Will flat EU pricing become a reality?
Considerations for the BioPharma industry and whether future EU pricing transparency rules will affect the current position

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**Objectives**

Prices of medicines currently vary across EU Member States due to several factors, some of which are beyond responsibilities of companies. They may result from: wholesaler or pharmacy margins, sales tax, pack sizes, distribution channels, exchange rate fluctuations, and perhaps most importantly, price-setting processes. National health and pharmaceutical policies and priorities also contribute to price variation.

Current EU pricing transparency rules only address process rather than the resulting levels of pricing and reimbursement. Member States compare and reference prices with each other in a process known as international reference pricing (IRP), in which prices are often set by taking an average or minimum of a specific set of ‘basket’ countries.

We aim to determine whether this will continue or whether Member States are likely to encourage manufacturers to adopt flat pricing at a lower level in the future. This approach was recently announced by Belgium and the Netherlands and they expect more countries to join after the pilot initiative. In addition, harmonization of health technology assessment methodology by EUnetHTA may extend to pricing in the future.

**Methods**

The Curia database2 was searched for all headed judgments relating to transparency directive 89/105/EEC. Those with consecutive numbers were reviewed to identify joint cases. We reviewed how legislation and case law, including that relating to parallel trade or grey market, reinforces national rights to set prices. Current price constraints and their interpretation were analyzed.

In order to balance the respective interests of Member States and the industry, Member States should:
- Allow differential pricing
- Restrict IRP to economically comparable Member States
- Exclude elements related to pharmaceutical regulation and policies from IRP, which are country-specific and likely to distort price comparisons
- Exclude countries under austerity measures from IRP and free movement.

Transparency laws in Europe are currently perceived by manufacturers as being useful, but quite limited in their influence and practical application. This is generally due to the transparency directive not taking account of current demand restrictions and the lack of power to impose penalties on Member States. However, the usefulness of the transparency directive, in trying to ensure Member States are fair and transparent in their application of national processes, should really become a consideration for manufacturers’ public affairs and market access departments, and not necessarily be seen as solely legal instruments.

The existing directive was expected to be modified in 2014, but at this stage, the existing directive will continue due to policy makers disagreement on a new directive.

**Results**

Thirty three cases have proceeded to the EU courts. Many of the cases were joint, thus only 10 outcomes of the 33 cases are presented in Table 1. Based on the review, the principle of EU Member State discretion in terms of price setting seems sacrosanct and it is unlikely that the legislators will be able to change this position.

Two key areas that appear from the cases reviewed are:
1. the setting of transparent timeliness for reimbursement and inclusion or exclusion from reimbursement categories
2. reasons for any restriction to reimbursement must be clearly stated, rather than simply imposing a restriction.

**Conclusions**

Currently, manufacturers’ strategies do not employ the flat pricing approach and instead, tend to be limited to broad price corridors with an expectation that confidential discount and/or risk sharing will be applied. Our review of the cases that have proceeded to the European court to date have focused on the timeliness and reasons for any restrictions to reimbursement. This has not been extended to include actual levels of pricing and reimbursement as this is out of scope of current rules.

Our conclusion is that flat pricing in the EU will not become a reality in the near future. However, the Netherlands and Belgium initiative could pave the way for flat pricing in the more distant future. Consequently, companies should plan for this and proactively seek to limit unreasonable actions on the national level.

**Table 1: Summary of Cases Reviewed**

<table>
<thead>
<tr>
<th>Case number</th>
<th>Names of parties</th>
<th>Summary of outcome</th>
</tr>
</thead>
<tbody>
<tr>
<td>271/14</td>
<td>LFB Biomedicaments</td>
<td>Restriction of reimbursement – Member States need to state reasons</td>
</tr>
<tr>
<td>691/13</td>
<td>Les Laboratoires Servier</td>
<td>The Member State needs to state reasons to justify their position regarding the limitation of reimbursement to a specific category of patients</td>
</tr>
<tr>
<td>471/07 and 472/07</td>
<td>AGIM – joined cases</td>
<td>No need for a Member State to review macroeconomic conditions after 8 years of price freeze</td>
</tr>
<tr>
<td>352/07 to 367/07</td>
<td>Joined cases</td>
<td>Need for reasons around measures regulating the price of medicines and inclusion in NHS insurance</td>
</tr>
<tr>
<td>311/07</td>
<td>Commission v Austria</td>
<td>Failure to set a time limit for inclusion in certain reimbursement categories</td>
</tr>
<tr>
<td>317/05</td>
<td>Pohl Boskamp</td>
<td>Need for suitable remedies even where none are laid down in national legislation</td>
</tr>
<tr>
<td>296/03</td>
<td>GSK v Belgium</td>
<td>Requirement to meet time lines in reimbursement decision making</td>
</tr>
<tr>
<td>245/03</td>
<td>MSD v Belgium</td>
<td>Where timelines are exceeded this does not mean that a product is automatically reimbursable</td>
</tr>
<tr>
<td>229/00</td>
<td>Commission v Finland</td>
<td>Failure to adopt laws to comply with Directive 89/105</td>
</tr>
<tr>
<td>424/99</td>
<td>Commission v Austria</td>
<td>Failure to adopt laws to comply with Directive 89/105</td>
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**References**


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