Medicines and Healthcare products Regulatory Agency
Board Meeting - public session

12 September 2016

Quarterly Report – BP Monitoring Report Q1 2016/17

Issue/purpose: The purpose of this paper is to provide the Board with the first quarterly report of progress against the 2016-17 agency business plan.

Summary/Key points:

This paper:

- sets out the agency's Quarter 1 position against the commitments made in the 2016-17 business plan for:
    - Targets (Annex A);
    - Activities (Annex B);
    - Metrics (Annex C); and
    - Further performance related work (Annex D).

Timings: For clearance at Board meeting

Action required: The Board invited to note:

- progress against delivery of the agency's business plan targets; activities; metrics and further performance related work at the end of Quarter 1 for 2016-17.

Links: The Medicines and Healthcare products Regulatory Agency's Business Plan 2016-17, Corporate Plan 2013-18 and Corporate Plan Refresh 2016.

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FOI/publication issues: The metric relating to "British Pharmacopoeia Chemical Reference Substances sales (in £ms)" is commercially sensitive and has been removed from this report.

It's also worth highlighting the attached report is used for internal tracking purposes and data has not been independently validated.

Sponsor: Jonathan Mogford

Agency's 2016-17 Business Plan Monitoring Report for Quarter 1 (April - June 2016)

1 Introduction

1.1 Following CET, the Board and DH's endorsement in April 2016, the Medicines and Healthcare products Regulatory Agency's Business Plan 2016-17 was published on 27 April 2016[1]. This paper provides the Board with an update on the agency's Quarter 1 position against the Targets, Activities, Metrics and further performance related work set out therein – each of which will be discussed in turn further below.

1.2 The Board will note that we have continued to use the same spreadsheet template that was in place for last year. This continues to be well received by the Cross Agency business planning representatives who were asked to input data, as usual; provide their own 'RAG' assessment; and briefly meet with Policy colleagues to discuss progress / clarify any concerns.

2 Targets

2.1 As set out in **Annex A**, the agency is 'on track' to meet the majority of its targets. There are five, which require further explanation, as set out below.

PM2(b)(c) - Medicines licensing - assessment of applications, specifically:

- % DCP RMS in 70 days
- % MR in 50 days
- % Type II assessed in 90 days

2.2 Licensing has stated that the reason for missing their 97% target during Q1 (% DCP RMS in 70 days) was due to a single procedure involving multiple strengths being missed. 91% was achieved for Q1.

2.3 The reason for missing their 97% target (% MR in 50 days) was due to a single procedure being missed by one day.

2.4 At the end of Q1 95% of Type II major variation applications were assessed within 90 days. The 97% target was missed largely as a result of resource constraints and due to the time necessary to train new assessors. The target remains challenging as the division remains below its budgeted headcount and the impact of the recently recruited staff has not yet been fully realised - reflecting the substantial training period required for new assessors. Recruitment of assessors is ongoing.

PM6 (a) - Standards and control - Biologics standards supply - 93% of all materials supplied within 6 working days

2.5 NIBSC has stated that there has been a large turnover of staff in the standards sales area resulting in a heavy reliance on temporary staff for the last six months. This has caused difficulties in meeting the turnaround target of 93%. For Q1, we achieved 85%.

PM8(b) - Answering Parliamentary Questions

2.6 One of the 18 PQs received in Q1 required rewriting. This was not requested by DH. The divisional team noticed a minor factual error and took action to correct it. We are currently

[1] https://www.gov.uk/government/publications/medicines-and-healthcare-products-regulatory-agency-business-plan-2016-to-17

at 5.5% for the number of cases returned for rewriting, marginally over our 5% target for the year. The team is still aiming to achieve its 5% for the financial year.

3 Activities

3.1 Of the **nine activities** due for completion in Q1, the respective divisions / centres reported **five** of these as having been '**completed**' by the end of Q1 (or thereabouts) as highlighted in **Annex B**. **Four** of these activities have been reported as 'risk of delay'.

3.2 In addition, three activities due in Q2 have been completed early, alongside an additional three allocated to Q1-Q4.

3.3 Divisions/ centres also provided a RAG rating for activities that are due in future quarters. Although the majority are 'on track', it's worth bringing to the Board's attention that there are six at 'risk of delay' as shown below.

3.4 Divisions have provided explanations for their delays and also a new expected completion date where possible as set out in Annex B.

3.5 The above is summarised in table below:

Status	Due date	Activity references
Completed	*Q1*	2u, 4k, 5Ai, 5Aii, 5Ci
	Q2	3f, 5Di, 5Gi
	Q1-Q4	4d, 4e, 4q
Risk of delay	*Q1*	2v, 3a, 4j, 5Fi
	Q2	3b
	Q3	2h, 5Bii
	Q4	2x, 5Civ
	Q1-Q4	5Biv

3.6 CET members have reviewed each of the activities at risk of delay and discussed possible mitigation measures with the relevant Directors.

4 Metrics

4.1 The Q1 metric updates are provided at **Annex C**. We continue to show the current year's performance against the equivalent for last year. This is helping us to develop a more meaningful illustration of agency performance over time.

4.2 As the Board will remember, in the 2015-16 business plan, we incorporated a small number of more outcome-based measures, which reflect the agency's contribution to public health across innovation and safety (medicines and devices) and ensuring a secure supply.

4.3 In the 2016-17 business plan, we:

- carried forward the additional metrics breaking down the number of Clinical Trials further;
- carried forward new metrics for Early Access to Medicines Scheme and Promising Innovative Medicines designations;
- added additional metrics on falsified medicines in the regulated supply chain and counterfeit devices incidents identified; and
- added a new metric from NIBSC on new innovative standards projects initiated.

4.4 In addition, we revised CPRD metrics (as agreed with DH sponsors) and added a new Devices metric setting out the number of NB audits conducted.

5 Further performance related work

5.1 In the 2015-16 business plan, we also made a commitment to carry out further performance related work on a few product related issues in medicines and devices.

5.2 Three new areas of 'further performance related work' have been identified for 2016/17. Progress is provided at **Annex D**.

6 Change control

6.1 As was the case for 2015-16 business plan monitoring, CET indicated it is not inclined to endorse any in-year changes to the commitments we made in the 2016-17 business plan.

6.2 Instead, CET endorsed maintaining an approach in which divisions / centres continue to report against the commitments set out in the published business plan and, only under the most exceptional circumstances, would support utilising formal change control.

6.3 The Q1 business plan monitoring report has been collated in line with this steer.

7 Conclusion / next steps

7.1 The Board is invited to note:

- progress against delivery of the agency's business plan targets, activities, metrics and further performance related work at the end of Quarter 1.