



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

28-29 April 2022 - Rome, Italy

CENTRO NAZIONALE SANGUE



with the patronage of





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28-29 April 2022

PLASMA IS «STRATEGIC» AND «ESSENTIAL».

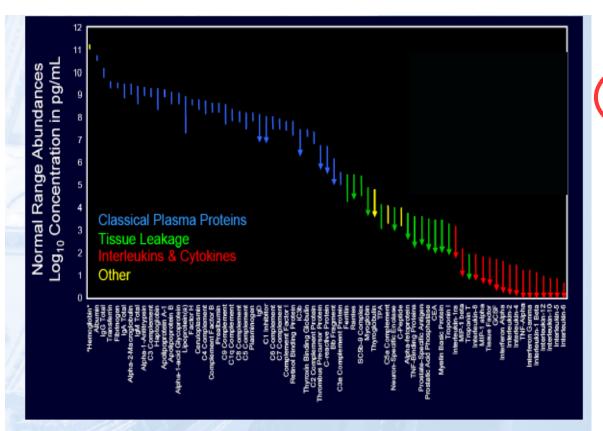


More than 1.000 plasma proteins...

Out of which around 250 identified

117 can be detected by a FDA validated test

Around 20 proteins are commercially available to be used in human therapy, effective, well tolerated and safe as to the transmission of infectious diseases



albumin	(47)	- fibrinogen	(7)
immunoglobulin (G)	(40)	- thrombin	(3)
IgM	(1)	- fibrin sealant	(9)
factor VIII	(26)	- prothrombin complex	(15)
- factor IX	(16)	- activated prothrombin	
- factor VII	(2)	complex	(1)
- factor XI	(2)	- antithrombin	(14)
factor XIII	(1)	- alpha-1 antitrypsin	(5)
protein C	(2)	- C1-inhibitor	(2)
activated protein C	(1)	- haptoglobin	(1)
von Willebrand factor	(3)	- SD-plasma	(3)



PLASMA IS «LIMITED» BUT «AVAILABLE»

There are restrictions that bring the available population of blood donors down to **37**% of a country's population. Unfortunately, **less than 10**% of that population actually do so on an annual basis. https://www.sbmf.org/the-importance-of-blood-donations/

90% of people who are eligible to donate blood are not currently doing so. https://www.euro.who.int/en/health-topics/Health-systems/blood-safety/data-and-statistics

The collection, testing and use of **BLOOD AND BLOOD** COMPONENTS in Europe



European Committee on Blood Transfusion CD-P-TS EDQM 2016 report







Table 1 Survey 2016

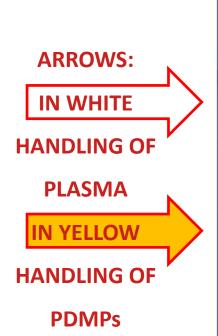
Donors, first time donors and inhabitants

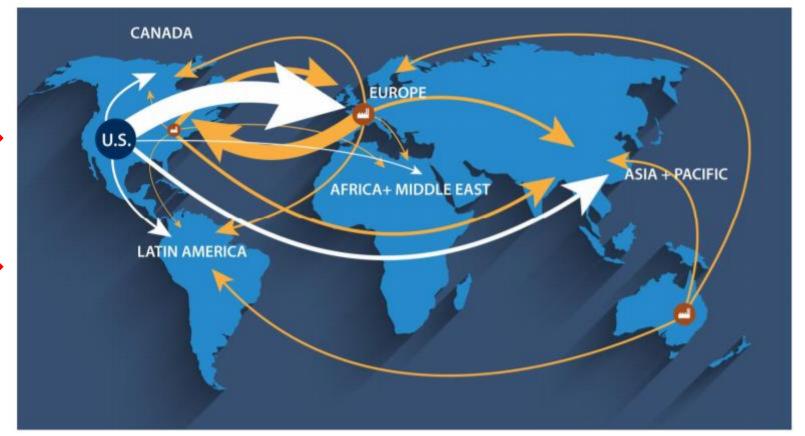
Country	Regular & Repeat Donors	First Time Donors	% First Time Donors	% First Time Donors Donating	% First Time Donors Tested only	Total Donors	Inhabitants (Millions)	Donors per 1 000 Inhabitants
Armenia	4 877	6 813	62	100	NA	10 911	2 999	4
Austria	211 341	34 420	14	99	3	244 411	8 765	28
Croatia	79 940	16 016	17	100	NA	95 956	4 171	23
Cyprus	18 601	1 185	6	100	0	19 786	0 326	61
Czech Republic	236 334	43 770	16	100	NA	273 842	10 579	26
Denmark	115 365	28 294	22	55	45	130 942	5 731	23
Estonia	27 851	5 303	16	100	0	33 154	1 316	25
Finland	105 706	13 999	12	95	5	119 705	5 731	22
France	1 336 814	283 261	18	99	NA	1 616 268	66 991	24
Georgia	32 833	13 276	20	100	0	67 690	3 907	17
Germany	2 069 571	416 308	22	86	14	1 934 014	82 522	23
Greece	308 781	61 756	17	70	30	370 537	10 500	35
Hungary	216 541	51 863	100	100	0	51 683	9 830	5
Ireland	69 391	12 048	15	85	15	81 439	4 758	17
Italy	1 370 556	401 748	24	69	31	1 687 627	60 666	28
Malta	NA	2 040	17	100	0	11 984	0 476	25
Republic of Moldova	44 989	18 570	29	100	0	63 559	3 553	18
Montenegro	8 423	4 835	33	100	0	14 621	0 620	24
Norway	108 682	19 031	19	50	50	99 166	5 258	19
Poland	464 715	156 447	25	NA	NA	621 162	38 437	16
Portugal	186 771	30 660	14	100	0	217 431	10 325	21
Romania	221 672	111 830	34	100	NA	333 502	19 710	17
Slovak Republic	113 820	32 254	23	78	22	139 063	5 429	26
Slovenia	52 452	9 548	15	100	0	62 000	2 063	30
Spain	955 560	220 901	19	NA	0	1 176 461	46 299	25
Sweden	185 493	28 293	13	NA	NA	213 786	9 992	21
Switzerland	206 958	25 387	11	100	0	232 345	8 400	28
United Kingdom	907 006	181 011	17	89	1	1 088 017	65 648	17

NA = Not Available

PLASMA IS "GLOBAL" HANDLING OF PLASMA AND PDMPs IN THE WORLD 2019







TOTAL PLASMA

FRACTIONATED

69 M LITERS

Courtesy of: D. Medica on behalf of GAEF – Gruppo Aziende Emoderivati Farmindustria adapted from P.Robert «Dans un Marché Mondialisé, Quel Accès des Patients Français aux Médicaments Dérivés du Plasma »?, November 11, 2020



PLASMA IS "PRICELESS" BUT NOT "COSTLESS"

While interventions on red blood cells transfusion caused its gradual decline, falling by almost 40% in some countries, a huge increase in the demand of some PDMPs (IG and albumin) led to an **impressive increase in plasma demand** making the plasma industry one of the most profitable: in 2020, plasma-derived medicines generated \$4.6 billion in sales in the EU (excluded UK)

Self-sufficiency in plasma products can and should be achieved only in relation to:

- appropriate demand
- evidence-based use of products under guidelines
 - formulated on the basis of well-designed, sufficiently powered and unbiased independent studies
 - accepted by professionals and scientific societies



PLASMA IS "HUMAN"

«Homo sum, humani nihil a me alienum puto» (P. Ter. Afer)

Unless appropriate manufacturing steps are introduced, every infectious agent present in blood is to be transfused to patients

33% of blood donations on average are given by women, although this ranges widely

Proportionally, more young people donate blood in low- and middle-income countries than in high-income countries

There are ethical reasons in plasma sector in favour of both donors and recipients





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♦ PLASMA

Welcome!