



Belgium

Recent program to increase plasmapheresis for PDMP

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Belgian Red Cross



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Facts & Figures: Belgian Blood Banking system

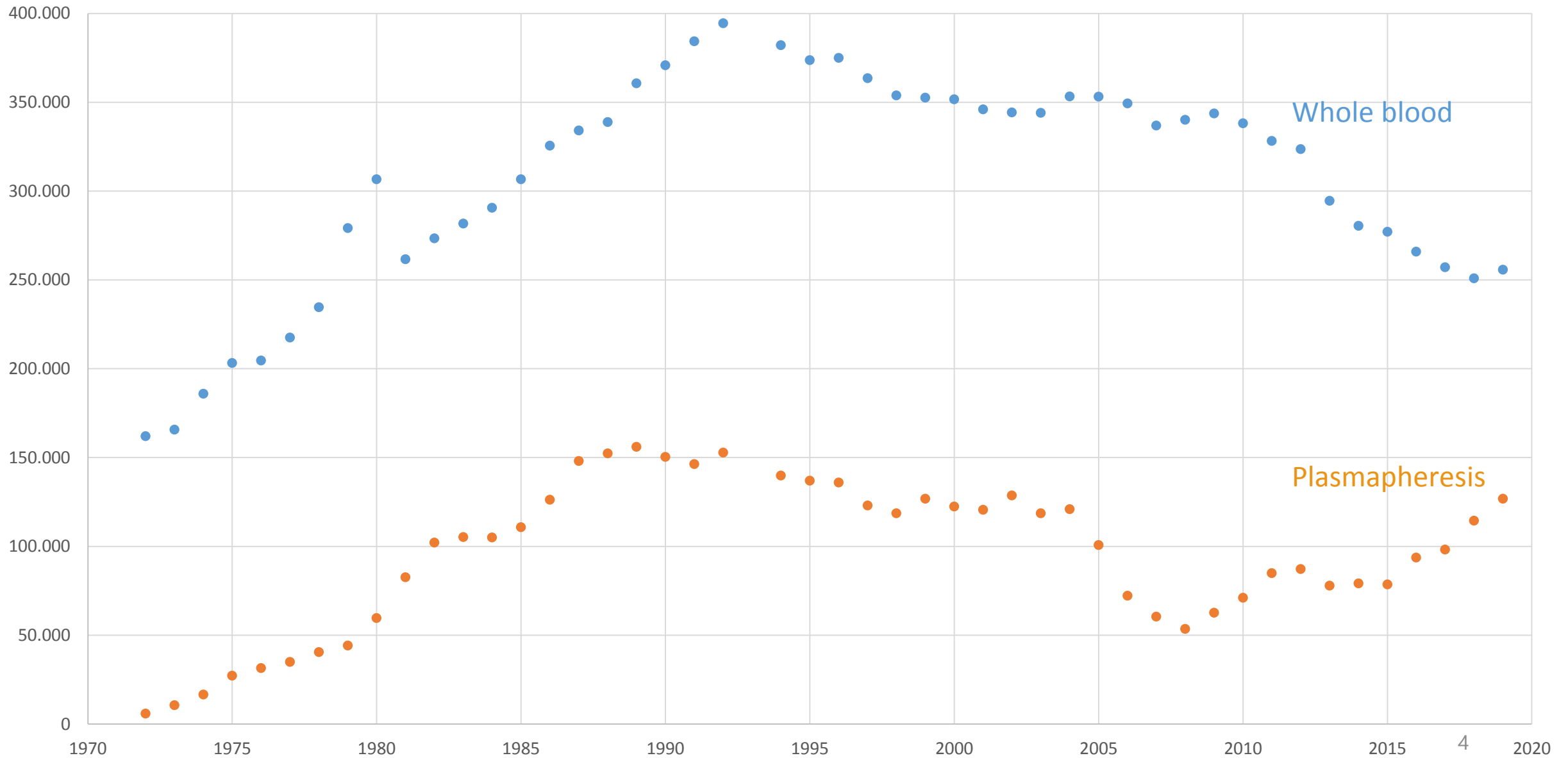
- 11,5 million inhabitants
- Separate legislation
 - Labile blood products (100% self-sufficient)
 - Stable blood products / PDMP (50% self-sufficient)
- Universal VNRD (whole blood, plasma, platelets)
- Responsibilities
 - Federal Ministry of Health
 - Competent authority: Federal Agency for medicines and health products



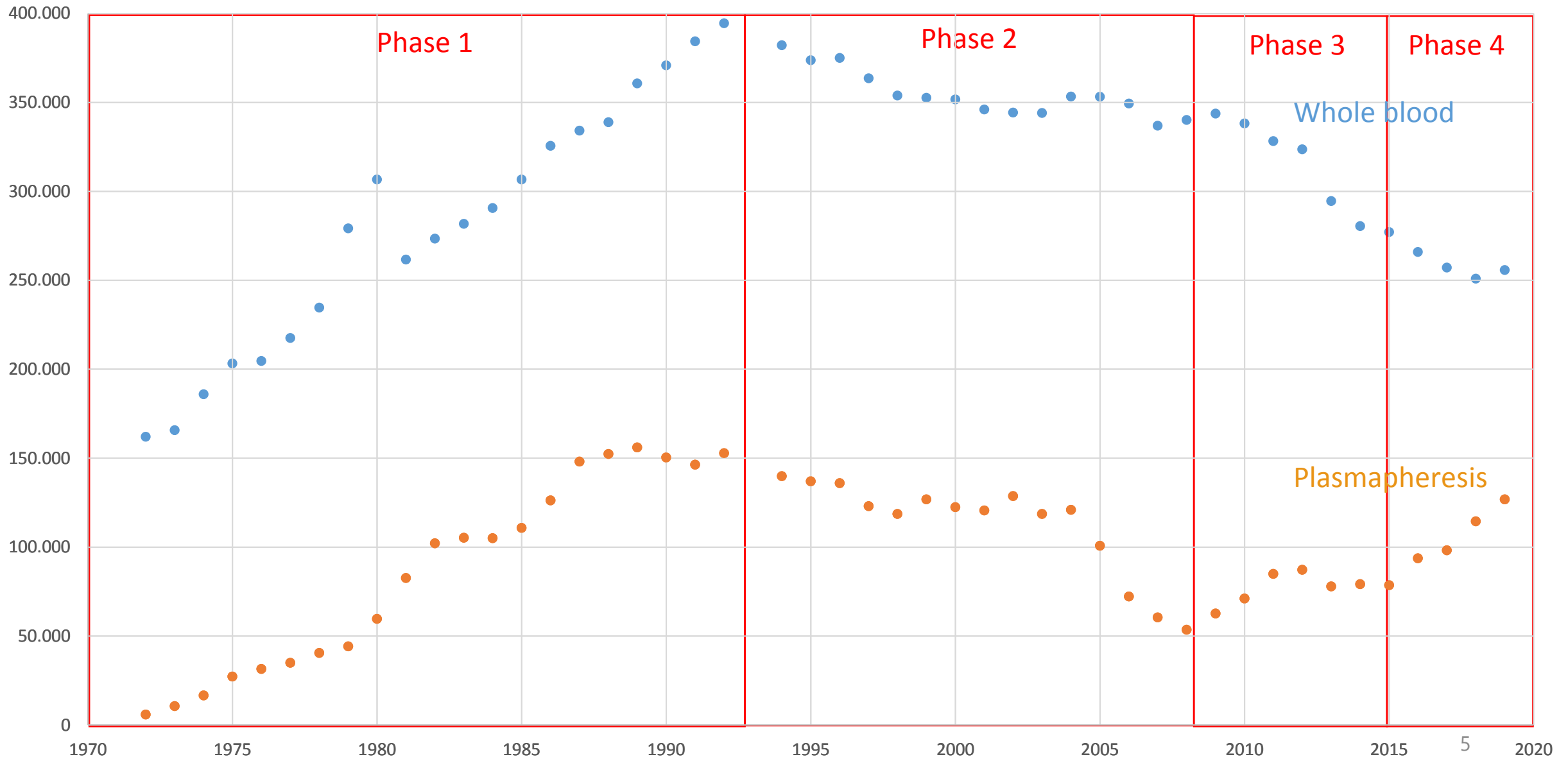
4 Licensed Blood Establishments

	Blood Establishment	% RBC
Flanders	Belgian Red Cross – Flanders	62
Frenchspeaking part	Belgian Red Cross - french community	32
	University Hospitals Charleroi	5
	University Hospitals Mont-Godinne	1

Historical overview of donations *(Flanders, Belgium)*



Historical overview of donations (Flanders, Belgium)



Initiative Belgian Government: measures taken

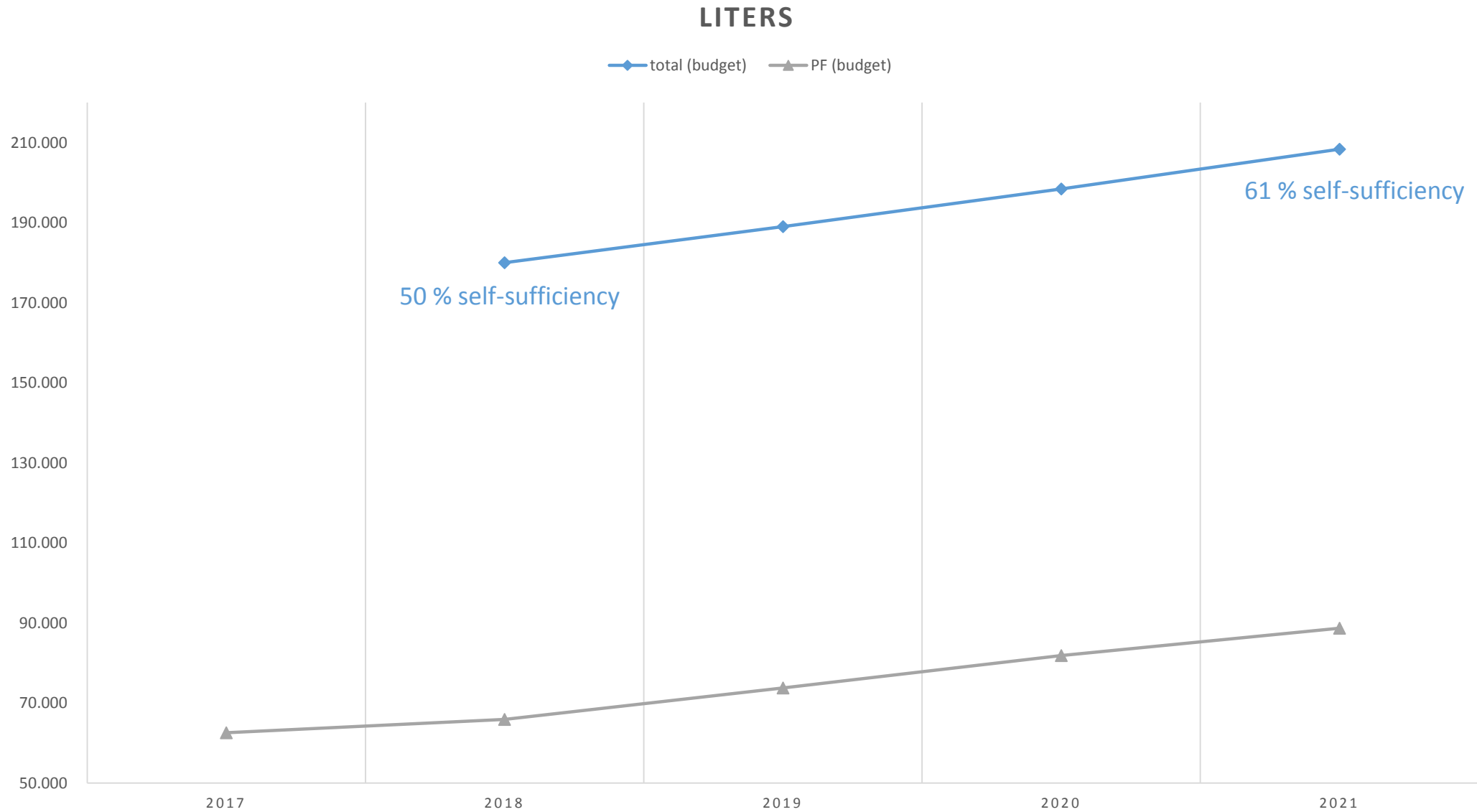
- Aim
 - risk mitigation for Belgian patients (access; price of end product)
 - fairness
- Roles & responsibilities
 - Blood Establishments: collection
 - + 5% / year over 4 years
 - Commercial companies: fractionation & distribution & sales
 - on the basis of 4-yearly tender
 - Belgian government: "honest" broker
- Tender for 50% of IVIG market (as driver) / 100 % albumin
- Specifications
 - Belgian plasma returns preferentially to Belgian patients
 - mandatory use of PDMP by hospitals at prices set by the MOH (thus controlling price setting)
 - surpluses (f.i. albumin) can be used abroad with approval of the MOH
 - strategic stock of
 - plasma: 2 months ($180.000/12 = 15.000 \times = 30.000$ L)
 - PMDP: 3 months
- Tender started 12/2017; won by CSL
 - new tender starts 12/2021
 - evaluation by different stakeholders by government planned



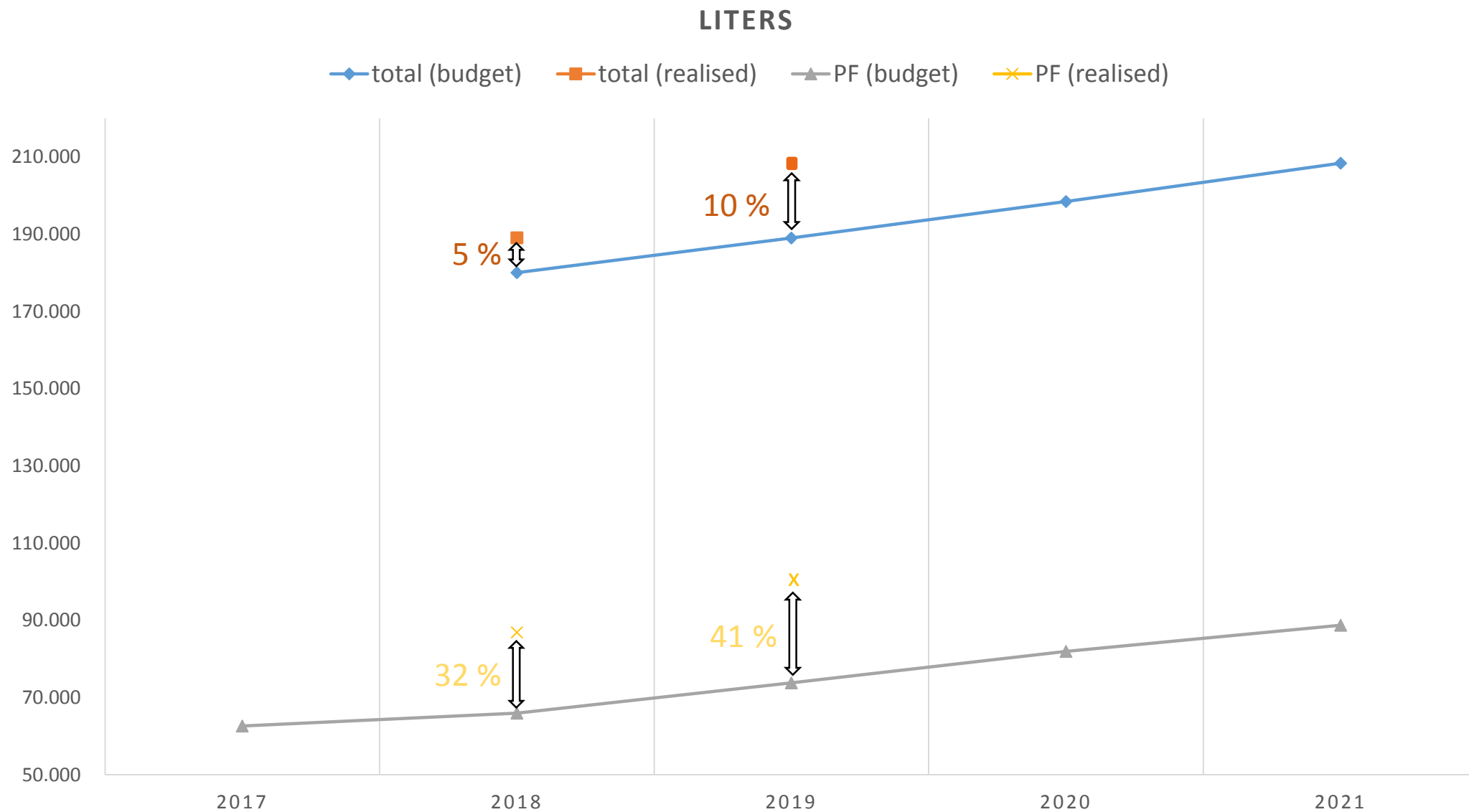
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Initiative Belgian Government: plasma budgeted

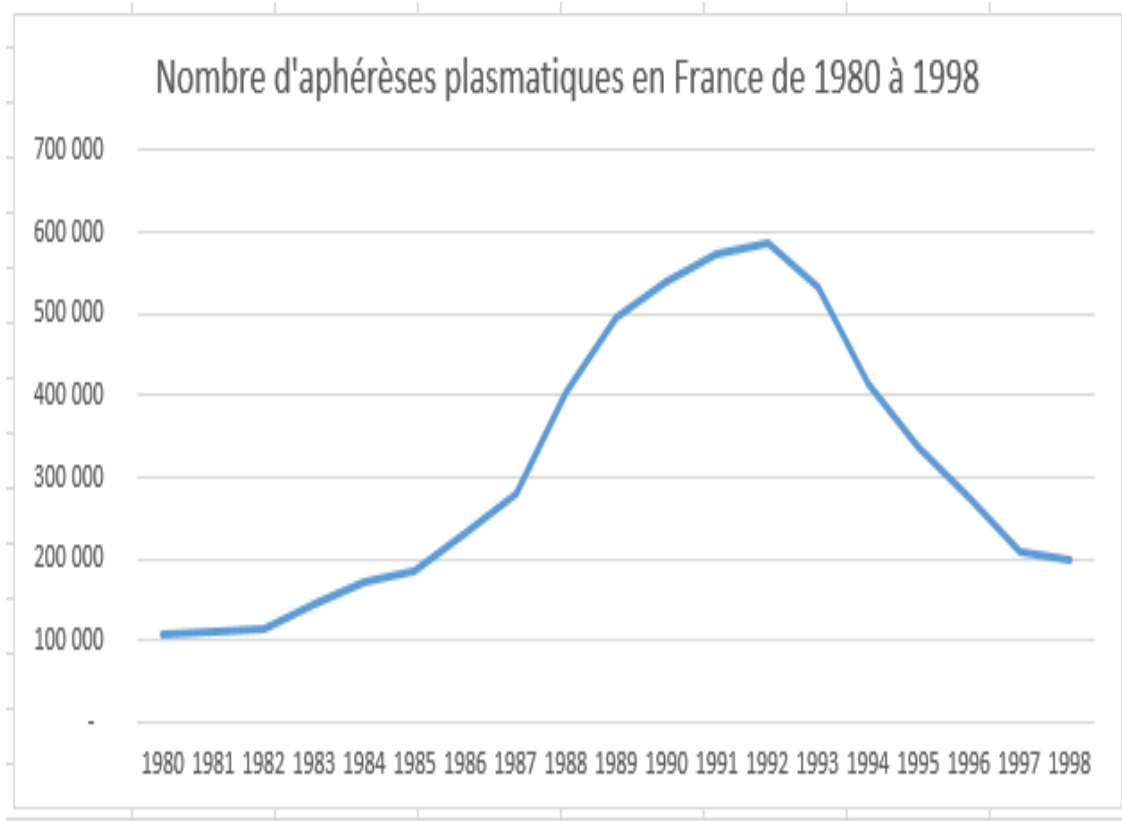


Initiative Belgian Government: plasma collected 2018/19



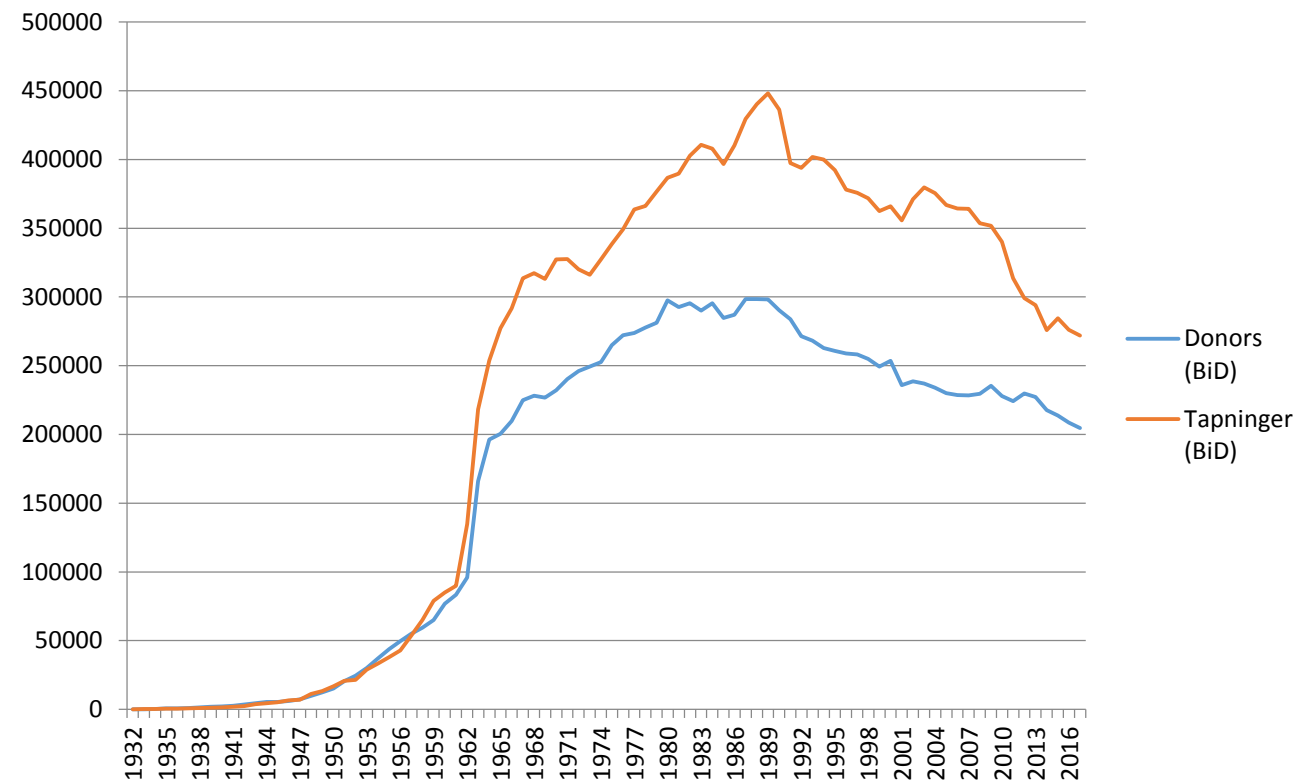
Similar pattern of PF donations in other countries

France



Courtesy EFS – A. Volle

Denmark



Courtesy J. Georgsen

Conclusions

- introduction of EU common market for pharmaceuticals w/o accompanying measures to ensure minimal levels of plasma sourcing from within EU
 - overlooked consequences that do not exist for chemical-derived pharmaceuticals:
 - import of cheaper plasma from outside EU
 - which led to erosion of the plasma donor base in many EU countries
- Belgian self-sufficiency
 - was/is 100 % for labile blood products that it legislates itself
 - was 100 % for stable blood products till introduction of EU common market, then dropped to 50%
 - lost 30 years because of this: will reach 1990 level in \pm 2022
- Belgian approach: possible to collect significant and increasing amounts of plasma
 - Without financial compensation or separate approaches
 - i.e. by expanding collection capacity & by traditional communication
 - but does require LT predictability of donor base management
 - regulatory conditions (re)created by Belgian government (*50% of market & locally*)
 - achieving higher EU independence for PDMP requires derogation of EU common market legislation to mandate minimal levels of sourcing from within EU (*f.i. annual increase over 10 yrs*)



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