What is the aim of the PARTNERS programme?

The recommendations of the Council of Europe's European Directorate for the Quality of Medicines and Healthcare (EDQM) on best practices on managing haemophilia care recommend minimum treatment levels of 4 International Units (IU) factor VIII replacement therapy per capita, minimum treatment levels of 0.5 IU factor IX replacement therapy per capita, and the establishment of national or regional tenders for factor concentrates that include both haemophilia clinicians and national haemophilia patient representatives. However, in several countries with developed healthcare systems but highly limited budgets, the volumes of factor replacement necessary to effectively treat haemophilia are not available.

In order to bridge the gap between the EDQM recommendations and current access in those countries, the EHC has developed the Procurement of Affordable Replacement Therapies - Network of European Relevant Stakeholders (PARTNERS) programme. This is a new and innovative approach to the sustainable procurement of treatment products for haemophilia A and haemophilia B in select countries meeting EHC specified criteria and located both inside and outside of the European Union. The programme aims to:

1. Assist countries to enable them to provide adequate levels of factor concentrate to improve access to treatment for people with haemophilia.
2. Involve clinicians and patient representatives in the procurement process to seek to improve treatment sustainability for healthcare systems.
3. Encourage participation by companies in tender or procurement processes that seek to improve standards of care for people with haemophilia within these countries.

What Countries are eligible?

A specific set of European countries that meet the following criteria will be eligible for inclusion in the PARTNERS programme. These eligibility criteria are:

- Countries that currently use less than 4 IU per capita of FVIII replacement therapy and/or currently use less than 0.5 per capita of FIX replacement therapy;
- Prophylactic treatment is not available to all children with severe haemophilia;
- Countries that are willing to use national-level tender or procurement processes for coagulation factor concentrates; and
- Countries where the national government, healthcare providers, National Member Organisations (NMOs) and manufacturers agree to participate in the PARTNERS programme.

What are Countries' commitments?

Countries committing to involvement agree to:

- Use national-level tender or procurement processes for coagulation factor concentrates;
- Include clinicians and EHC NMO representatives on a long-term basis in the tender/procurement system;
- Award contracts to the winning bid(s) of at least a three-year duration; and
- Increase factor purchase without decreasing the national haemophilia budget and agree in principle to at least double the current national purchased amount of factor replacement therapies over the three year duration of contracts awarded or until the minimum IU/per capita set by the European Directorate for the Quality of Medicines and Healthcare (EDQM) at any given time is met.

What are the company commitments?

The development of PARTNERS also requires the commitment of companies manufacturing haemophilia products. To make the programme successful, by achieving a sustainable level of access to products for patients in eligible countries (with the option to opt out from no more than three participating countries), companies committing to involvement in the programme must express a willingness to participate in the national tender/procurement processes of the eligible and participating countries and agree to provide those therapies in the participating countries at a price below a maximum price.

How will PARTNERS work in conjunction with local authorities?
All tenders or procurement processes will be run by the national authorities under national tender or procurement procedures. The program will not limit supply and the price cap is intended to ensure that prices do not increase.

Is this sustainable?
Under the PARTNERS programme, individual countries agree to increasing factor purchase volumes without decreasing the national haemophilia budget, and agree in principle to at least double the current national purchased amount of factor replacement therapies over the three-year duration of contracts awarded or until the minimum IU/per capita set by the EDQM at any given time is met. To facilitate this, participating companies must offer to provide those therapies in the participating countries at a price below a maximum price.

How will regulatory compliance/market approval work in countries where the coagulation product is not already licensed?
Regulatory compliance will vary between countries and this will be discussed during initial meetings with countries regarding the project.

How will product safety be ensured?
All recombinant products are registered with the EMA and all plasma derived products are registered with competent authorities and the participating manufacturers have established histories of good manufacturing processes and proven safety and efficacy.

What additional assistance exists for patients and clinicians?
It is important to maximising the benefits of the programme that there is meaningful involvement of patients and clinicians on national tender boards. The EHC has supported and will continue to support the development and involvement of patients and clinicians in decision making for national tender boards.

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