THE UK PHARMACEUTICAL PRICE REGULATION SCHEME (PPRS) - CONSIDERATIONS OF VOLUNTARY VERSUS STATUTORY REGULATIONS AND HOW TO NEGOTIATE PRICING


Objectives

The UK operates free pricing of new chemical entities (NCEs) via the 2014 PPRS, which was a radical departure from its predecessors, focussing on industry’s obligation to repay the Department of Health (DH) for growth in the NHS drug expenditure beyond certain limits. These repayments currently exceed original estimates1,2, reducing certainty for members of the PPRS. The statutory regulations impose higher price cuts at the outset, aiming to ensure those not in the PPRS do not have an advantage. As NHS sales from new NCEs launched after Jan 1st 2014 are exempt from PPRS payment calculations and price cuts, we explore implications for company and product scenarios based on the current process for setting price as shown in Figure 1.

Methods

15 case studies of small (n=5), medium (n=6) and large companies (n=4) were reviewed to identify the implications for manufacturers with established portfolios compared to those with new launches after January 2014 under the PPRS and statutory regulations. We review legal options for companies who consider themselves unfairly treated.

Results

Based on the range of companies reviewed, we identified 7 main scenarios and key considerations as shown in Table 1. Evidence exists of an imbalance in the PPRS impact on companies, thus negatively affecting the UK as an early launch market. The PPRS potentially amounts to an unlimited payment to the DH and worryingly payments are allocated to an undefined pot rather than to the original budget holder.

Price rises are possible, subject to justification, and are increasingly being sought as a way to overcome UK price cuts and PPRS payments respectively. Companies have successfully challenged the application of the statutory regulations and price reductions to products already covered by a tender, partly due to their impact on international reference pricing.

A clear process is laid out for dispute resolution in Figure 2, applicable when any PPRS scheme member considers themselves unfairly treated. Precedent cases should be reviewed before considering this process, as MAP BioPharma experience suggests a greater success rate with informal negotiation than when the formal process is engaged. Judicial review may also be an option as reviewed in a previous poster presentation.4

It should be noted that DH recently published a consultation on proposed changes to the regulations, which runs until December 4th 2015. Four options are being considered, and they could dramatically change the considerations in Table 1, if implemented:

Option 1: A further cut in maximum price
Option 1a: Option 1 including new products
Option 2: A percentage payment by companies replacing the existing price cut
Option 2a: Option 2 including new products

Conclusions

Companies supplying mainly mature products are disproportionately affected by price impact compared with larger companies with a broader international portfolio.

This imbalance is leading to an increase in price rise applications for those more established products.

Companies with a pipeline of NCEs, which are commonly more expensive, are the winners despite being a significant contributor to NHS expenditure.

A combination of the current consultation relating to the statutory regulations (relevant to companies subject to the regulations, who do not sign up to the PPRS), plus the variable PPRS payment (for those companies signed up to the PPRS) has created a difficult choice for companies, as they decide if they should join the PPRS or remain subject to the statutory regulations, which are likely to change in 2016.

Table 1: Scenarios for companies to consider before deciding if the PPRS or statutory regulations should apply to their company

<table>
<thead>
<tr>
<th>Scenarios</th>
<th>Option most likely to benefit the company (statutory regulations or PPRS)</th>
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<tbody>
<tr>
<td>NCE, no other products</td>
<td>PPRS (freedom of pricing) for products launched after 1st January 2014</td>
</tr>
<tr>
<td>One established product</td>
<td>Statutory regulations if hospital products and tenders; PPRS for community products or no tenders</td>
</tr>
<tr>
<td>Hospital vs. community pharmacy dominance</td>
<td>Statutory regulations if hospital products and tenders; PPRS for community products or no tenders</td>
</tr>
<tr>
<td>Likelihood of future price rise</td>
<td>PPRS or statutory regulations (price rise process is practically equivalent)</td>
</tr>
<tr>
<td>Branded NHS sales &lt;£5m</td>
<td>PPRS (freedom of pricing) (N.B. total revenue could be £100m as long as branded &lt;£5m)</td>
</tr>
<tr>
<td>Branded NHS sales &gt;£5m</td>
<td>Dependent upon range of products and if they are new or established – see first four rows</td>
</tr>
<tr>
<td>Cancer drugs</td>
<td>PPRS to take advantage of lower amount included (capped % taken into total NHS spend)</td>
</tr>
</tbody>
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References:


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