Minutes - PPRS Formal Review 11th October 2017, ABPI offices

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Minutes of last meeting
• The minutes of the last meeting were agreed. On actions arising, a number of points were made:
  o ABPI said it remained concerned that NHS England gave an incomplete picture of medicines spend in its public statements. For example, at a recent RMOC event, an NHS leader had said that “the medicines bill is now £16.8bn with £1 in every £7 of NHS expenditure being spent on medicines”, and “this figure will go north of £20bn by 2021”. ABPI said it believed the NHS was often quoting data which didn’t in fact represent the actual ‘net’ spend on NHS medicines. DH pointed out that the figures used at the RMOC event would have been global figures including generics, statutory scheme, oxygen etc as well as PPRS spend. DH said they had discussed spend data with NHS Digital and urged NHS Digital to ensure that all publications were clear when spend data was being quoted on a list price basis. DH also confirmed that they had briefed NHS England and Ministers on the importance of using net rather than list prices when referring to medicines spending. DH asked ABPI to also ensure industry statements were also accurate in their use of statistics, for example differentiating between PPRS growth and overall growth in medicines spending.
  o It was noted that Brand Equalisation sales had been discussed at the last Formal Review. ABPI said its position remained that the interpretation of BE sales was more complex than originally foreseen at the start of the scheme and that this item should be taken into negotiations on the next scheme.

Data review (waterfall: joint spend analysis)
• The joint latest ‘waterfall’ analysis of medicines spend was reviewed, which showed that branded medicines spend to the NHS across the UK had grown by 3.6% for the year ending Q1 2017. Measured spend covered by the PPRS had grown by 4.18%
over the same period. After PPRS payments were taken into account, PPRS measured spend was capped at an average per year of 1.1%. ABPI pointed out this was flat if adjusted for inflation.

- DH said that NHS reported accounts data for all medicines spend (branded, generics and certain other medical supplies e.g. oxygen) was previously estimated being 7.0% in 2015/16 and then 5.0% in 2016/17, but 2016/17 growth had been revised down to 2.3%.
- Both sides agreed a further workshop was necessary to understand the dynamics of spend between different pricing schemes. This should include an analysis of some key therapy classes including Hep C. It was also noted that industry did not have access to data from Pharmascan so was ABPI was not in a position to use this data for forecasting purposes.
- The joint waterfall analysis was agreed to be of value to the public debate on medicines, but the presentation of data wasn’t in the public domain. Both sides agreed the need to share the aligned view of spend with relevant policy groups such as Kings Fund. Both sides agreed to develop a version of the waterfall analysis and supporting explanatory messages, with the DH and ABPI logo. ABPI agreed to prepare this.

Operational report

- DH noted that a number of products had been subject to ‘genericisation’ (branded medicine presentations not subject to exclusivity, being switched to non-brand generic presentation) without informing the Department, as was required under the terms of the PPRS. DH also continued to hold discussions with a small number of companies which had disagreed with the Department’s position on brand equalisation. ABPI stated that guidelines from DH on what might be reasonable justification for price increases would be more helpful than being set as a result of CMA investigations.

Feedback on the 2014 PPRS

- DH presented an operational summary of the 2014 scheme. Both sides recognised that the main technical aspect of the scheme (i.e. reporting and payments) had been managed well considering the complexity and unique design of the scheme.
- ABPI said it would respond to the paper in due course but said it believed that regardless of the principles set out in the PPRS, there have been ongoing challenges to the adoption of NICE guidance and duplication of medicines evaluation within NHSE.
- The role of NHS England in shaping medicines policy has significantly evolved since the 2014 scheme started. ABPI felt that, as a result of the lack of direct transparency of PPRS money back into the local system, NHS cost containment activities had continued. DH pointed out that the growth in PPRS revenues had not kept pace with the growth in branded medicines spending overall, increasing cost pressures on the NHS which led to the changes to the scheme agreed at the end of 2016. NHS was under enormous pressure now and going forward due to higher demand. ABPI said that the NHS England agenda was now overwhelmingly one of cost minimisation.
- ABPI said that it seeking a Judicial Review against NICE should not have been necessary were it not for the fact that NICE had introduced a policy change part way
through the PPRS, and that industry perceived that there remained a lack of clarity around how the process would operate.

- ABPI noted that the AAR and LSIS were currently independent reports that government hadn’t yet responded to. It was concerned that the AAR might lead to a limited focus on uptake by narrowly considering the innovations in scope.
- ABPI said it was vital to ensure the independence of NICE was not undermined: the role of NICE in independent value based assessment on medicines was important in global industries’ perception of the UK market.
- DH noted that no requests had been made in the 2014 PPRS for flexible list pricing. ABPI said that it believed this was because more often products would be sold at lower than list price, and that the type of flexibility really needed was in the commercial arrangements including Multi-indication Pricing (MIP).
- DH agreed to confirm what work was being undertaken by OLS in reviewing the PICTF uptake indicators.
- DH asked ABPI to share its views and analysis of the impact of new product launches going forward.

AOB

- ABPI said that ongoing foreign exchange impacts on the value of the Pound had been significant for industry. ABPI suggested a scenario planning exercise in order to consider mitigating plans as a result of a weaker pound. DH said it also recognised that impacts needed to be considered and was working on a risk assessment on supply shortages. DH would continue to involve ABPI in supply chain policy work.
- ABPI said it would respond to the consultations following the Health Service Medical Supplies (Costs) Act. It said it recognised the case for stability between the PPRS and statutory schemes in 2018. The information regulations caused industry concern because of the lack of clarity on the circumstances in which information notices might be issued to companies with branded medicines, and the clause which suggests the DH could require estimates of research and development data for product presentations. DH made the point that the consultation provided clear examples of the circumstances in which DH may request cost information for individual products: for example, when investigating potential excessive prices for generic medicines or (as is the case now) when considering a price increase application for a branded medicine.