

# **PARTNERS: Procurement of Affordable Replacement Therapy- Network of European Relevant Stakeholders**

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ECRD, Vienna 2018

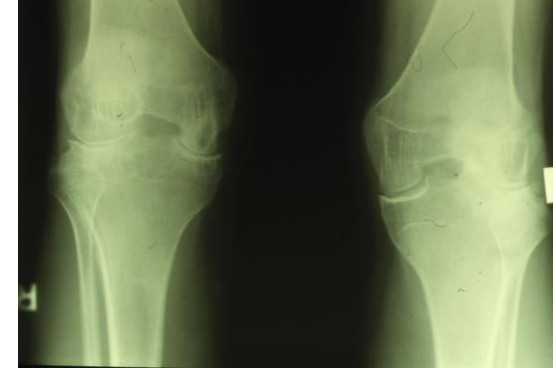
# Haemophilia

- Inherited bleeding disorders- A ( FVIII) and B (FIX)
- Carried on X chromosome
- Females are carriers, mainly affects males
- Von Willebrands- affects both males and females
- Rare bleeding disorders: inherited deficiency of other coagulation factors (FV,FVII, FX,FXI, FXIII)



# Haemophilia - Severity

- Severe < 1%
- Moderate 1 to 5 %
- Mild 5 to 40%
- Severe - spontaneous bleeds



Aura

Pain, Heat,

Swelling

Damage

Early Treatment



# Haemophilia Treatment

## Treatment regimes:

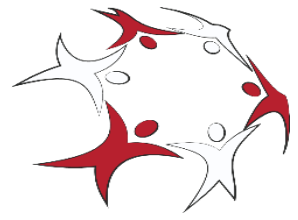
- **On- demand.** Treat bleeds when they occur
  - does not prevent joint damage
  - early treatment...at home is essential
- **Prophylaxis**- treat to maintain FVIII or FIX level above 1% to prevent spontaneous bleeds and preserve joint function
- Prophylaxis is optimum treatment for both children and adults



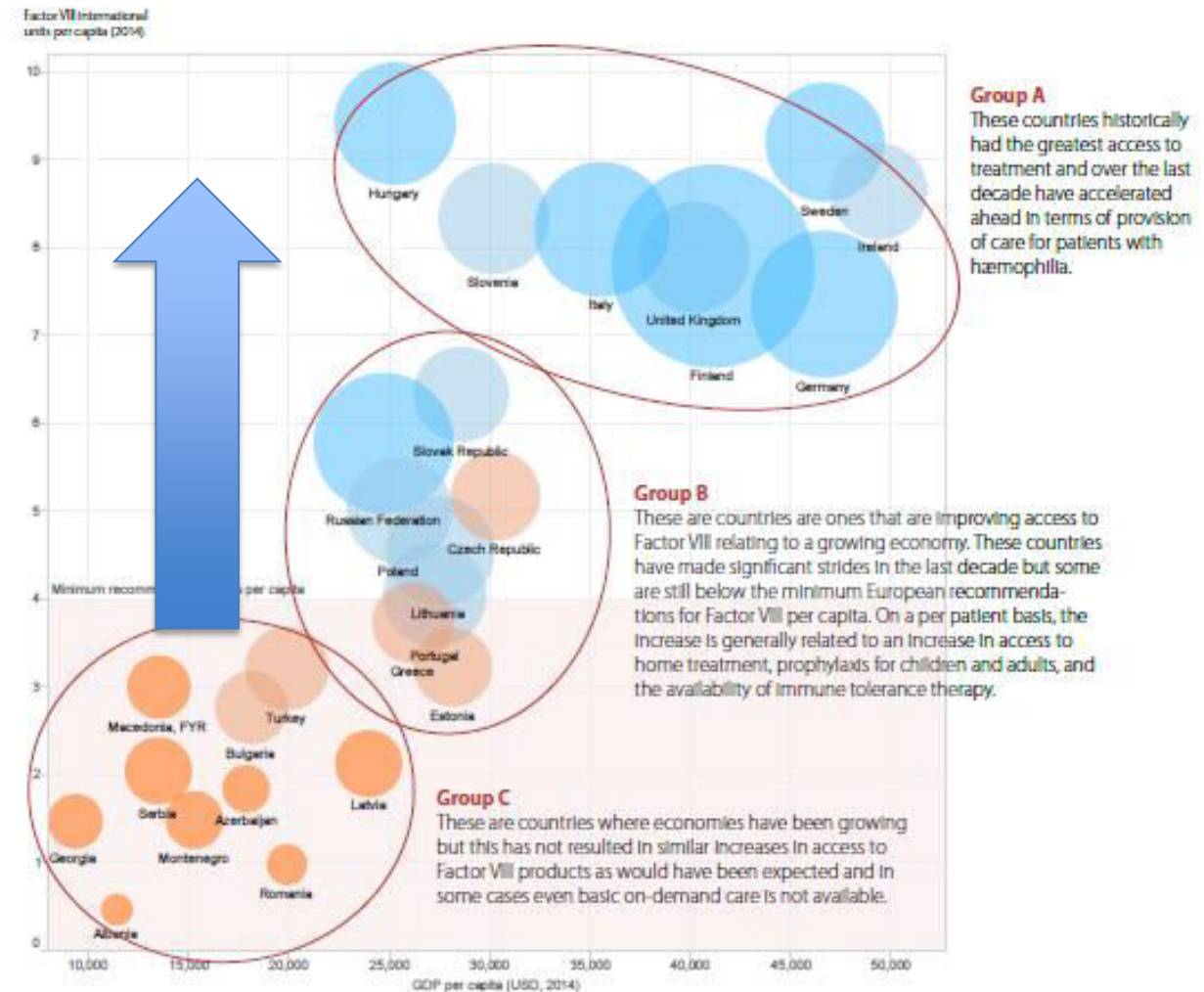


# EHC Survey 2015

## Significant disparity of access across Europe



- 3 Distinct Groups
  - Countries who have had access and are accelerating in terms of access
  - Countries who have had limited access with limited economic resources but improvements in co-ordination of care and tendering have resulted in improvements
  - Countries with limited resources with disparate approaches to care and purchasing
- **PARTNERS** programme assists countries to move beyond economic constraints!!



# Barriers to achieving minimum levels of factor use

- Cost – economics
- Reference pricing – companies unable to sell at lower price in emerging countries
- Lack of or ineffective national tender/procurement process
- Lack of involvement of clinicians/NMO representatives in tender/procurement
- 1 year budget cycles and tenders – no medium term planning
- *Systematic inertia*

# Proposed solution

- Real and sustainable increase in access to factor concentrates at affordable cost
- European countries who meet defined criteria would be certified by EHC as eligible for inclusion in programme
- Companies agree to provide FVIII/FIX below a ceiling price which is significantly lower than the European median price
- Procurement would be for initial 3 year term
- Countries would have to purchase more than current amount – at least doubled over 3 years until EDQM minimum achieved

# Inclusion criteria based on EDQM 2016 and 2013 Recommendations

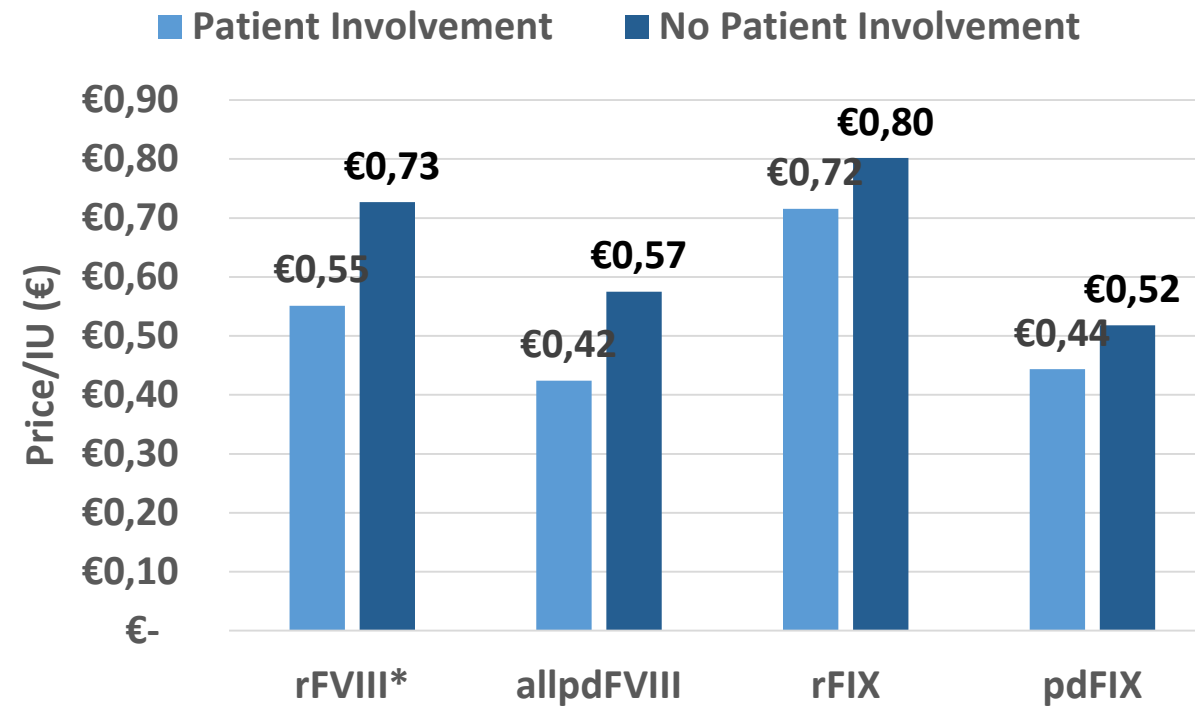
Recommendation 3\*: The minimum consumption of factor VIII concentrate in any country should be 4 IU/capita of general population.

Recommendation 4\*: The minimum consumption of FIX concentrate in a country should be 0.5 IU/ per capita of general population.

Recommendation 9\*: National or regional tenders for factor concentrates are encouraged and should always include both haemophilia clinicians and national haemophilia patient representatives.

Recommendation 4\*\* (2013): Prophylaxis for children with severe haemophilia is already recognised as the optimum therapy

# Economic Impact of clinician and Patient Involvement in National Tenders



# PARTNERS - Initial eligible countries

- Albania
- Armenia
- Azerbaijan
- Belarus
- Bosnia- Herzegovina
- Bulgaria
- Estonia
- Kyrgyz Republic
- Latvia
- Macedonia
- Romania
- Serbia
- Turkey
- Ukraine



# FVIII 4 IU per capita potential increased use per year

Country	Total IU 390 (million)
Albania	10.1
Armenia	11.7
Azerbaijan	21.3
Belarus	20.0
Bosnia-Herzegovina	12.5
Bulgaria	13.7
Estonia	1.7
Kyrgyz Republic	23.4
Latvia	3.8
Macedonia	2.1
Romania	59.4
Serbia	14.2
Turkey	47.2
Ukraine	149.1

# PARTNERS- Progress to date

- Visits to 10 countries to meet with Health Ministry, Clinicians and Haemophilia patient organisation
- Scoping exercise on current tender/procurement system in each country and identification of barriers and opportunities
- PARTNERS Advisory Board established with participation from pharmaceutical companies – Kedrion, Sobi, Pfizer
- Major progress in several countries
- First Ministries of Health to agree participation
  - Albania, Kyrgyz Republic, Ukraine



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# PARTNERS Beyond Procurement...

- Patient Benefits
  - Immediate increase in access
  - Planned progress on a National level
  - Involvement in product choice
  - Platform for regular discussion and interaction with payers and Ministry of Health
  - Key role in national programme development
  - Minimise the likelihood of shortage
  - Increased Transparency
  - Improvement in National Treatment Protocols
  - Improvement in local access

# PARTNERS Beyond Procurement...

- Clinician Benefits
  - Planned progress on a National level
    - Surgery, prophylaxis, ITI
  - Define national protocol on product choice
  - Key role in national programme development
  - Minimise the likelihood of shortage in Centres
  - Different cost structure allows for greater investment in haemophilia care

# PARTNERS Beyond Procurement...

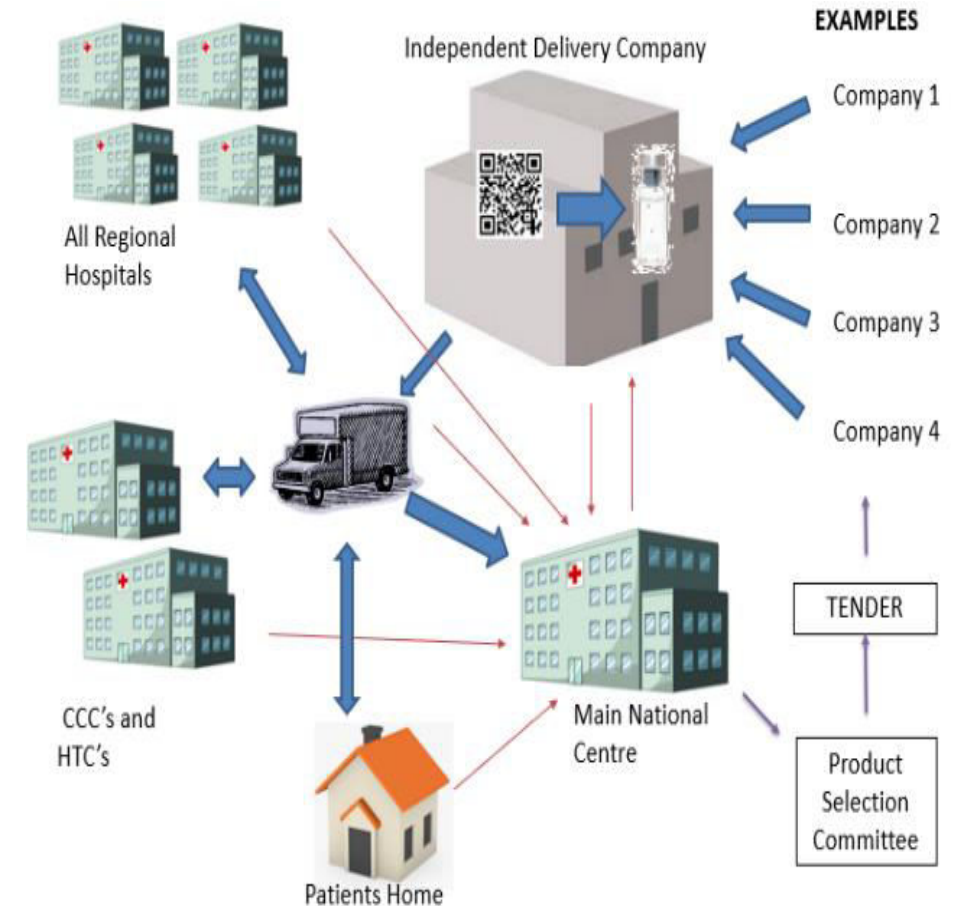
- Payer Benefits
  - Transparency of National Spending and Procurement
  - Improved Stock control
  - Significant increase in access
  - Greater predictability of hospital budget over long term
  - Greater predictability of supply
  - Optimum choice of products chosen by experts
  - Ensures optimum Budget allocation

# PARTNERS Beyond Procurement...

- Benefits for Pharmaceutical companies
  - Certainty on volumes of factor to be purchased
  - Significant increase in volumes of factor purchased
  - Allows for optimised planning and forecasting
  - Assisting in development of sustainable treatment
  - Fulfilling duty of social responsibility

# Ensuring PARTNERS get treatment to where it is needed

- Parallel Importing Issues\*
- National Health System owning product title
  - Distributors provide Logistic services
- Defined Volumes contracted over 3 year contract
- Direct Provision of product to patients homes
- Track and Trace system
  - Falsified Medicines Directive 2019



\*<https://www.politico.eu/pro/q-and-a-with-romania-s-health-minister-florian-bodog/>

# Example: Romania -31 separate tenders for CFC's



4 Hospitals hemophilia programmes in Bucharest

# Example: PARTNERS Albania

## Current Process

- 2016
  - 0.87 IU/capita
  - **2.5 million IU**
  - 120 – 150 patients.
  - Sporadic budget availability
  - Large purchase off contract on emergency basis

## PARTNERS Programme

- Year 1
  - **4 million IU vs. 2.5 million IU in 2018 for the same budget.**
- Years 2 and 3
  - Small increase per year in budget after year 1
- **3 year contract 16.5 million IU of FVIII (±20%).**

# Changing the future

- Haemophilia market is changing with more SHL, EHL CFC's and novel products coming on the market – increasing competition
- We do not want to see a situation where increased access to treatment and care is limited to well resourced countries
- Access to treatment must improve at a faster pace in many countries
- PARTNERS will help countries to increase access to treatment by assisting with organisation and economic viability of procurement