Product Choice: What Does it Mean?

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Ideal World

• Each doctor / haematologist treating any PWH will be fully au fait with all the products and all developments and will be able to individually choose the product the PWH receives in consultation with the PWH.

• Each PWH will be fully conversant with all the products and will understand the similarities, differences, pros and cons of each and will be able to take a full role with their doctor in choosing the optimum product for them.

• Ideal world
  – no budget constraints
  – treatment costs manageable
  – treatment for all
GDP per Capita (€) v FVIII per Capita

Reality

- Cost / budget constraints / lack of priority by or willingness of governments to prioritise haemophilia treatment – all limit availability of treatment.

- Europe (35 country survey – 17 countries have a national tender) – countries with a national tender more likely to have improved treatment.

- Ireland
  - 1996 – 1.3 IU/P.C.
  - 2003- Nationl Tender... 3.5 IU/P.C.
  - 2012 – 8.12 IU/capita
Reality

• Doctors – many very knowledgeable, especially full time specialists / directors or doctors in CCC’s, but many have a limited or cursory knowledge.

• PWH – some knowledgeable especially leaders or key volunteers for NMO’s. Majority have a cursory or little knowledge.
Level of knowledge: For PWH

- Very few would read or have access to journals or conferences or tailored non-pharma educational materials on the products.

- Training carried out for small number of key leaders.
Level of knowledge: For PWH

- Many exposed to pharma materials....companies of course will highlight materials which show their product in the best light (and often make sure you are aware of materials which denigrate the competition).

- Exposure to materials varies greatly.
Level of knowledge: For PWH

• Ireland – members get educational lectures at conferences, materials written in newsletters, key leaders trained.

• Germany – good materials on website.

• Canada – newsletter, website.

• Good exchange network among NMO leaders, especially those who have been trained.

• USA – allow direct marketing to patients.
When you want a therapy that’s free of blood-based additives...

ADVATE is the clear choice

- Based on the same full-length factor VIII molecule as RECOMBIVASE (Antihemophilic Factor (Recombinant))
- Low incidence of inhibitor formation (<1% in previously treated patients)
- Up to 93% of bleeding episodes resolved with 1 or 2 infusions
- There have been no confirmed reports of serious viral transmissions with recombinant factor VIII therapies

[Antihemophilic Factor (Recombinant), Plasma/Albumin-Free Method]

Ready for tomorrow, today

Please see Brief Summary of Prescribing Information on adjacent page.

Good things come in ADVATE packages...

[Antihemophilic Factor (Recombinant), Plasma/Albumin-Free Method]
For hemophilia A patients...

**Kogenate® FS with BIO-SET®**

The Only Self-Contained, Needleless rFVIII Reconstitution System

**SAFE**
No exposed needles during reconstitution

**EASY**
Only 2 parts—prefilled diluent syringe and product vial!

**FAST**
Fewer than half the steps to prepare infusion

Please consult with your healthcare provider to determine if Kogenate® FS is appropriate for you.

Kogenate® FS is a recombinant Factor VIII treatment indicated for the treatment of hemophilia A. The most frequently reported adverse events were local injection site reactions, dizziness, and rash. Known hypersensitivity to mouse or hamster protein may be a contraindication to the use of Kogenate® FS.

**For more information, please see brief summary on following page.**

Kogenate FS
Antihemophilic Factor (Recombinant)
Formulated with BIO-SET™ Needlesless Reconstitution System
Major Concern

• Doctors / NMO’s who talk up and accept therapeutic equivalence.

• There may be small differences between products in each class, but there are differences which should be analysed, considered and not excluded from the decision mechanism.

• This opens the door for cost to be the only criteria.
Major Concern

- If all the products are the same, why do they need the doctors or key PWH in the room when decision is being made?...Just let the Government or procurement officials choose the cheapest (they will argue that they are all licensed and they all contain FVIII).
Consequences

• Tender can take place without input from key doctors of NMO

• Cost becomes the only selection criteria (allowable under EU law) instead of M.E.A.T.

• Governments make decisions based on ideology – use national products or self sufficiency.

• If doctors and NMO’s do not insist on their role or abrogate their responsibility…officials with no real knowledge of the products fill the void and then start to get involved in more and more clinical decisions.
Solution

- Vigilance, knowledge, formal involvement in selection process by doctors and PWH leaders.

- Should never allow health officials to be sole choosers of products.

- Price must and will always be a consideration, but should not be the sole consideration.

- National, regional or multi country tenders good – as long as key doctors and NMO’s are involved.
Facing Reality

• Reality – many non specialist doctors do not know enough about the products to choose. Welcome the input of expert clinical colleagues from their country (doctor who sees two PWH twice a year….can he be expected to keep up to date?)

• Majority of PWH do not have this knowledge...and do not have the interests to acquire it. They trust their doctor. They trust the involvement of their NMO. They take what they are provided with by their doctor or insurance company.
Solution

• Limited choice is fine...as long as the choice is being made by the right people.

• Always have a procedure to deal with exceptional cases – named patient basis

• Reality is Government / Health insurance officials will be involved in the process and cost is always a consideration.
• Must have key doctors and NMO’s involved formally.

• Train them together with health officials
  – Brazil / Peru / Lebanon / Ireland.