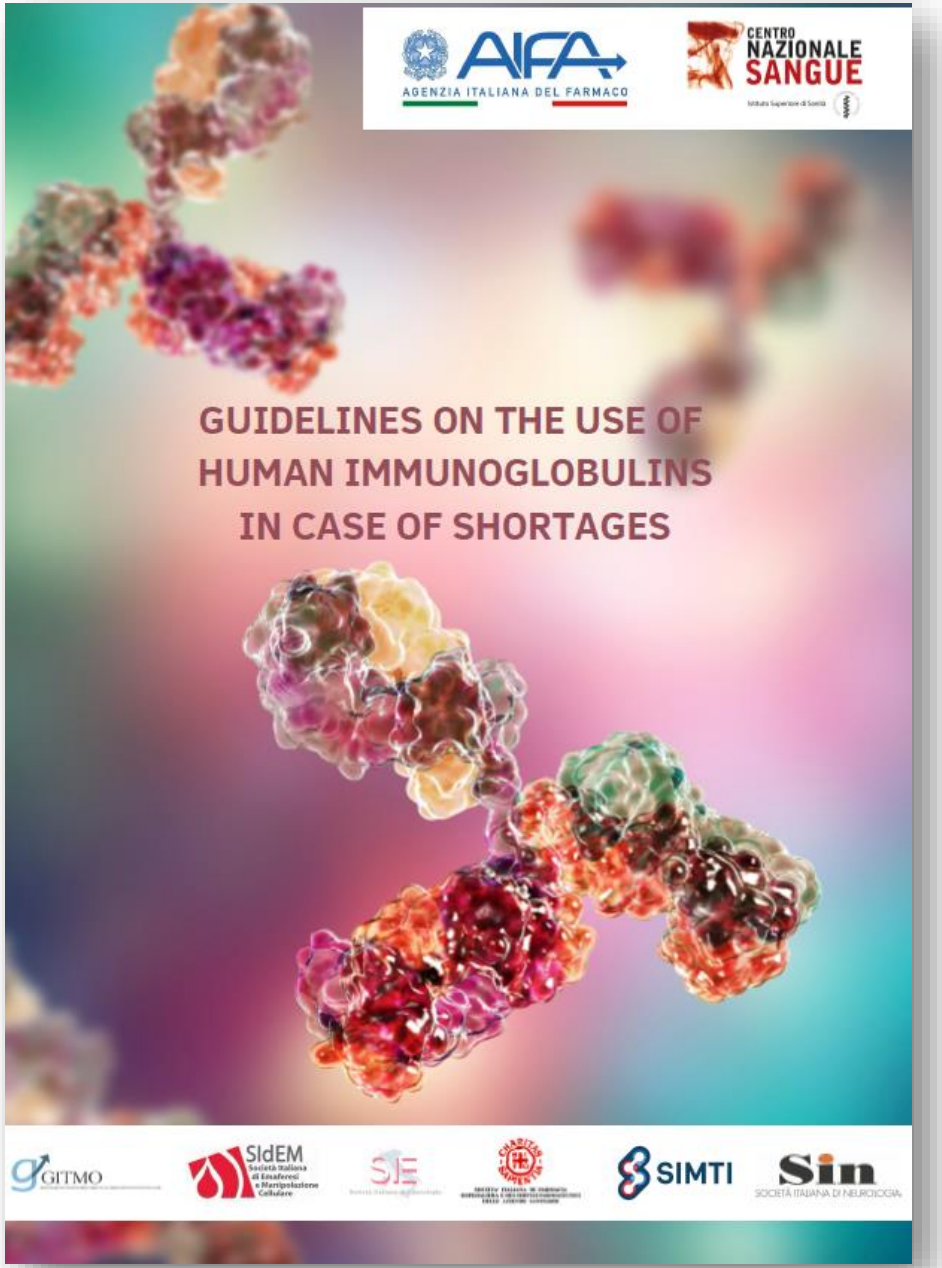
Plasma per frazionamento necessario al raggiungimento dell'obiettivo '18 kg / 1.000 pop'

18 kg / 1.000 pop. → 1.115.303 kg → 211.133 kg

Plasma per frazionamento necessario al raggiungimento dell'obiettivo '90% domanda Ig'

1.348.886 kg → **444.787** kg

Data sources: - Programma di autosufficienza nazionale del sangue e dei suoi prodotti, anno 2025



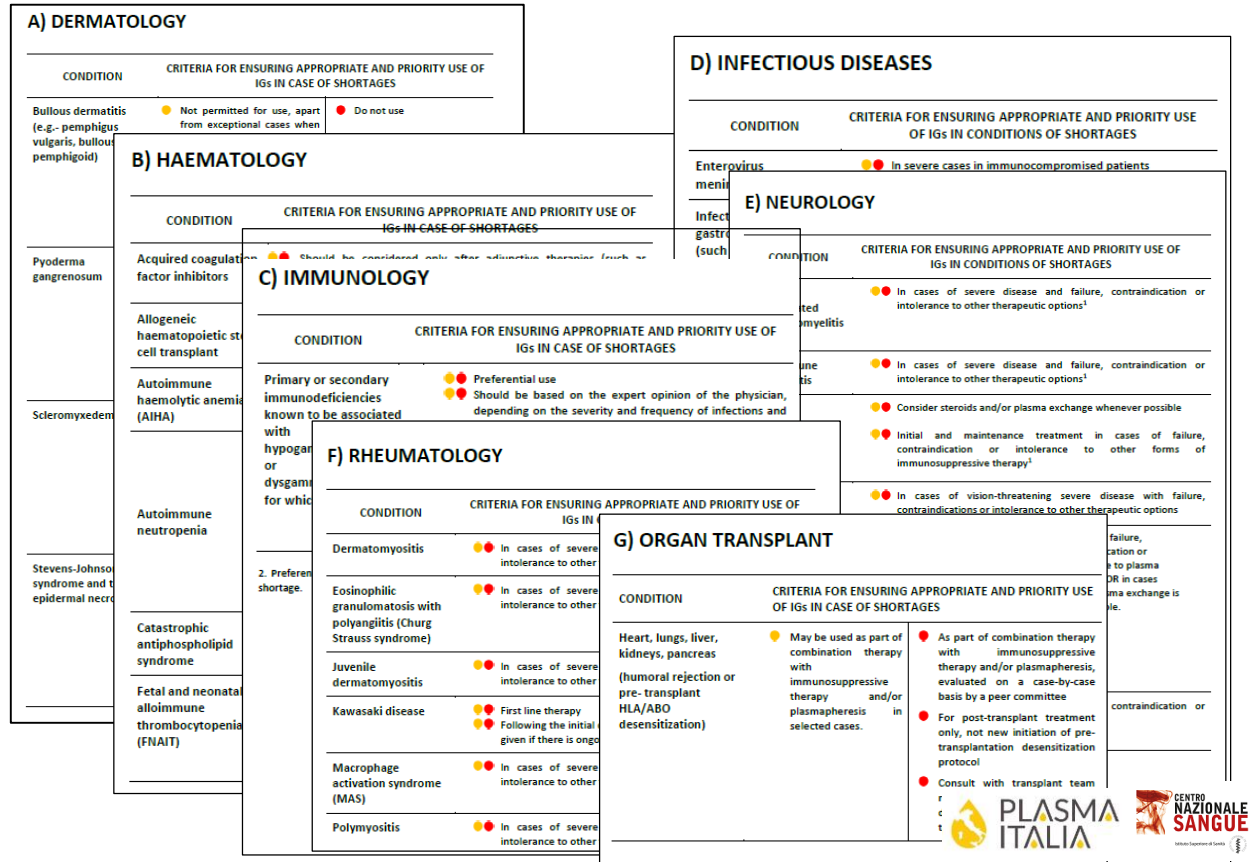
“GUIDELINES ON THE USE OF HUMAN IMMUNOGLOBULINS IN CASE OF SHORTAGES”
https://www.centronazionalesangue.it/wp-content/uploads/2022/02/Documento-uso-IG-in-condizioni-di-carenza.pdf
https://www.aifa.gov.it/-/documento-indirizzo-aifa-cns-uso-immunoglobuline-umane-condizioni-carenza

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).

Inventory level	Description and activities
Green	IG supply/inventory meets demand. • 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	Ig supply/inventory levels are reduced or there are signs that short-term demand may outstrip capacity. **Reduce use by 10 to 20%:** • 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: o 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. o Initiating local and provincial processes to support an adjudication process in the event of a red phase advisory.
Amber	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: o No viable alternatives; **and/or** o 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	There is a critical and prolonged Ig shortage. **Reduce use by over 50%:** • Limit IG use to clinical circumstances when there are: o 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: o No viable alternatives; **and/or** o 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: o No viable alternatives; **and/or** o 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).



A) DERMATOLOGY

CONDITION	CRITERIA FOR ENSURING APPROPRIATE AND PRIORITY USE OF IGs IN CASE OF SHORTAGES	
Bullous dermatitis (e.g.- pemphigus vulgaris, bullous pemphigoid)	● Not permitted for use, apart from exceptional cases when	● Do not use
Pyoderma gangrenosum		
Scleromyxedem		
Stevens-Johnso syndrome and t epidermal necro		

B) HAEMATOLOGY

CONDITION	CRITERIA FOR ENSURING APPROPRIATE AND PRIORITY USE OF IGs IN CASE OF SHORTAGES
Acquired coagulation factor inhibitors	
Allogeneic haematopoietic st cell transplant	
Autoimmune haemolytic anemia (AIHA)	
Autoimmune neutropenia	
Catastrophic antiphospholipid syndrome	
Fetal and neonatal alloimmune thrombocytopenia (FNAIT)	

C) IMMUNOLOGY

CONDITION	CRITERIA FOR ENSURING APPROPRIATE AND PRIORITY USE OF IGs IN CASE OF SHORTAGES
Primary or secondary immunodeficiencies known to be associated with hypoga or dysgamm for whic	●● Preferential use ●● Should be based on the expert opinion of the physician, depending on the severity and frequency of infections and

2. Preferen shortage.

D) INFECTIOUS DISEASES

CONDITION	CRITERIA FOR ENSURING APPROPRIATE AND PRIORITY USE OF IGs IN CONDITIONS OF SHORTAGES
Enterovirus meni	●● In severe cases in immunocompromised patients
Infec gastr (such	

E) NEUROLOGY

CONDITION	CRITERIA FOR ENSURING APPROPRIATE AND PRIORITY USE OF IGs IN CONDITIONS OF SHORTAGES
ted myelitis	●● In cases of severe disease and failure, contraindication or intolerance to other therapeutic options[1]
une tis	●● In cases of severe disease and failure, contraindication or intolerance to other therapeutic options[1]
	●● Consider steroids and/or plasma exchange whenever possible
	●● Initial and maintenance treatment in cases of failure, contraindication or intolerance to other forms of immunosuppressive therapy[1]
	●● In cases of vision-threatening severe disease with failure, contraindications or intolerance to other therapeutic options

F) RHEUMATOLOGY

CONDITION	CRITERIA FOR ENSURING APPROPRIATE AND PRIORITY USE OF IGs IN
Dermatomyositis	●● In cases of severe intolerance to other
Eosinophilic granulomatosis with polyangiitis (Churg Strauss syndrome)	●● In cases of severe intolerance to other
Juvenile dermatomyositis	●● In cases of severe intolerance to other
Kawasaki disease	●● First line therapy ●● Following the initial given if there is ongo
Macrophage activation syndrome (MAS)	●● In cases of severe intolerance to other
Polymyositis	●● In cases of severe intolerance to other

G) ORGAN TRANSPLANT

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)	● 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

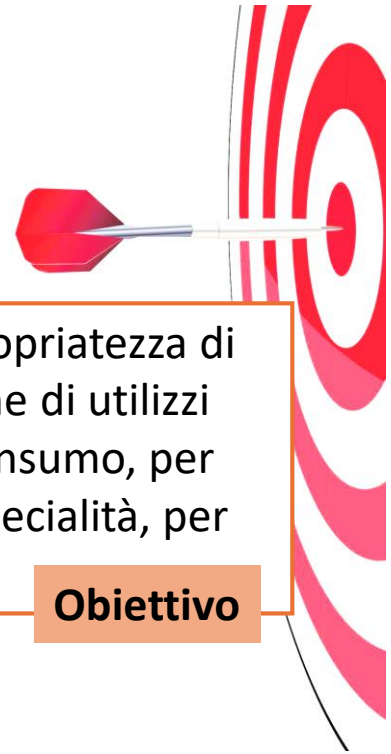
PLASMA ITALIA

CENTRO NAZIONALE SANGUE

CCM – Area Azioni centrali 2024
Studio di appropriatezza di utilizzo clinico delle IG polivalenti in Italia (2025-2026)

Unità Operative

1. SRC - Regione Calabria
2. Settore Assistenza Ospedaliera - Centro Regionale di Farmacovigilanza – Direzione Generale Cura della Persona, Salute e Welfare - Regione Emilia-Romagna
3. SRC - Regione Marche, Azienda Ospedaliero Universitaria delle Marche
4. Area Farmaci e Dispositivi - Direzione Regionale Salute e Integrazione Sociosanitaria, Regione Lazio
5. SRC – Regione Ouglia, Azienda Ospedaliera Universitaria Policlinico di Bari / Dipartimento Gestione del Farmaco della Regione Puglia – Area Farmaceutica della Asl Bari
6. SRC – Regione Sicilia
7. SRC / Settore Assistenza Farmaceutica e Dispositivi - Direzione Sanità, Welfare e Coesione Sociale della Regione Toscana
8. SRC- Regione Umbria
9. SRC – Regione Valle d'Aosta - Ospedale "Umberto Parini", Aosta
10. Dipartimento di Medicina e Chirurgia - Università degli Studi di Milano-Bicocca
11. Ente di riferimento a livello nazionale per le valutazioni di appropriatezza nell'utilizzo clinico dei MPD (*da individuare*)
12. AIFA - Ufficio Qualità dei prodotti e Contrasto al Crimine Farmaceutico
13. AGENAS - Dipartimento Area Sanitaria
14. ISS – Dipartimento di Statistica
15. **CNS – Area plasma e MPD (coordinatore)**



Definire la misura del grado di inappropriatezza di utilizzo di IG attraverso l'individuazione di utilizzi *off-label* e la rilevazione dei dati di consumo, per singola struttura sanitaria e singola specialità, per patologia e intervento terapeutico.

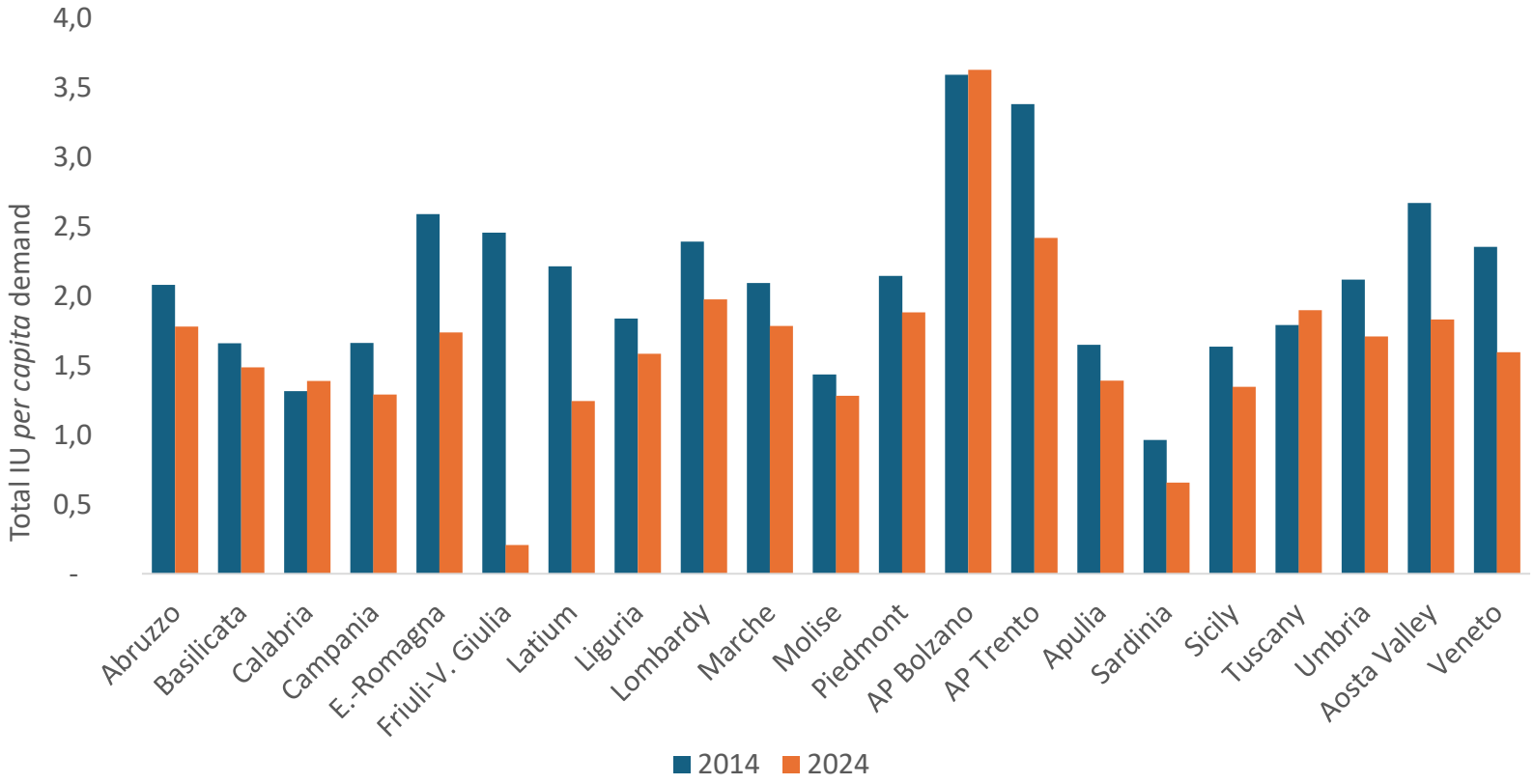
Obiettivo

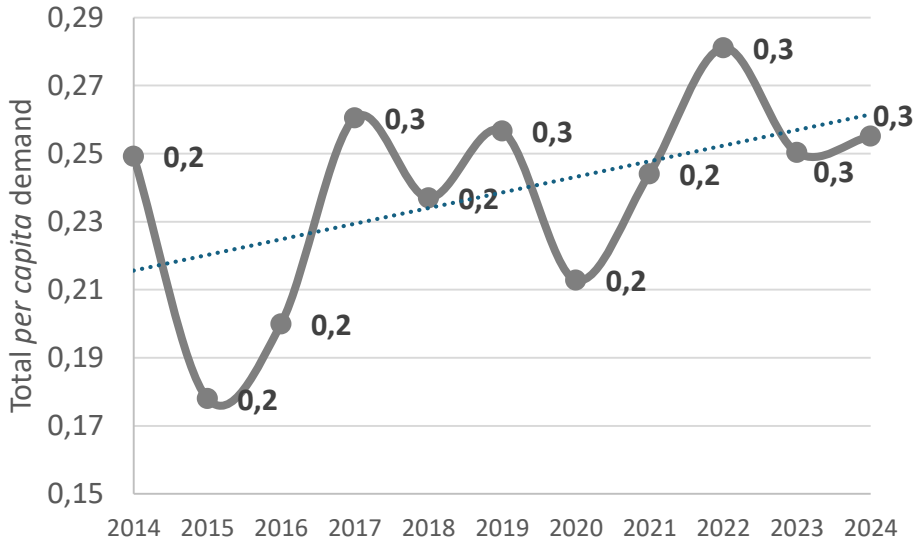
PLASMA ITALIA

CENTRO NAZIONALE SANGUE

Immunoglobuline specifiche

Anti-cytomegalovirus immunoglobulins





Δ% 2024 vs 2014= +2,4%

Δ% annual average= +1,7%

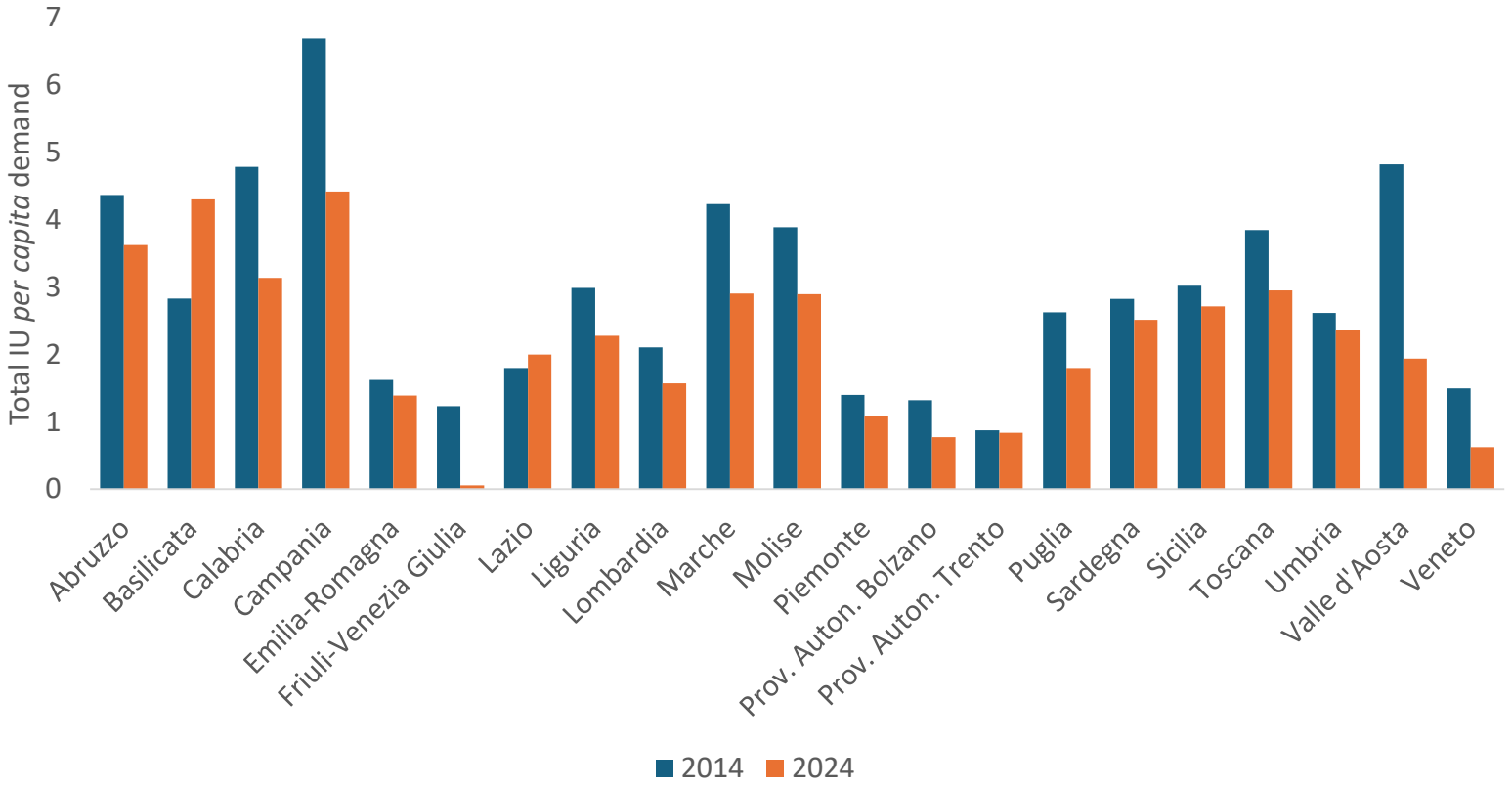
Estimate expenditure Year 2014/2024

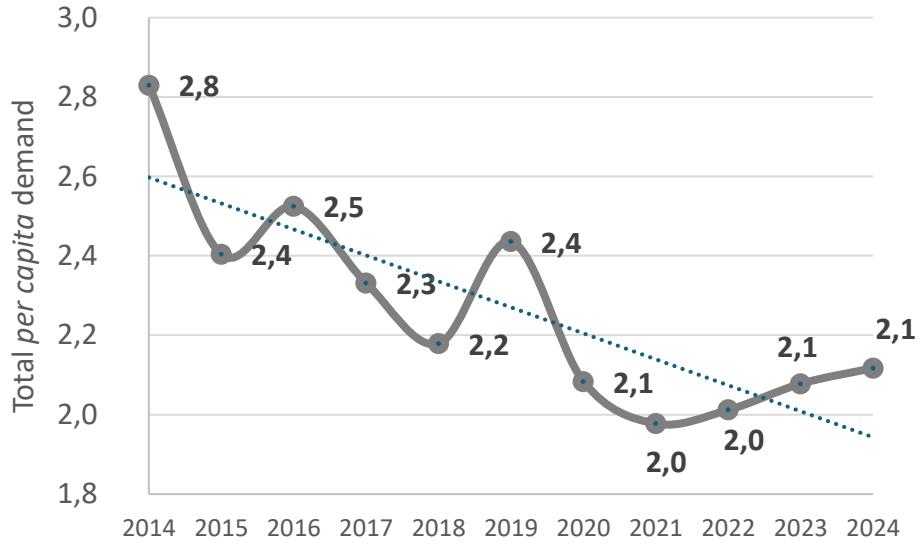
	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
€	2.511.263	1.899.002	2.162.392	3.569.978	2.533.887	2.840.113	2.262.176	2.556.137	2.983.290	2.722.953	2.748.309
€ p.c.	0,04	0,03	0,04	0,06	0,04	0,05	0,04	0,04	0,05	0,05	0,05

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

Dati Preliminari

Anti-tetanus immunoglobulins





Δ% 2024 vs 2014= -25,2%

Δ% annual average= -2,5%

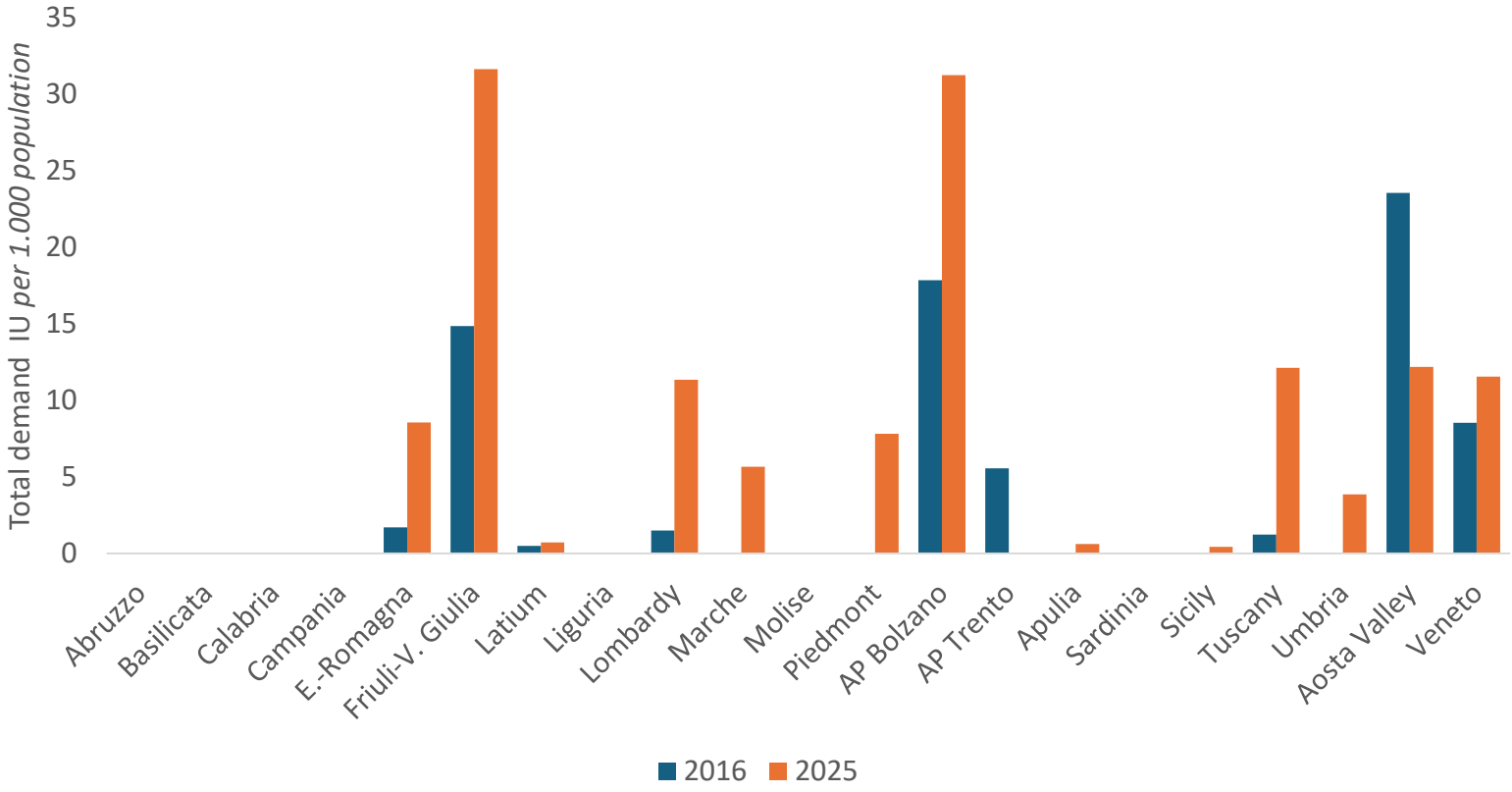
Estimate expenditure Year 2014/2024

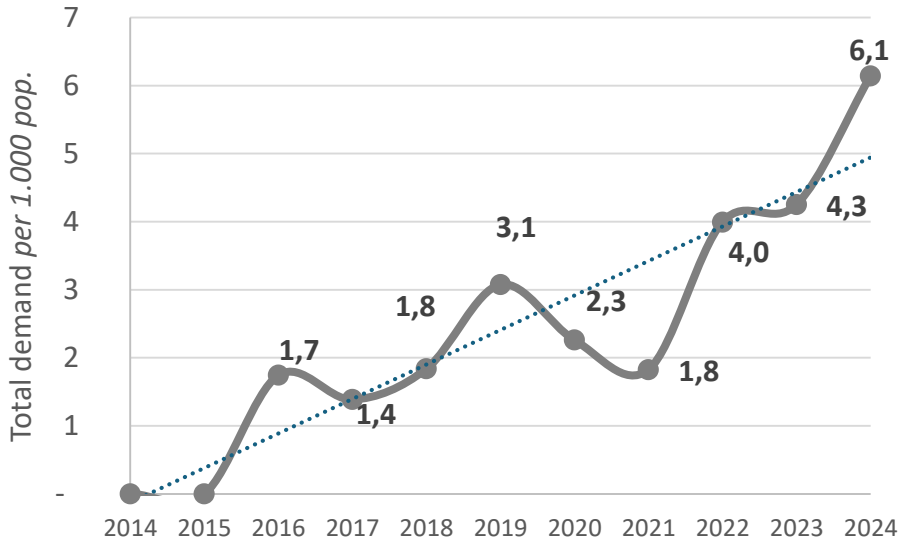
	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
€	5.518.068	5.338.292	5.218.910	4.142.835	4.376.814	6.302.202	6.765.882	6.286.734	6.173.548	6.533.899	8.176.178
€ p.c.	0,09	0,09	0,09	0,07	0,07	0,10	0,11	0,11	0,10	0,11	0,14

Dati Preliminari

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

Anti-rabies immunoglobulins





Δ% 2024 vs 2016= +252,2%

Δ% annual average= +25,4%

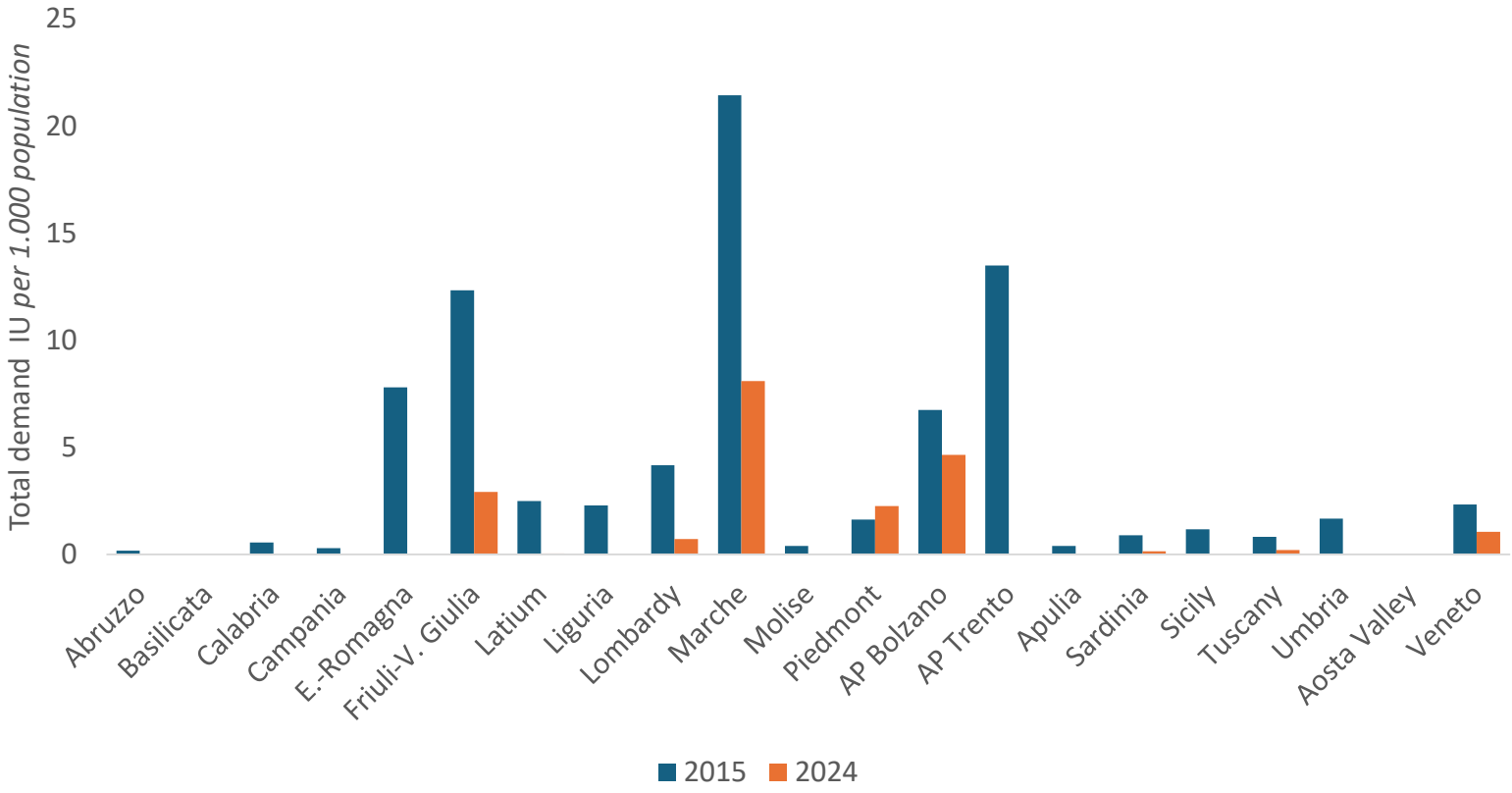
Estimate expenditure Year 2014/2024

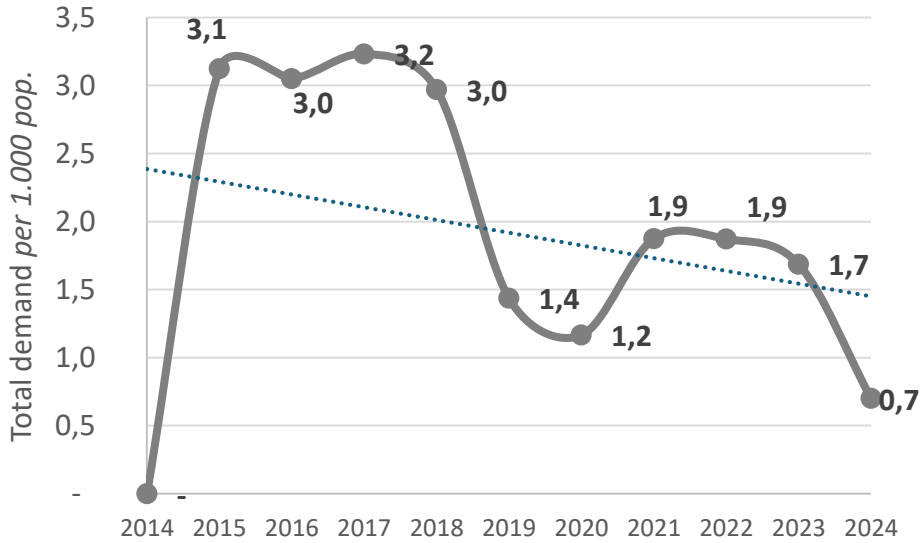
	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
€	-	-	77.600	54.880	79.879	133.349	96.912	77.724	169.354	180.242	260.229
€ p.c.	-	-	0,001	0,001	0,001	0,002	0,002	0,001	0,003	0,003	0,004

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

Dati Preliminari

Anti-varicella immunoglobulins





Δ% 2024 vs 2014= -77,6%

Δ% annual average= -9,2%

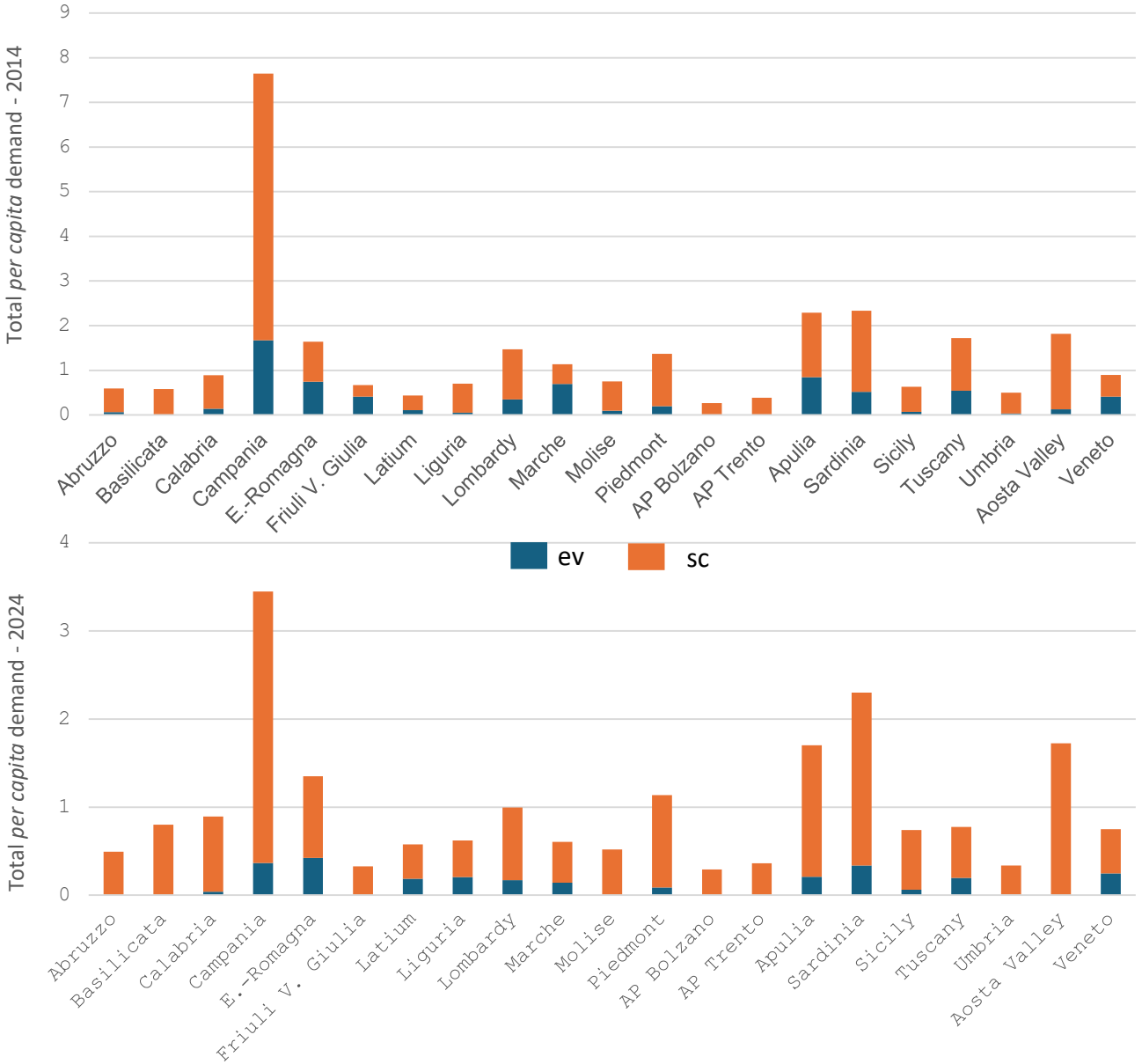
Estimate expenditure Year 2014/2024

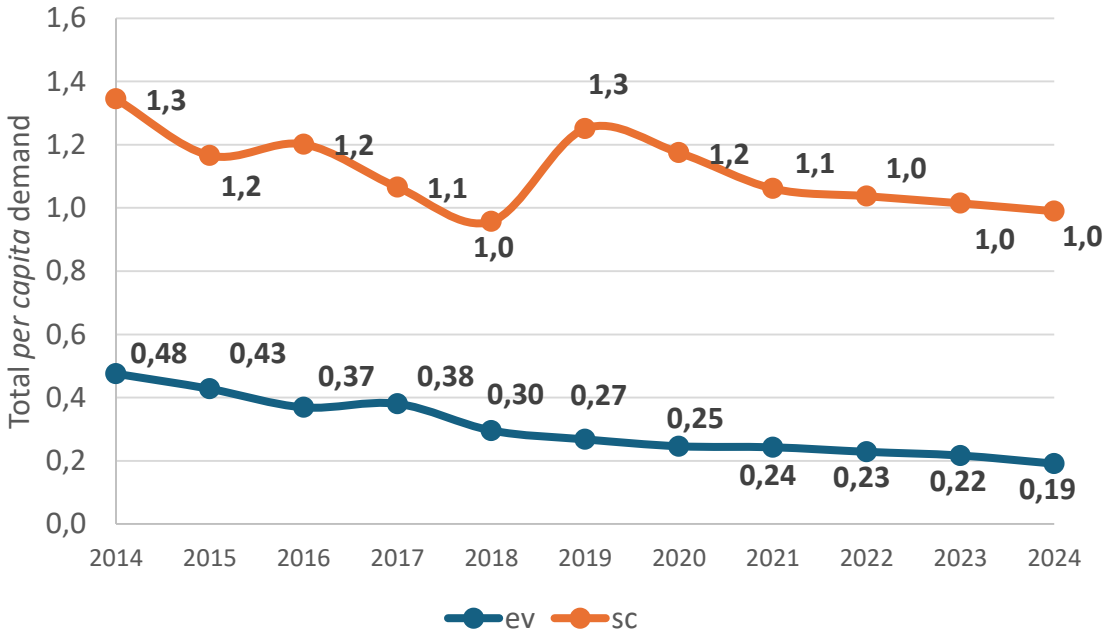
	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
€	-	123.663	120.060	126.638	116.991	95.540	45.106	79.908	78.890	71.195	29.368
€ p.c.	-	0,0020	0,0020	0,0021	0,0019	0,0016	0,0008	0,0013	0,0013	0,0012	0,0005

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

Dati Preliminari

Anti-hepatitis B immunoglobulins





ev

Δ% 2024 vs 2014= -59,9%

Δ% annual average= -8,5%

sc

Δ% 2024 vs 2014= -26,4%

Δ% annual average= -2,7%

Dati Preliminari

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

Anti-hepatitis B immunoglobulins - Estimate expenditure 2014 - 2024

Estimate expenditure Year 2014/2024 (SC)

	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
€	30.980.964	31.224.486	29.676.970	29.171.612	28.787.298	26.151.194	25.575.155	23.470.865	22.457.852	22.442.589	21.357.364
€ p.c.	0,51	0,51	0,49	0,48	0,48	0,43	0,43	0,40	0,38	0,38	0,36

Estimate expenditure Year 2014/2024 (IV)

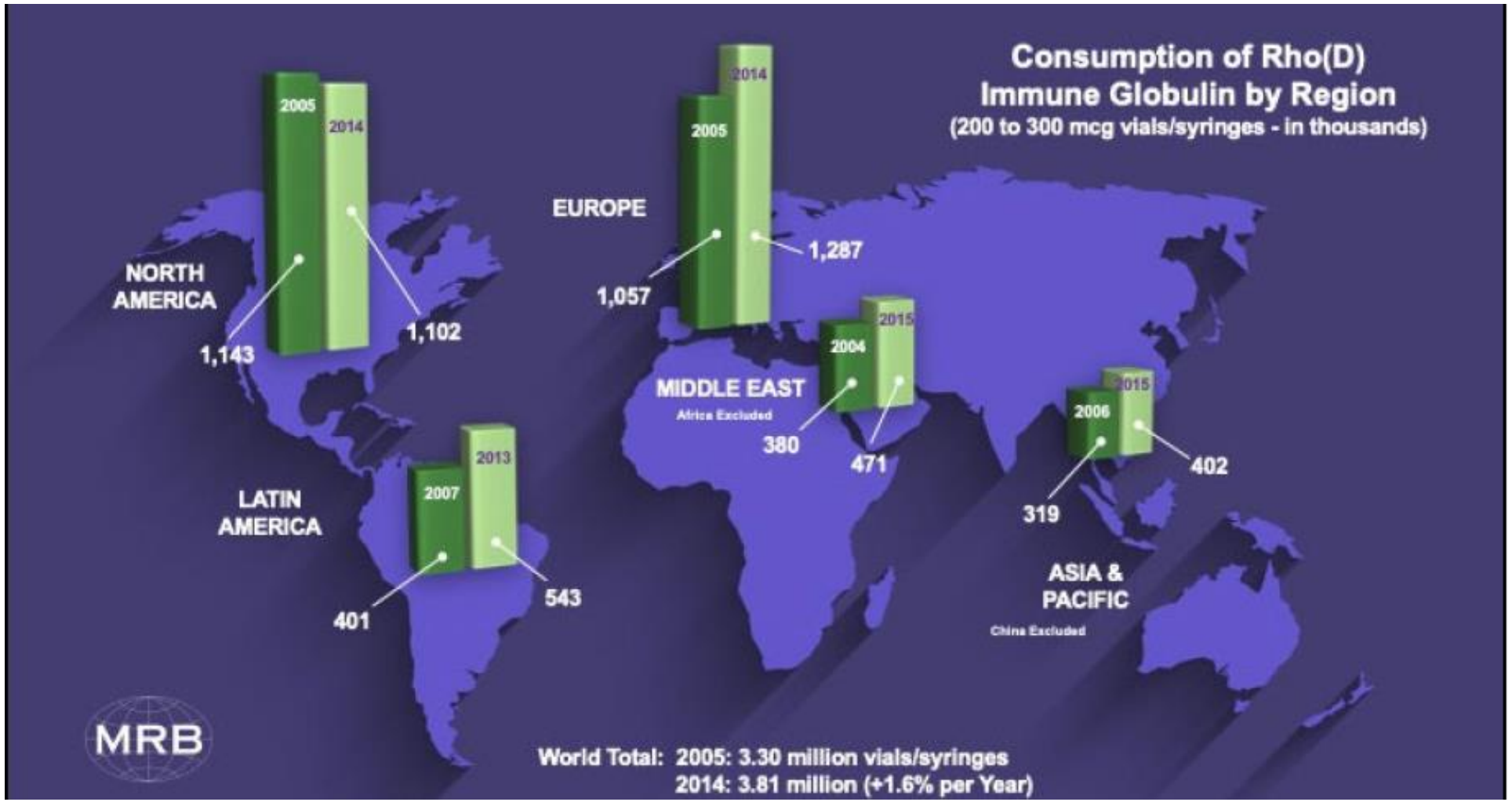
	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
€	5.943.501	4.879.822	4.081.333	3.966.870	2.766.110	2.338.232	2.022.478	1.630.844	1.404.760	1.319.782	1.115.611
€ p.c.	0,10	0,08	0,07	0,07	0,05	0,04	0,03	0,03	0,02	0,02	0,02

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

Dati Preliminari

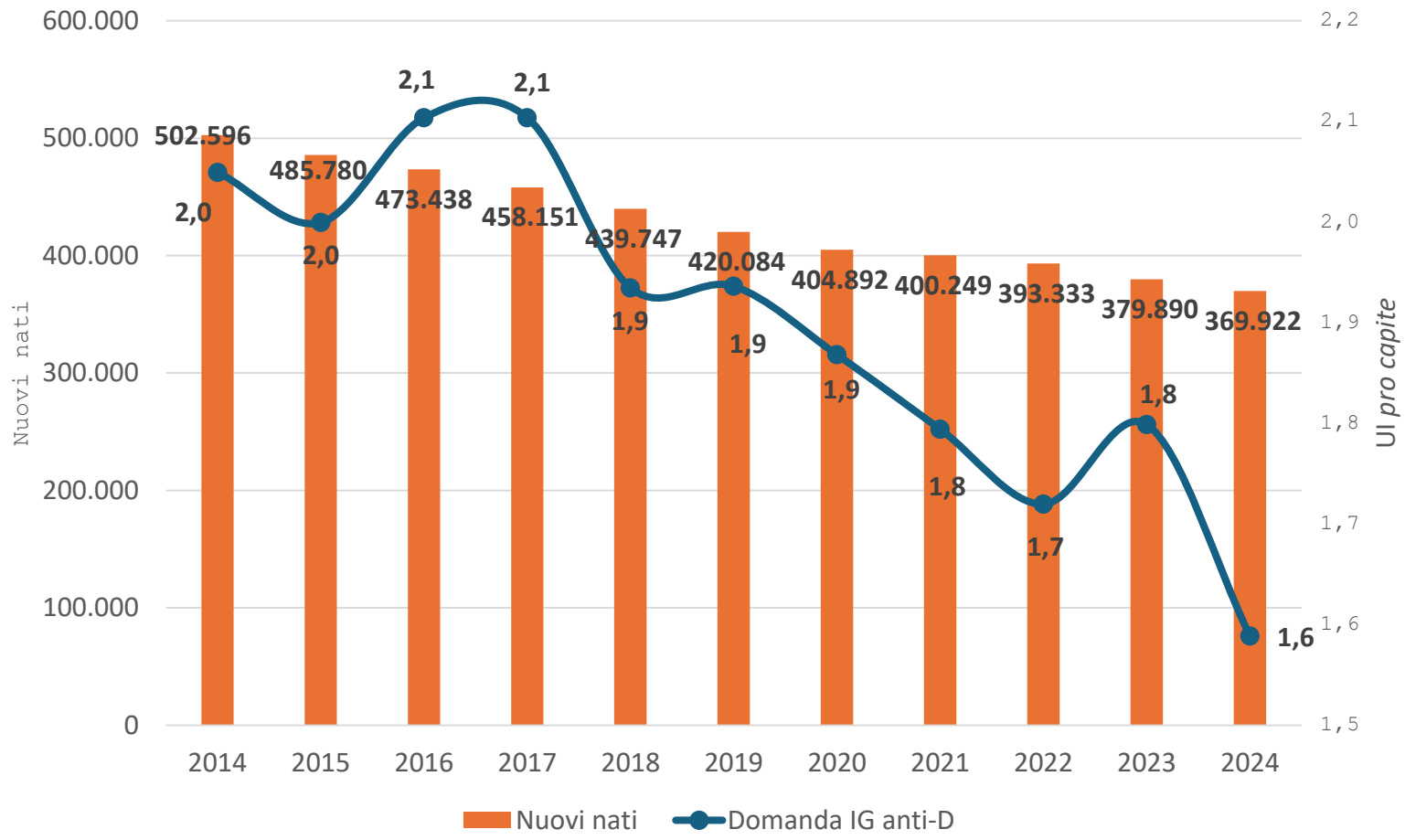
Immunoglobuline anti-D

Il consumo globale di Ig anti-D



Courtesy of: P. Robert, Marketing Research Bureau «THE WORLDWIDE Rh (ANTI-D) IMMUNE GLOBULIN MARKET». Anti D Immunoglobulin: Exploring Collection, Production and Alternatives Webinar Series September 18, 2023

Domanda Totale nazionale di Ig anti-D

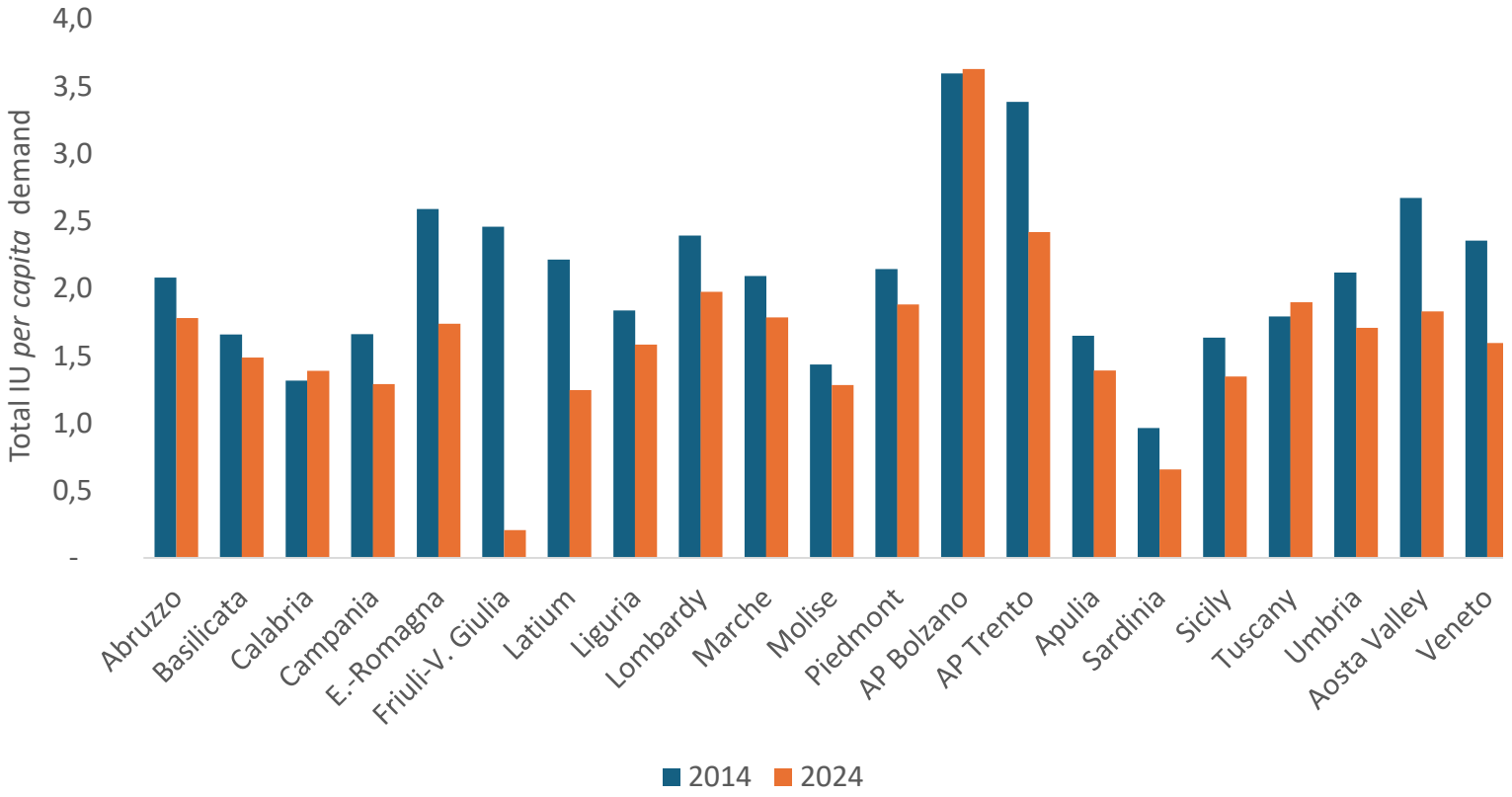


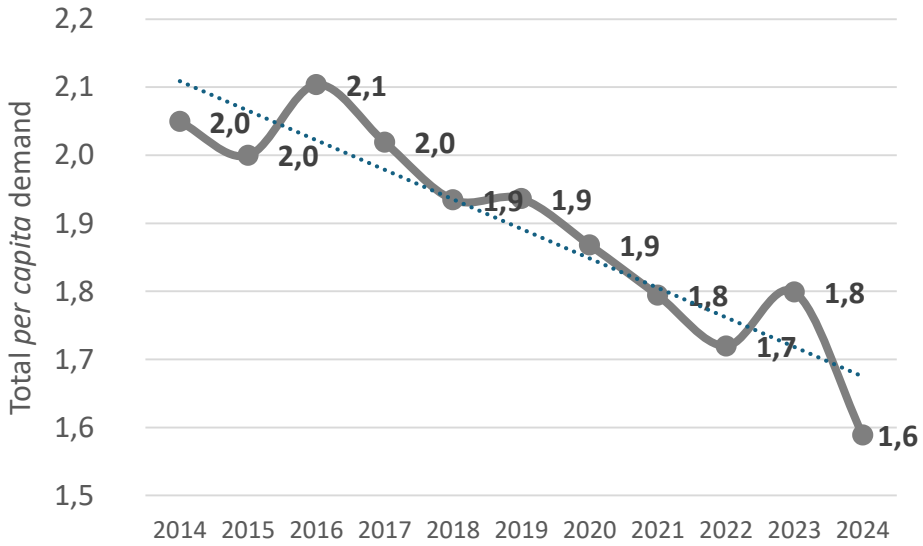
A livello nazionale dal 2014 al 2024 la domanda ha seguito sostanzialmente l'andamento delle nascite, mostrando un trend in decremento (-22,5%); tuttavia nel 2023 si è registrato un lieve incremento del **+4,6%** rispetto all'anno precedente.

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

Dati Preliminari

Anti-D immunoglobulins





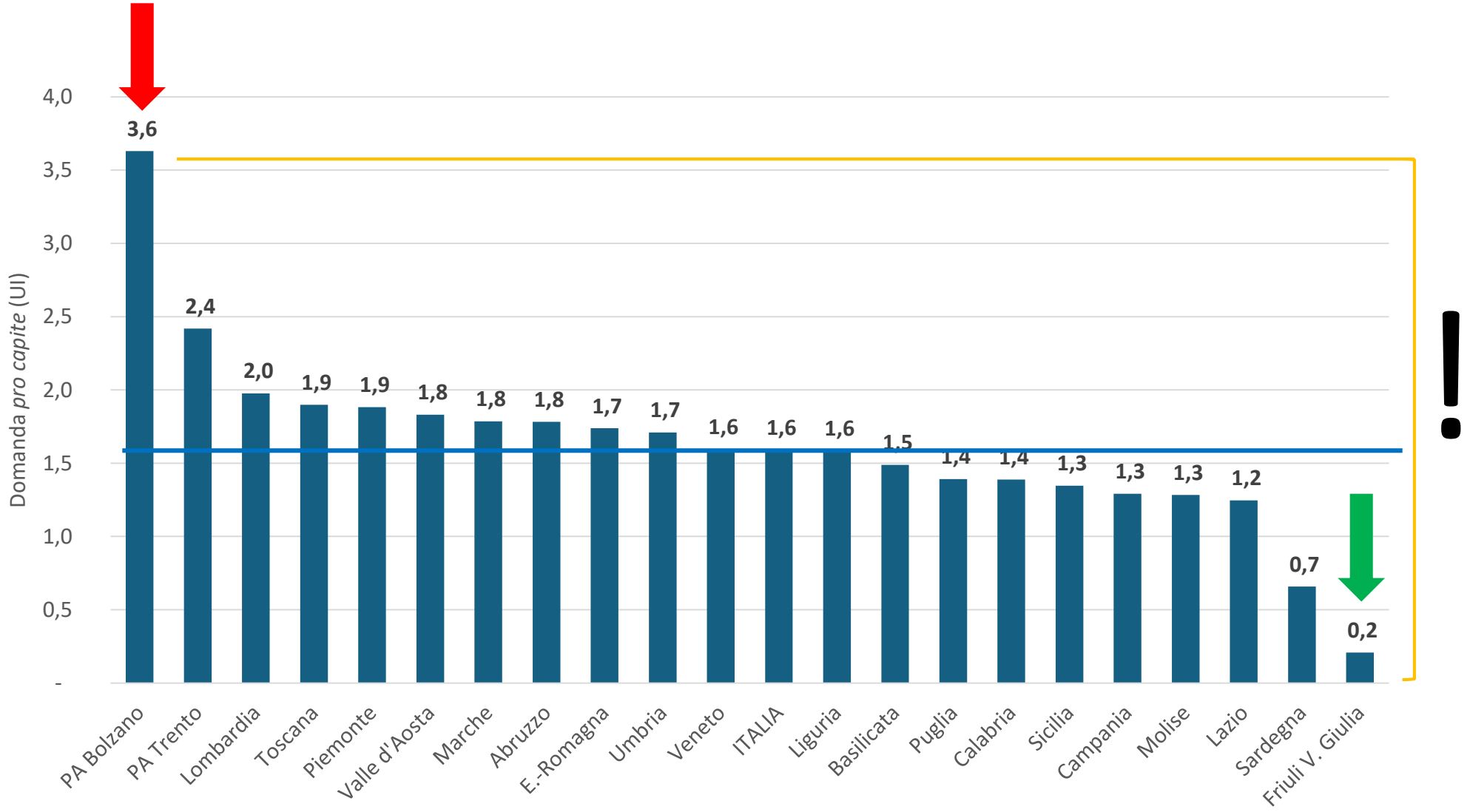
Δ% 2024 vs 2014= -22,5%

Δ% annual average= -8,9%

Dati Preliminari

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

Domanda totale nazionale/regionale di IG-anti D – Anno 2024



!

Dati Preliminari

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

Soluzioni alternative nel campo della ricerca

«***Europe needs more plasma***» si applica anche al plasma anti-D, ma sono necessarie soluzioni diverse.

ELSEVIER

Transplant Immunology

Volume 10, Issues 2–3, August 2002, Pages 199-204

Monoclonal anti-D development programme

Belinda M Kumpel

ELSEVIER

Transfusion Clinique et Biologique

Volume 13, Issues 1–2, March–April 2006, Pages 58-64

Original article

Monoclonal anti-D antibodies toprevent alloimmunization: lessons from clinical trials

Anticorps monoclonaux anti-D pourlaprévention etl'allo-immunisation: leçons desessais cliniques

R. Béliard

Original Article

Obstet Gynecol Sci 2020;63(3):315-322

https://doi.org/10.5468/ogs.2020.63.3.315

pISSN 2287-8572 · eISSN 2287-8580

Obstetrics & Gynecology Science

Recombinant anti-D for prevention of maternal-foetal Rh(D) alloimmunization: a randomized multi-centre clinical trial

Rahul Vishwanath Mayekar, MD[1], Gopalkrishna Vinayak Paradkar, MD[2], Archana Anilkumar Bhosale, MD[1], Rekha Sachan, MS[3], Sumalatha Beeram, MS[4], Ashok Ramachandra Anand, MD[5], Shuchita Ramesh Mundle, MD[6], Yamini Trivedi, MD[7], Rashmi MD, MS[8], Kiran Pandharinath Patole, MD[9], Pradip Wamanrao Sambarey, MD[10], Gautam Vinod Daftary, MBBS[11], James John, MD[11], Ganesh Harishchandra Divekar, MBBS[11]

Department of Obstetrics and Gynaecology, [1]Lokmanya Tilak Municipal Medical College & Lokmanya Tilak Municipal General Hospital, Mumbai, [2]Rajiv Gandhi Medical College & Chhatrapati Shivaji Maharaj Hospital, Thane, [3]King George's Medical University, Lucknow, [4]Gandhi Medical College and Hospital, Secunderabad, [5]Grant Medical College and Sir J.J. Group of Hospitals, Mumbai, [6]Government Medical College and Hospital, Nagpur, [7]AMC MET Medical College and Sheth LG General Hospital, Ahmedabad, [8]Apollo BGS Hospital, Mysore, [9]Dr. Vasantrao Pawar Medical College and Research Centre, Nashik, [10]Byramjee Jeejeebhoy Government Medical College and Sassoon General Hospitals, Pune; [11]Clinical Research and Pharmacovigilance, Bharat Serums and Vaccines Limited, Navi Mumbai, India

Vox Sanguinis (2001) **81**, 213

© 2001 Blackwell Sc

REVIEW ARTICLE

Monoclonal anti-D for immunoprophylaxis

M. L. Scott

International Blood Group Reference Laboratory, National Blood Service, Bristol, UK

Vox Sanguinis

Routine antenatal prophylaxis with anti-D has become accepted as desirable, but concerns have been expressed about the adequacies of supply and safety of polyclonal anti-D. Human monoclonal anti-D has been produced using Epstein–Barr virus (EBV)-transformed peripheral B cells, sometimes coupled with fusions to myeloma cell lines. More recently, molecular biology techniques have been used to produce human monoclonal anti-D in a variety of different ways. Many monoclonal antibodies (mAbs) have been characterized for fine specificity and *in vitro* functional activity in International Workshops. Two mAbs have been shown to cause red cell clearance and immunosuppression in male volunteers. Considerations for the future development of monoclonal anti-D for prophylactic use are reviewed.

Received: 31 May 2001, revised 25 July 2001, accepted 27 July 2001

Key words: anti-D, HDN, monoclonal, prophylaxis.

ORIGINAL ARTICLE

Enhanced opsonisation of Rhesus D-positive human red blood cells by recombinant polymeric immunoglobulin G anti-G antibodies

Dylana Díaz-Solano, Jaheli Fuenmayor, Ramon F. Montaño

Cellular and Molecular Pathology Laboratory, Experimental Medicine Centre, Venezuelan Institute of Scientific Investigation (IVIC), Caracas, Venezuela

PLASMA ITALIA

CENTRO NAZIONALE SANGUE

Screening prenatale RHD fetale

«***Europe needs more plasma***» si applica anche al plasma anti-D, ma sono necessarie soluzioni diverse .

NEJM 1998

PRENATAL DIAGNOSIS OF FETAL RhD STATUS BY MOLECULAR ANALYSIS OF MATERNAL PLASMA

Y.M. Dennis Lo, M.R.C.P., N. Magnus Hjelm, F.R.C.Path., Carrie Fidler, Ph.D., Ian L. Sargent, Ph.D., Michael F. Murphy, F.R.C.Path., Paul F. Chamberlain, M.D., Priscilla M.K. Poon, Ph.D., Christopher W.G. Redman, F.R.C.P., and James S. Wainscoat, F.R.C.Path.

prenataltest®

A Clinical Service in the UK to Predict Fetal Rh (Rhesus) D Blood Group Using Free Fetal DNA in Maternal Plasma

Ann NY Acad Sci 2004

KIRSTIN FINNING, PETER MARTIN, AND GEOFF DANIELS

Transfusion 2012

Report of the first nationally implemented clinical routine screening for fetal *RHD* in D– pregnant women to ascertain the requirement for antenatal RhD prophylaxis

Frederik Banch Clausen, Mette Christiansen, Rudi Steffensen, Steffen Jørgensen, Christian Nielsen, Marianne Antonius Jakobsen, Rikke Dyhrberg Madsen, Karina Jensen, Grethe Risum Krog, Klaus Rieneck, Ulrik Sprogøe, Keld Mikkelsen Hornburg, Niels Grunnet, and Morten Hanefeld Dziegiel

Noninvasive Fetal RhD Status Determination in Early Pregnancy

Fetal Diagn Ther 2014

Sebastian Manzanares[a] Carmen Entrala[b] Mar Sánchez-Gila[a] Francisco Fernández-Rosado[b] Davinia Cobo[a] Esther Martínez[b] Luis Molina[b] Rosa Reche[a] Alicia Pineda[a] José Luis Gallo[a]

Sensitivity of fetal *RHD* screening for safe guidance of targeted anti-D immunoglobulin prophylaxis: prospective cohort study of a nationwide programme in the Netherlands BMJ2016

Masja de Haas,[1,2,3] Florentine F Thurik,[1,4] Catharina P B van der Ploeg,[5] Barbera Veldhuisen,[1,3] Hoang Hirschberg,[6] Aicha Ait Soussan,[1] Heleen Woortmeijer,[3] Frithjofna Abbink,[7] Godelieve C M L Page-Christiaens,[4] Peter G Scheffer,[4] C Ellen van der Schoot[1]

TRANSFUSION MEDICINE Official Journal of the British Blood Transfusion Society

Transfusion Medicine | ORIGINAL ARTICLE

Fetal *RHD* detection from circulating cell-free fetal DNA in maternal plasma: validation of a diagnostic kit using automatic extraction and frozen DNA

D. Londero,[1] T. Stampalija,[2] D. Bolzicco,[1] E. Castro Silva,[2] M. Candolini,[1] C. Cortivo,[2] C. Dreossi,[1] I. Fantasia,[2] V. Pecile[2] & V. De Angelis[1]

[1]*Department of Transfusion Medicine, ASUI-Udine, Udine, Italy, and* [2]*Unit of Fetal Medicine and Prenatal Diagnosis, Institute for Maternal and Child Health, IRCCS Burlo Garofolo, Trieste, Italy*

Received 30 March 2018; accepted for publication 5 May 2019

Screening prenatale RHD fetale Regione Friuli Venezia Giulia

- Guidare l'appropriatezza nella somministrazione della profilassi anti-D
- Ridurre consumo emoderivati

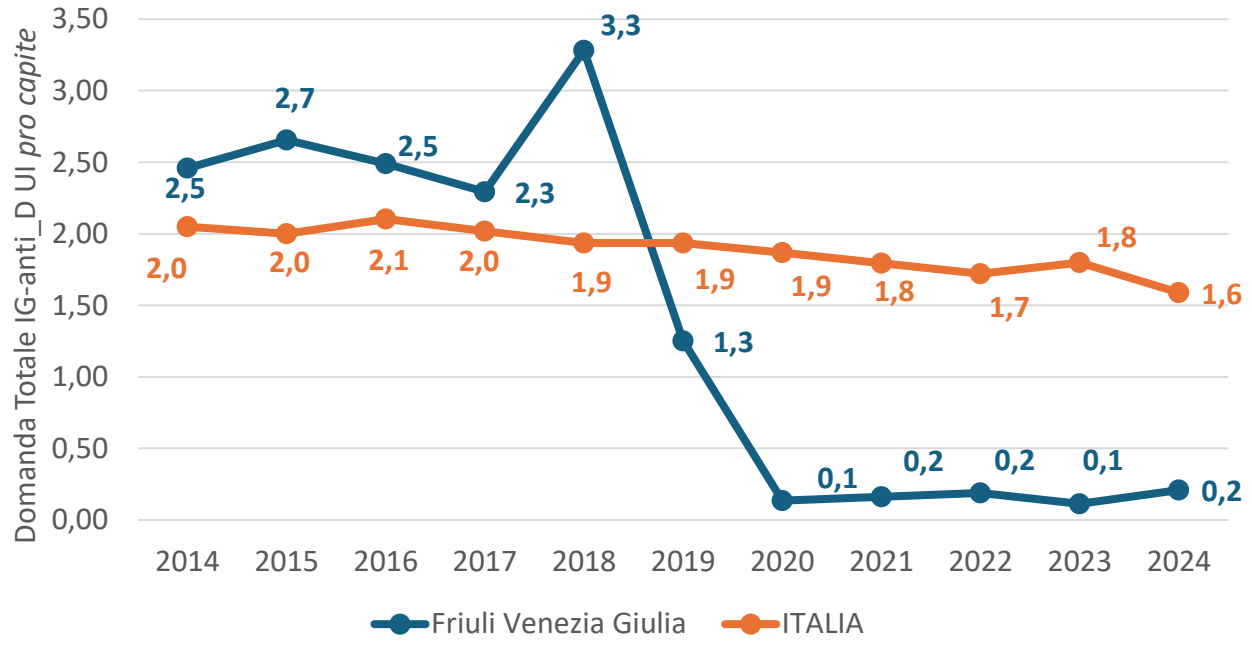
PLASMA ITALIA

CENTRO NAZIONALE SANGUE

Domanda Totale di Ig anti-D – Anni 2014 - 2024 (FVG vs Italia)

Regione	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
				UI	UI	UI	UI	UI	UI	UI	UI
Friuli V. Giulia	3.022.250	3.259.500	3.040.500	2.791.500	3.988.750	1.520.250	162.000*	195.000	225.000	135.000*	249.000*
ITALIA	**124.569.375**	**121.566.000**	**127.620.125**	**122.330.125**	**117.007.375**	**116.867.750**	**111.419.375**	**106.277.375**	**101.433.500**	**106.128.750**	**93.692.625**

*Domanda privata



Fino all'anno 2018 la domanda *pro capite* della Regione Friuli V. Giulia superava la domanda *pro capite* nazionale.

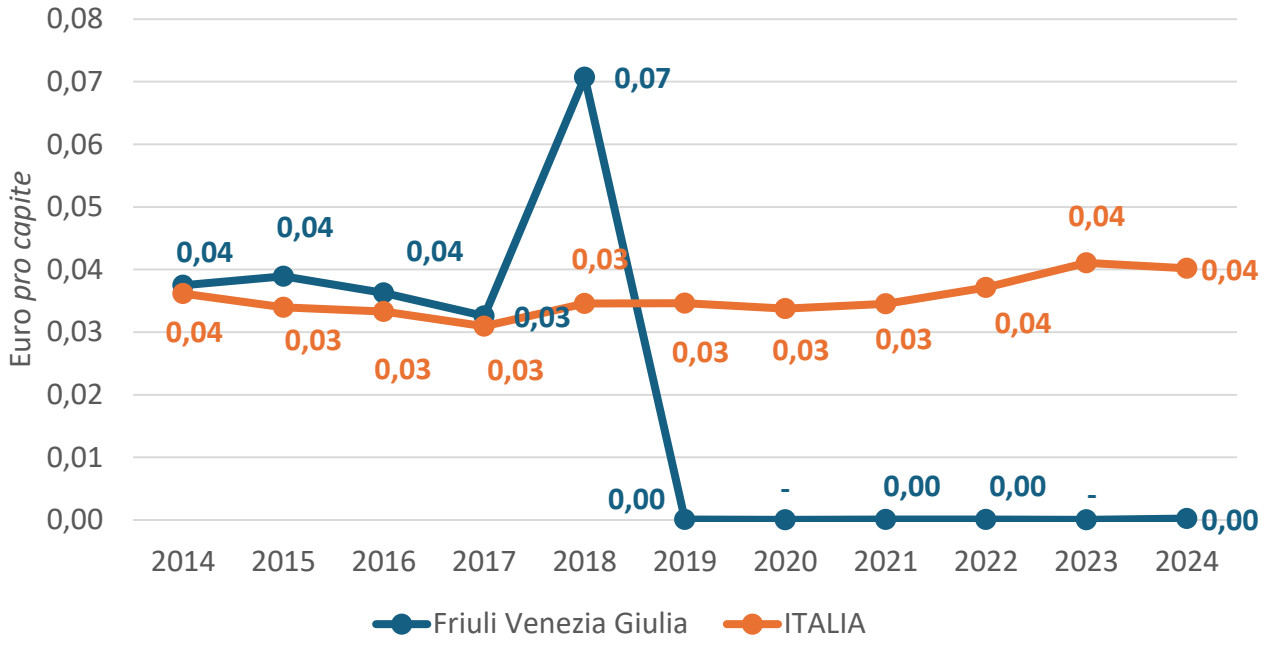
Dati Preliminari

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

Stima della spesa per l'acquisto di Ig anti-D – Anni 2014 - 2024 (FVG vs Italia)

Regione	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	2024
	Euro p.c.	Euro p.c.	Euro p.c.	Euro p.c.	Euro p.c.	Euro p.c.	Euro p.c.	Euro p.c.	Euro p.c.	Euro p.c.	Euro p.c.
Friuli V. Giulia	0,04	0,04	0,04	0,03	0,07	0,00	-*	0,00	0,00	-*	0,00*
ITALIA	0,04	0,03	0,03	0,03	0,03	0,03	0,03	0,03	0,04	0,04	0,04

*Domanda privata

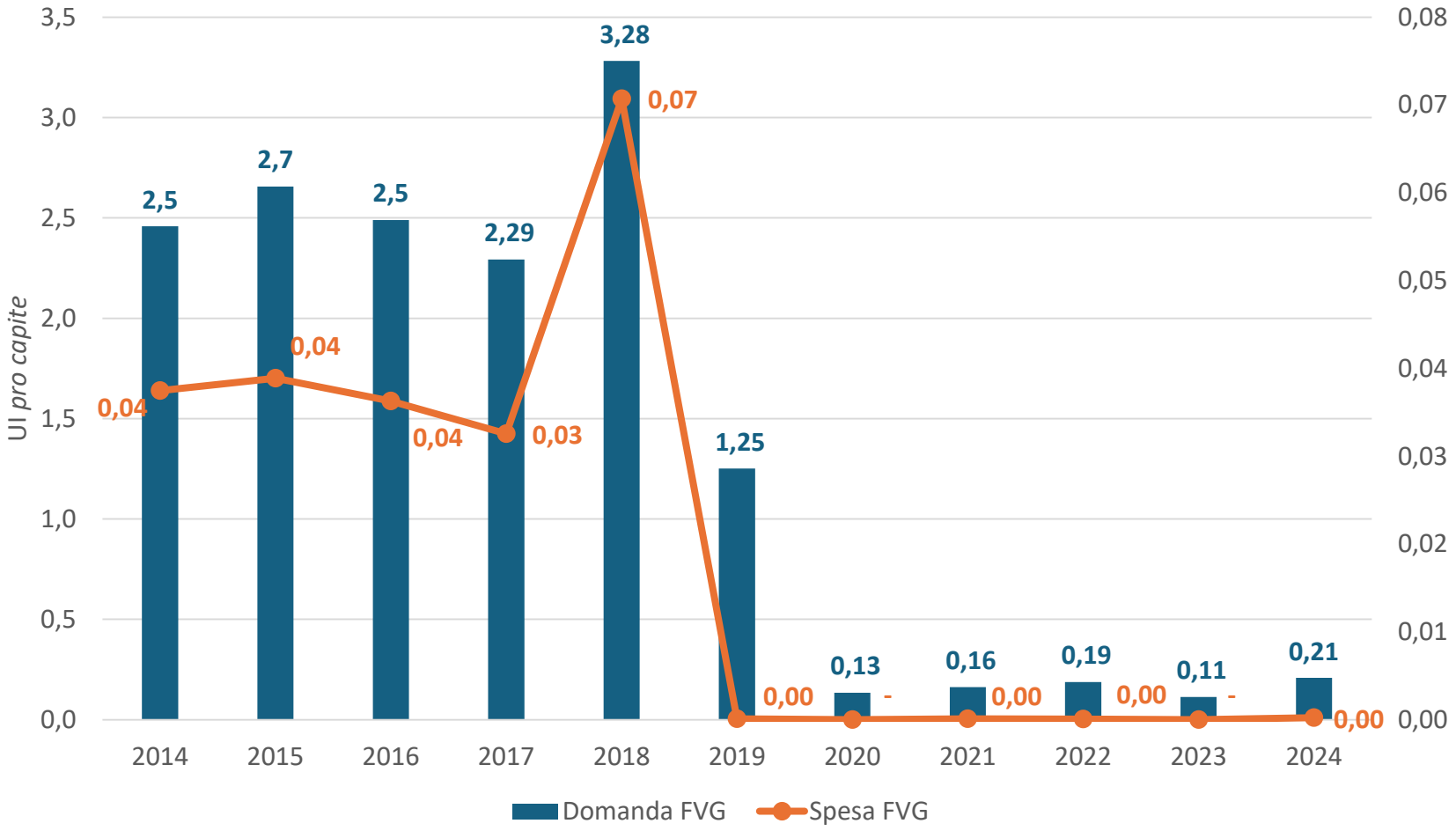


Fino all'anno 2018 la spesa *pro capite* della Regione Friuli V. Giulia superava la spesa *pro capite* nazionale.

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

Dati Preliminari

Domanda totale e spesa per le ig anti-D – Regione Friuli V. Giulia



Domanda 2014: **3.022.250 UI** (**2,5 UI/*pro capite***)

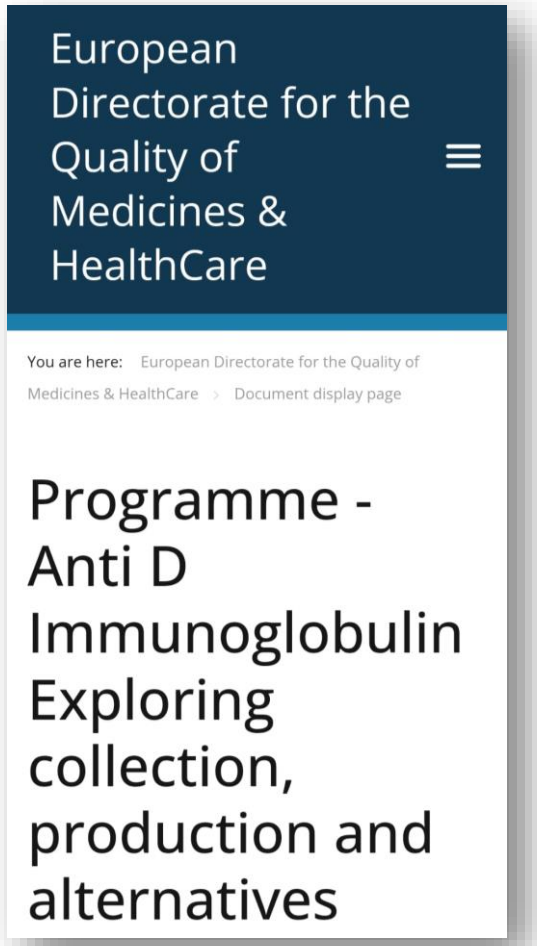
Domanda 2024: **249.000 UI** (**0,21 UI/*pro capite***)

Stima della Spesa SSN 2014: **euro 45.756** (**0,04 euro/*pro capite***)

Stima della Spesa SSN 2024: **euro 259** (la domanda registrata risulta essere sostanzialmente tutta domanda privata)

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

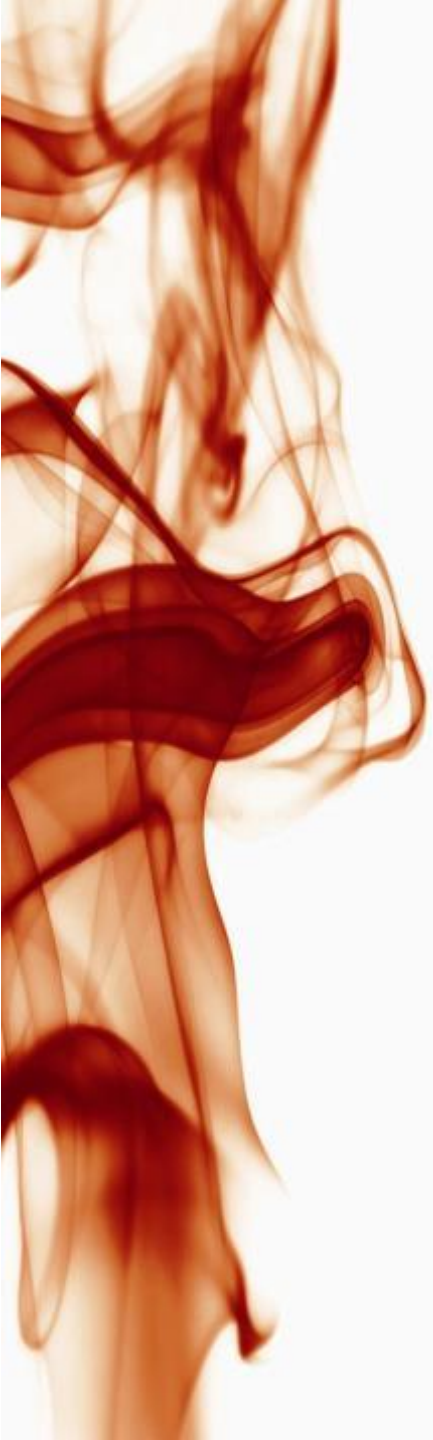
Riflessioni in corso



CENTRO NAZIONALE SANGUE
Istituto Superiore di Sanità

- **Appropriatezza d'uso delle Ig anti-D in gravidanza: implementazione di un programma unico di gestione razionale dell'immunoprofilassi prenatale**

PLASMA ITALIA



ONLY ONE

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Grazie per l'attenzione