Minutes - PPRS Formal Review 2nd May 2018

10:30 RM G7: 39 Victoria St

DHSC:
Liz Woodeson
Helen Lovell
Richard Mattison
Andina Ward
William Olivier

ABPI:
Richard Torbett
David Watson
Paul Catchpole
Geoff Bailey
Simona Bianchi
Ryan Hollingsworth

Minutes of last meeting:

The minutes of the last meeting were agreed, on actions arising, a number of points were made.

1. ABPI had been in conversation with OLS in regard to sharing methodology on PICTF uptake indicators. This had been very constructive with further meetings planned for 10 May.
2. Discussions had developed with the Department and the ABPI surrounding new product launches, there were also parallel conversations with the life sciences council, (scheduled 16 May) DHSC agreed to share information arising from this. **Action: DHSC**

Waterfall

3. The latest waterfall analysis of Q3 was presented. Joint analysis by ABPI and DHSC highlighted the bottom-up growth in spend to the NHS across the UK for branded medicines were 3.6% for the 12 Months to September 2017. Top-down data regarding medicines spend at list price had shown a 5% increase, while the difference between the two (residual / discount / wholesaler margin) had also increased 10% for the same period. DHSC also explained that estimate figure used for companies with sales less than £5m have continued to remain flat.
4. DHSC mentioned that collation of Q4 2017 waterfall data was in progress; this would also include a latest estimate on statutory scheme spend.
5. ABPI mentioned that further to the last formal review meeting, where it was agreed to share the aligned view of spend with relevant policy groups, they had been in discussion
with the Kings Fund about waterfall data. It was thought a future round table meeting would be beneficial. DHSC commented on their own discussions with Kings Fund, and DHSC agreed would take the lead in co-ordinating this round table once all the available data had been collated and analysed. **Action: DHSC**

**PPRS operations update**

6. The new PPRS digital system had been positively received by companies, while the next system phase for statutory scheme companies was under development and should be on-line by June.

7. DHSC stated that the 2014 PPRS had only seen two disputes which had escalated up to a full dispute resolution panel, and currently there were no on-going disputes. This was welcomed by the ABPI.

8. ABPI queried what decision making processes were used in relation to product launches. DHSC stated that the Department had developed a framework of areas that was reviewed and assessed. The aim being to try and assess fairly and logically against other products and companies of similar size etc. The Department are in regular discussion with companies to get to the bottom of their costs. It is half financial but half about understanding what the product is and its purpose. There are also frameworks guidelines for the newly established stat scheme, which DHSC agreed to share. **Action: DHSC**

9. DHSC agreed to ascertain if information on the number of product launches could include details on whether a new presentation had a new indication attached to it. **Action: DHSC**

10. ABPI enquired if there were definitive and aligned view as to what constitutes a new medicine and what is a significant new indication. This would help members with navigating the NICE assessment process. ABPI agreed to produce a short paper on their members’ interpretation and circulate to DHSC to discuss. **Action: ABPI**

**PAS transfer**

11. Both ABPI and DHSC agreed that the transfer of Patient Access Scheme functions from the Department to NHS England had largely gone well but there were a few issues raised by companies. One area which would need refining was the backlog in the decisions communicated by the Commercial Medicines and Devices Investment Group. One scheme went to NICE appraisal committee without the PAS simple discount being agreed in time.

12. ABPI also reported that some companies felt it was unclear who to contact within NHS England.

13. Both DHSC and ABPI agreed the continued need for complex schemes, even though they were currently only used in a small percentage of schemes, this is especially true for schemes for medicines coming out of the CDF.
**ACTION: ABPI and DHSC take raise the backlog issue with NHSE.**

**Statutory scheme**

14. DHSC reported that the statutory scheme regulations were laid on 1 April. DHSC operations had facilitated two workshops in Leeds and London. ABPI commented on the positive feedback received from members. Draft operational guidance has also been produced and distributed. DHSC would be grateful for any feedback from companies. The maximum price list had also been produced and was available on-line.

15. The BSA portal was in the advanced stages of development with a target of June for full availability. The Department will then write out to companies explaining this, guidance will also be produced on how to use the system as well as the frameworks around use/process. Guidance was only finalised after the 1st quarter as we wanted to make sure companies were satisfied with the content. DHSC agreed to share draft guidelines with the ABPI. **Action: DHSC**

**Information powers**

16. DHSC mentioned that the consultation was now closed and the Department was now finalising the regulations. Changes in response to feedback included amendments to the proposals for the provision of information within 24 hours about volumes and prices of unbranded generic medicines and special medicinal products from manufacturers, importers and wholesalers.

17. DHSC would endeavour to share the new legislative draft in due course. Regulations would look to be laid in June. **Action: DHSC**

18. ABPI made suggestion of a possible workshop on the information regulations and how they are applied. Feedback was supportive of parallel trading not being part of the new rules.