Fair And Affordable Pricing

*(FAAP)*

Platform for strategic cooperation within and above the V4+ group

Dominik Dziurda

FAAP Coordination Committee

Facing the challenges: Equity, Sustainability and Access

*Lisbon, 29-30 November 2018*
Fair and affordable pricing (FAAP) - diagnosis (1/2)
Reimbursement process (*Country perspective*)

Informal consultations

- Application
- Refinement
- Value assessment
- Value appraisal
- Price negotiations
- Decision
- Implementation
Horizon scanning

Regulatory process

1. Horizon scanning

2. Joint strategy

3. Joint process (synchronization)

4. Joint negotiations

5. Joint procurement

6. Availability management

7. Reimbursement guidelines for therapeutic areas

Fair and affordable pricing (FAAP) – diagnosis (2/2)

Reimbursement process (*EU perspective*)
## Fair and affordable pricing (FAAP)

### General facts

<table>
<thead>
<tr>
<th>Area</th>
<th>Description</th>
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</thead>
<tbody>
<tr>
<td><strong>Legal basis</strong></td>
<td>Memorandum of Understanding on cooperation in the field of fair and affordable pricing of medicinal products of 3rd of March 2017, Warsaw, Poland</td>
</tr>
</tbody>
</table>
| **Strategic objectives** | To improve and facilitate access to effective and affordable medicinal products for the service of citizens of the countries involved  
To develop methods and modalities of cooperation and negotiations |
| **Participants** | Hungary, Republic of Lithuania, Republic of Poland, Slovak Republic, Czech Republic (*observer status*), Latvia (*invited guest*) |
| **Activities**  | 7 regional meetings, technical consultation on specific disease areas (e.g. breast cancer) |
Fair And Affordable Pricing (FAAP)
Political and socioeconomic determinants

- Population of 56 mln of citizens within active collaboration with potential to extend to almost 70 mln
- Political collaboration within Visegrad group is a driving force for this initiative

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<thead>
<tr>
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<tbody>
<tr>
<td>Poland</td>
<td>37 967 209</td>
<td>1 784</td>
<td>369</td>
</tr>
<tr>
<td>Czech Republic</td>
<td>10 553 843</td>
<td>2 482</td>
<td>433</td>
</tr>
<tr>
<td>Hungary</td>
<td>9 830 485</td>
<td>1 966</td>
<td>566</td>
</tr>
<tr>
<td>Slovakia</td>
<td>5 426 252</td>
<td>2 170</td>
<td>566</td>
</tr>
<tr>
<td>Lithuania</td>
<td>2 888 558</td>
<td>1 992</td>
<td>541</td>
</tr>
<tr>
<td>Latvia</td>
<td>1 968 957</td>
<td>1 597</td>
<td>452</td>
</tr>
</tbody>
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FAAP Initiative
Key ideas/principles underlying the Initiative

1. **Similar socioeconomic and health-related needs and challenges** as well as geographic proximity as an underlying factor for close collaboration between Participants

2. Focus on facilitation of access to effective and affordable medicinal products for the service of citizens of the countries involved

3. FAAP initiative should be perceived as a **complementary, missing element allowing better proactive preparation of local reimbursement systems for innovation** (regional topic-specific reimbursement strategy)

4. Focus on **certain modalities of pricing** - any variables which specify the availability of medicinal products within national reimbursement system e.g.: clinical characteristics of patients, length of treatment, expected reimbursement mechanism, financial conditions etc.

5. **The Memorandum** which constitutes the legal basis for the FAAP initiative **is not intended to create any legal obligations under domestic or international law**.
# Fair and affordable pricing (FAAP)
## Structure and resources

<table>
<thead>
<tr>
<th><strong>Governing body</strong></th>
<th>Ministers of Health</th>
<th>Decision-taking body</th>
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</thead>
<tbody>
<tr>
<td><strong>Process management</strong></td>
<td>Coordination committee (designated representatives of each participating country)</td>
<td>Process coordination, Manage communication on behalf of coordination committee. Chairman (Dominik Dziurda, PL) Vice-chairman (Neringa Bernotiene, LT)</td>
</tr>
<tr>
<td><strong>Working groups</strong></td>
<td>Analytical group (topic focused technical team) Legal group (legal counsels from each participating country)</td>
<td>Preparation of supportive analytical materials SL, LT, HU, PL (coordination) Legal advice to coordination committee Hungarian leadership</td>
</tr>
</tbody>
</table>
## Fair and affordable pricing (FAAP)

### Ways of working

<table>
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<tr>
<th>Area</th>
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<tbody>
<tr>
<td><strong>Assumption</strong></td>
<td>Mutual cooperation can make public reimbursement system more efficient</td>
</tr>
</tbody>
</table>
| **Objectives (What)** | To *improve and facilitate access* to *effective and affordable* medicinal products  
                             To develop methods and modalities of *cooperation* and *negotiations* |
| **Methods (How?)**    | • Participation in expert meetings  
                             • Exchanging information  
                             • Organizing pilot negotiations |
| **Pilot negotiations**| *Tactical goal*  
                             To achieve common position on certain confidential modalities of pricing of medicinal products (*in specific context*)  
                             
                             *Strategic goal*  
                             To *develop effective procedures of negotiations*  
                             To identify elements, that can be included into International Agreement |
Fair and affordable pricing (FAAP)

SUMMARY

• The ultimate goal of FAP initiative is the development of methods and modalities of cooperation and negotiations with MAHs concerning pricing of certain medicinal technologies in order to improve and facilitate access to effective and affordable medicinal products on V4+ level.

• Above can be delivered through long-time cooperation focused on:
  • Building an active institutional network within the region
  • Exchange of expertise and experience in the field of reimbursement and pricing
  • Common assessment of desired options for treatment management

• Taking learning-by-doing / pilot approach the process assumes preparation of coherent regional negotiation strategy of development of public reimbursement system for specific disease area, which could stand as guidelines for national processes

• Pilot process should allow to build recommendation on development an International Agreement concerning fair pricing
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FAAP Coordination Committee

Facing the challenges: Equity, Sustainability and Access

Agency of Health Technology Assessment and Tarrification, Warsaw, Poland

Lisbon 29-30 November 2018