Minutes
PPRS Formal Review meeting between ABPI and the Department of Health
22 September 2016, 14:00 to 16:00

1. Health Service Medical Supplies (Costs) Bill

DH presented a summary of the changes to legislation:
- To amend the powers to allow a payment mechanism in the statutory scheme, with detail to be set out in regulations, which will be the subject of further consultation;
- To give DH powers over pricing of high price generics;
- To provide a statutory footing for provision of data and information;
- Specific enforcement provisions relating to a payment scheme, alongside existing enforcement powers relating to price or profit controls.

ABPI welcomed action on pricing of generic medicines where there was no effective competitive market. ABPI supported the DH plan to consult further on the details of how the legislation would be brought in practice. ABPI asked that the further consultation should consider the need for changes in reporting to be proportionate, not overly bureaucratic, and appropriately targeted.

ABPI agreed with the intention to better align the statutory and voluntary schemes. Regarding the information provisions, the powers replace existing wide powers, and further engagement will be taking place to inform the development of regulations. The first meeting is 30 September, to which ABPI is invited.

2. Scheme operation update

DH reported that there were no major issues with the operation of the scheme. One case with the Dispute Resolution Panel was outstanding. DH said it had continued to discuss the exclusion of some brand equalisation sales with several companies. ABPI confirmed its agreement with the overall operational running of the scheme.

ABPI said it did not agree with the way leavers and joiner's data was managed, specifically around the potential effect of large mergers on PPRS growth, if the acquired company sales were lost from previous year's growth. DH said that an agreement with the ABPI about the treatment of joiners and leavers was in place, but it was content to discuss this matter at a joint meeting.
3. **Review of PPRS Growth and PIs**

DH noted that following a period of higher growth in the first year of the scheme, recent PPRS Measured Spend growth had been much slower. The latest 9 months PPRS Measured Spend growth was 0.75%, and if this continued in Q3 2016 might result in no PPRS payment being needed in 2017. This was in marked contrast to both parties’ expectations at the start of the scheme.

DH noted that factors contributing to the reduction in growth were parallel imports, divestments, and leavers. Both sides agreed that Parallel Imports (PI) had caused some of the slowing of PPRS growth, but ABPI were of the view that the data on the PI impact on payment percentage was overstated. This would be followed up in a separate meeting. ABPI said that even with the weaker pound there did not appear to be evidence of a slowing in PI to the UK, but change remained possible in 2017. ABPI noted that only 20 medicines accounted for half of the PI, and 40 medicines almost two thirds.

DH said that administrative data such as PCA and Pharmex showed growth in NHS spend. ABPI raised concerns that Pharmex was not an accurate measure of growth or prices.

ABPI suggested that the impact of discounts given to the NHS was a significant factor in the declining growth of PPRS Measured Spend. The gap between PPRS Measured Spend and the PPRS member company sales measured at list prices, minus all possible exclusions, could be attributed to increasing discounts given by companies directly to the NHS. An ABPI survey had noted discounts had increased over the last 4 years, and ABPI raised examples they had heard from companies of increased procurement activity on NICE-approved medicines.

DH challenged the view that discounting was the most significant factor. DH queried feedback on procurement, noting that the system did not engage in therapeutic tendering, and that in most cases companies would simply submit their PAS price to any tender process. The NHS had to follow procurement rules. DH further noted that, many companies have lobbied the Department, seeking to be supported in entering into complex deals with the NHS, including discounting arrangements. ABPI agreed that it would seek examples from companies that go further than DH’s explanation of the issues.

ABPI reported that many of its members were concerned around what they believe to be forthcoming significant policy developments in the way the NHS manages the introduction of new medicines and manages their overall cost. Industry is keen to play a constructive role and, it is critically important that industry, through the ABPI, is fully engaged and that any changes are consistent with the PPRS. The concern of many companies, at the moment, is that some
potential changes being considered may be perceived as being against the spirit if not the letter of the PPRS.

ABPI noted that the government had recently strengthened its message that pharmaceuticals is a strategic sector for the UK economy and should be central to a new UK industrial strategy. The industry’s perception of increasing lack of engagement on policy change coupled with the more aggressive approach to procurement, noted above, is at odds with this message. DH stated that it would continue to proactively engage with the ABPI on policy issues, for example the development of the Bill, and encourage its partners to do the same.

4. International Price comparisons

DH advised that ministers had an interest in understanding the costs of medicines in the UK compared to other countries, and whether the UK was getting ‘a good deal’. ABPI said that data on true net prices across Europe did not exist, even at a company level, because of the complex mix of separate individual country and local arrangements including mandated and discretionary margins, rebates, sales taxes etc.

5. Mid-scheme reconciliation exercise

DH updated the ABPI on plans for a mid-scheme reconciliation exercise. Both sides recognised again the difficulties in using administrative data to reconcile with individual company data.

ABPI proposed an exercise to jointly review current and future sales of branded medicines in the UK. This should provide an aligned view of the growth in the ‘medicines bill’, based on all available data sources. One objective would be to understand the difference between the increase as reported in the administrative data (Pharmex + PCA) and the PPRS growth. ABPI said it would provide an outline proposal to DH in October. Both sides agreed that it was important to work together to understand what the dynamics of NHS medicines spend.

6. AOB

ABPI proposed that discussions be opened on the compatibility of current patient access scheme (PAS), PASLU operations, and the desire for more flexibility in commercial arrangements being driven by NHSE. Multi-indication Pricing (MIP) was identified by ABPI as one area where the current DH position is not consistent with what ABPI believed to be required to respond to innovative multi-indication medicines. It was noted that managing combination use in oncology, which promised great hope to patients, will be a key challenge for the NHS in the coming years. ABPI reiterated its previous proposal that a review of these
arrangements should be carried out as soon as the AAR report was published. DH noted that it would need to consider the AAR recommendations, but that multi-indication pricing was an important issue that warrants discussion.