

# PATIENT INVOLVEMENT IN THE PORTUGUESE TENDER PROCESS

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# PORTUGAL

1,000 people with hemophilia \*

4,10 u.c. per capita (2014) \*

60 % - Recombinants \*

40 % - Plasma Derived \*

90 % Children in Recombinants \*

95 % children on prophylaxis \*

25 % adults on prophylaxis \*

No National Hemophilia Commission

No National Registry

5 major hemophilia centers with an informal multidisciplinary team, but with no legal frame as Comprehensive Treatment Centers

5 major hemophilia centers recognized by EUHANET

\* APH data



# TENDER PROCESS

Plasma derived – Hospital tender (central catalogue in study)

Recombinants – Central catalogue defines the maximum price  
- Hospital opens tender

## Legal Procedures

Pre-opening rules defines :

Jury (3-5 persons, at least one Immuno-hemotherapist -IT)

Criteria ( only price since 2013 )

Timeline for tender opening and to present proposals

Term of contract ( 2/3 years)

Companies must have market authorization (Infarmed)

Formal Advice from Patients organization-APH (when asked)



# APH INVOLVEMENT IN THE TENDER

Tender  
opening

APH receives the proposals

Active role

Formal and non binding written advice (Since 2008)

APH gives advice based on :

- Scientific specifications (safety, efficacy, quality, labeling...)
- Infarmed RCM ( Drug characteristics resumé )
- Scientific publications
- Patients previous experience with the products
- Clinicians or IT Scientific opinion

# APH INVOLVEMENT IN THE TENDER

## Active role

Since 2013 APH :

- Remembers the jury about the paradox between having an IT in the jury and the price being accepted as the only criteria
- Mentions Kreuth III recommendations

Since 2015 APH :

Emphasizes Resolution CM/Res (2015) 3, from the Council of Europe

# APH INVOLVEMENT IN THE TENDER

## Preventive role

Aknowledging when a tender is on the way

Letters to hospital boards remembering that our formal advice is legally necessary (before the tender opens)

Informal meetings with IT/clinicians to hear their opinion and concerns

Inform all the patients about tender opening and their legal right of non-switching (Informed consent)

Promotion of meetings between patients and the president of the jury





# APH INVOLVEMENT IN THE TENDER

## Preventive role

Since 2013, a copy of our formal advice is sent to the hospital board and to the Minister of Health, emphasizing :

- the anachronism of price being the only criteria face to Kreuth III/CoE 2015 resolution
- decisions based only on price doesn't mean that the Government will save money
- the danger of IT/clinicians opinion not be taken in consideration
- HIV/HVC infections occurred in a price based only situation

Let Companies know that the tender will not be discussed and that our advice is based only on scientific and objective criteria

# FINAL REMARKS

## A patients organization should

Master the tender legal framework

Have skilled and trained people capable to evaluate the products characteristics

Let know the patients that a tender is happening

Have good relations with IT/clinicians

Be prepared as last resort to proceed to court and press, if the tender procedures were not respected

Make constant pressure against price being the only criteria



THANK YOU

