National Procurement Systems for Coagulation Factor Concentrates: Challenges and Opportunities

Recombinant Factor VIII Tender Scoresheet

<table>
<thead>
<tr>
<th>Availability of Supply</th>
</tr>
</thead>
<tbody>
<tr>
<td>Ability to vary Amount Agreed</td>
</tr>
<tr>
<td>Number of Sites of Manufacture (Number of Sites)</td>
</tr>
<tr>
<td>Guaranteed Minimum Supply (Minimum of Supply)</td>
</tr>
<tr>
<td>Storage Facilities in Country (Availability of Supply)</td>
</tr>
</tbody>
</table>

Brian O’Mahony
Hemophilia Asia
July 2014
GUIDE TO NATIONAL TENDERS FOR THE PURCHASE OF CLOTTING FACTOR CONCENTRATES

Brian O'Mahony

WORLD FEDERATION OF HEMOPHILIA
<table>
<thead>
<tr>
<th>Year</th>
<th>Country</th>
<th>Prophylaxis</th>
<th>On-Demand</th>
<th>Surgery and Other Interventions</th>
<th>Prevention and Education</th>
</tr>
</thead>
<tbody>
<tr>
<td>2012</td>
<td>France</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>2013</td>
<td>Italy</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>2014</td>
<td>Germany</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>2015</td>
<td>Spain</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>2016</td>
<td>Portugal</td>
<td>Yes</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

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GDP per Capita (€) v FVIII per Capita

Procurement of Factor Concentrates

- Government: 13
- Government/Clinicians: 9
- Government or Payers/Clinicians/Patients: 10
- Did Not Respond: 2

National Tender for procurement of Factor Concentrates:
- Yes: 17, 51%
- No: 18, 49%

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Good National Tender Systems

- Formal involvement of clinicians, haemophilia organisations, regulators, in the process.

- Process formally includes stakeholders with expertise on products, issues.
Why National Tenders? - Opportunities

- Improved comparative assessment of the products

- Price placed realistically on list of criteria
  : not sole criteria
  : weighing depends on resources

- Assists in development of higher standards of care nationally
National Tenders - Opportunities

- National assessment of demand and use
- National budget
- Cost effective
- Contingency Planning – flexibility
- Stakeholder ‘Buy-In’
National Tenders – Opportunities

- May help to minimise impact of shortages.
  - Stock holding agreement.
  - National system of distribution and stock monitoring.
National Tenders - Advantages

Broad Based Tender Commission with Appropriate Expertise

- Better award criteria
- Better analysis of criteria
- More expertise than individual hospitals, clinicians, officials, insurance companies
National Tenders - Challenges

- **Limits range of products available**
  - Number of suppliers
  - Clinicians may use other licensed products

- **Limits clinical freedom**

- **Unsuccessful company may withdraw from country**
  - Limiting future choice
Developing a Tender Process

- Decide on Contracting Authority
- Establish Tender Commission
  - Single integrated commission
    : Ireland, England, Canada
Tender Commission – 2 tier

(a) Scientific Advisory Group.

(b) Tender Commission.
- Acts on advice from scientific group.
- Brazil, Uruguay.
- Degree of “overlap” essential.
EU Tenders

**Criteria**
- Price
- Most Economically Advantageous (MEAT)

**Methods**
- Open
- Competitive Dialogue
- Restricted
- Negotiated
M.E.A.T. - Possible Selection Criteria

- Safety, Quality, Efficacy
- Supply
- Cost
- Scientific, Technical Support
- Range of Products
- Consumer, Physician preference
- Mix of Products
Steps in Tender Process

1. Ensure tender within remit of commission
2. Determine Product requirements
3. Determine the award criteria
   - Price
   - Most economically advantageous tender (MEAT)
   - Develop detailed scoring criteria
Steps in Tender Process

4. Specify the type of tender
   - Open, negotiated

5. Specify number of suppliers

6. Quantity Purchased, Term of Tender

7. Scoresheets, based on award criteria

8. Publish Call to Tender

9. Receipt of tenders

10. Commission Review Tenders
Steps in Tender Process

11. Decision
   - Score each product for each sub criteria on score sheets

12. Communication of Decision

13. Debriefing meetings with companies

14. Publication and Disclosure
   - Publish Results
     - Range of prices
     - Successful Companies
     - Commercially Sensitive
       - Information not disclosed
Confidence in Tender Process

- Clear, transparent procedures, and decision framework.
- Involvement of clinicians, haemophilia organisations.
- Same information/rules apply to all companies.
- Debriefing meetings.
# Comparison of Tender Systems

<table>
<thead>
<tr>
<th></th>
<th>Canada</th>
<th>Australia</th>
<th>UK</th>
<th>Ireland</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Contract Holder</strong></td>
<td>Canadian Blood Service (CBS)/ - HemaQuebec</td>
<td>National Blood Authority (NBA)</td>
<td>PASA / National Commissioning Board</td>
<td>Hospital – National Haemophilia Centre</td>
</tr>
<tr>
<td><strong>Usual Term</strong></td>
<td>5 years</td>
<td>3 years Option +1/2 years</td>
<td>3 years Option +1/2 years</td>
<td>2 years Option +1/2 years</td>
</tr>
<tr>
<td><strong>Annual FVIII Use</strong></td>
<td>150 Million</td>
<td>127 Million</td>
<td>300 Million</td>
<td>28 Million</td>
</tr>
<tr>
<td><strong>FVIII per /capita</strong></td>
<td>6.3 IU/capita</td>
<td>5.9 IU /capita</td>
<td>7.5 IU/capita</td>
<td>8.2 IU/capita</td>
</tr>
</tbody>
</table>

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## Comparison of Tender Systems

<table>
<thead>
<tr>
<th>Advisory Commission / Commission</th>
<th>Canada</th>
<th>Australia</th>
<th>UK</th>
<th>Ireland</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Members</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>• 1 PWH- CHS</td>
<td>1 PWH- CHS</td>
<td>1-2 Doctors</td>
<td>3 Doctors</td>
<td></td>
</tr>
<tr>
<td>• 1 Haemophilia Doctor</td>
<td>1 Haemophilia Doctor</td>
<td>1 Nurse</td>
<td>2 PWH – IHS</td>
<td></td>
</tr>
<tr>
<td>• 1 PID</td>
<td>1 PID</td>
<td>1 PWH – HFA</td>
<td>2 Doctors</td>
<td></td>
</tr>
<tr>
<td>• 1 PID Doctor</td>
<td>1 PID Doctor</td>
<td>3 NBA</td>
<td>1 Nurse</td>
<td></td>
</tr>
<tr>
<td>• 2 External Advisors (know business)</td>
<td>2 External Advisors (know business)</td>
<td>Working Group</td>
<td>2 PWH- UKHS</td>
<td></td>
</tr>
<tr>
<td>• CBS / HemaQuebec Regulator</td>
<td>CBS / HemaQuebec Regulator</td>
<td>2 Commissioners</td>
<td>2 Commissioners</td>
<td></td>
</tr>
<tr>
<td>• 1 Nurse</td>
<td>1 Nurse</td>
<td>1 Nurse</td>
<td>1 Nurse</td>
<td></td>
</tr>
<tr>
<td>• 3 NBA</td>
<td>3 NBA</td>
<td>2 Ministry of Health</td>
<td>2 Ministry of Health</td>
<td></td>
</tr>
</tbody>
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<th>Ireland</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Score sheets</strong></td>
<td>No – Just say which products acceptable</td>
<td>No</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Examine Safety, Quality and Efficacy</strong></td>
<td>Yes</td>
<td>No- Job of Regulator. All products licensed</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Regulator / Virologist</strong></td>
<td>No</td>
<td>No</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Predict Supply and Demand</strong></td>
<td>Yes</td>
<td>Give Indicative Quantities</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td><strong>Preferred Number of Suppliers</strong></td>
<td>≥2</td>
<td>2</td>
<td>All get a share</td>
<td>≥1</td>
</tr>
<tr>
<td><strong>Examine Price</strong></td>
<td>No</td>
<td>Yes</td>
<td>Yes – Reverse Auction</td>
<td>Yes</td>
</tr>
</tbody>
</table>

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## Comparison of Tender Systems

<table>
<thead>
<tr>
<th>Tenders</th>
<th>Canada</th>
<th>Australia</th>
<th>UK</th>
<th>Ireland</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Recombinant CFC</td>
<td>Recombinant CFC</td>
<td>Recombinant CFC</td>
<td>Recombinant CFC</td>
</tr>
<tr>
<td></td>
<td>Plasma-derived CFC</td>
<td>Plasma-derived CFC</td>
<td>Plasma-derived (included but very low amount)</td>
<td>Plasma-derived (FX / vWF),</td>
</tr>
<tr>
<td></td>
<td>IVIG</td>
<td>IVIG</td>
<td></td>
<td>Note: Recommendation for Fibrinogen</td>
</tr>
</tbody>
</table>
Ireland

- **HPSMAB**
  - Clinicians (3)
  - Haemophilia Society (2)
    - plus 1 External advisor
  - Regulator
  - Blood Transfusion Expert
  - Ministry of Health
  - Health purchasing authority
  - Contract Holder
  - Virologist

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Number 8 of 2012

CLOTTING FACTOR CONCENTRATES AND OTHER BIOLOGICAL PRODUCTS ACT 2012

ARRANGEMENT OF SECTIONS

Section
1. St. James's Hospital Board to procure and make available clotting factor concentrates and other biological products.
2. Prescription of certain products and adoption of references to Irish Blood Transfusion Service.
3. Revocation.
4. Short title and commencement.
I H S Involvement

- **Serious commitment**
  - Not token
- **Considered choice of volunteers**
  - Knowledge, education
  - Resources required
- **Long Term Commitment**
  - Ireland, 5 year renewable terms
Results of work in Ireland

- 2002 - pre Tender committee, Irish prices were 20% above Eu average
- 2008 – Irish prices 26% below EU average
- 2012- Irish prices for Recombinant FVIII 56% below EU average
- More competitive tenders
- Handling fees removed
Thailand

- First National Tender in 2006
- Prior to 2006 – used Cryoprecipitate
- Tender for Purchase of 30 million units
Thailand

- Unrealistic expectations on Price initially
- Based on short dated product and semi-donation
- Pre tender discussion on Price
- Importance of First Tender understood
- Post Tender Negotiation on Price possible
Issues

- Are you allowed to negotiate on price after tender submitted?
- Electronic auction?
- Term of tender
- Build in flexibility – term v minimum quantity
- System for maintaining clinical freedom
Issues

- Issue timely call for tender:
  - many examples where countries have left this too late—supply shortages

- Use scoresheets—eliminates bias, articulates rationale for choice and leaves record of decision making process
<table>
<thead>
<tr>
<th>Category</th>
<th>Score</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety</td>
<td>100</td>
<td>(40%)</td>
</tr>
<tr>
<td>Quality</td>
<td>36</td>
<td>(15%)</td>
</tr>
<tr>
<td>Efficacy</td>
<td>40</td>
<td>(16%)</td>
</tr>
<tr>
<td>Supply</td>
<td>18</td>
<td>(8%)</td>
</tr>
<tr>
<td>Technical Support</td>
<td>8</td>
<td>(3%)</td>
</tr>
<tr>
<td>Price</td>
<td>45</td>
<td>(18%)</td>
</tr>
</tbody>
</table>

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Resources for Tender Commission

- Publications
- Websites
- Journals
- Contacts
- Conferences
- Training
Training for Tender’s

Training courses for Doctors, Patient leaders and Ministry of Health:

Brazil
Peru
Lebanon
Kuwait
Colombia
Honduras
Training Course for Patient leaders

WFH Staff
UK
Germany
Sweden
Italy
France
New Zealand

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7. Do patients benefit from national tenders for clotting factor concentrates?

1. Yes. 61%

2. No 22%

3. Do not know. 17%
8. Do governments or other purchasers benefit from national tenders for clotting factor concentrates?

1. Yes. 81%
2. No 11%
3. Do not know. 8%
9. Do manufacturers benefit from national tenders for clotting factor concentrates?

1. Yes. 27%
2. No 54%
3. Do not know. 19%
Tenders – Manufacturers View

- Equal & fair process for companies engaged in tender process
- Appropriate assessment of award criteria

Source Industry Presentation, WFH Global Forum 2007

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Collaborative tenders

- Central America
- Gulf states and Saudi Arabia
- Baltic countries?
Challenges

**Longer acting factors:**

- Selection criteria vs. conventional recombinant will be difficult.
- Price per unit will not be directly comparable.
- Companies marketing existing products will devise “new models.”