



Medicines & Healthcare products Regulatory Agency

Board Meeting

Report of Quarter 1 Delivery against the Agency Business Plan 2019/20

16 September 2019

Issue/ Purpose:

To report to the Board on progress against the Business Plan in the first quarter of the year.

Summary:

As is to be expected, almost all objectives are currently showing as Green/on track, not least as many have a Q4 delivery date. The paper highlights, on an exception basis, those few objectives where delivery is currently at risk.

Resource implications:

EU Referendum implications:

Responding to Brexit is a key priority in the business plan.

Implications for patients and the public:

Strong delivery against targets demonstrates the Agency's focus on public health responsiveness, accountability to Parliament, and FOI requests

Timings: As usual, the quarterly business plan report will be a key paper for the Quarterly Accountability Meeting with the Department of Health and Social Care on 20 September.

Action required by Board:

The Board is asked to note the report and raise any concerns/questions.

Links:

Corporate Plan 2018-23

Author(s):

Patience Wilson, Judith Thompson Policy Division

Which of the themes in the Corporate Plan 2018/2023 does the paper support?

all

If relevant, which Business Plan strategic activity does it support?

all

CET Sponsor:

Jonathan Mogford

Quarter 1 report on progress against the Business Plan 2019/20

Introduction

Introduction

1. This paper summarises delivery against the business plan in Quarter 1, for which further details are given in **Annex A**.

Report against business plan objectives and priorities (Annex A)

2. Divisions/centres have provided a RAG rating for the business plan objective deliverables. At the end of Quarter 1, most are showing as green/on track. The exceptions are:

- **One rated red**
 - 1a(ii) - **Acting on lessons learned from/implications of the Infected Blood Inquiry** on the Agency's ways of working and impact - because actions were not met by the original deadlines. Actions are in hand in Q2 to deliver on the lessons learned.
- Six are currently rated **amber** as below; actions are in hand in Q2 to remediate delays:
 - 1a(iii) – **MDR/IVDRs** – work to support future compliance with the standards has been delayed
 - 1a(iv) – **HRA** – expanding the combined ways of working pilot with the HRA
 - 1a(v) – **FMD** supporting stakeholders into compliance with the safety features
 - 1b – **Brexit** – although no deal preparations are continuing – including laying a further SI – and FEP engagement is advanced, we have not yet developed a formal plan as the Brexit outcome is still unclear.
 - 1d(i) – **International strategy** – Re-signing of the India MOU is heavily delayed, and the China MOU implementation is dependent on prosperity funding.
 - 5a – **Operational Transformation** – progressing action on the OTPBC, and plans to move the programme back to amber

Report against Business Plan Targets (Annex B)

3. At present, we are on track to meet the majority of our targets, with only 3 currently at risk of being missed:

- **PM4(b) – Medical devices alerts:** Target is to issue 95% within 10 days; actual performance in Q1 was 80%
- **PM8(b) – PQs:** Target is to answer 100% on time; actual performance in Q1 was 96% as one of the 28 PQs answered in Q1 was returned late
- **PM11(a) – cybersecurity:** Target is for 95% to be resolved within 15 days of being reported: actual performance in Q1 was 75%. The target was missed because of an

unusually high number of complex incidents, an increase in reporting of security incidents, and Information Security Officer vacancy.

Metrics (Annex C)

4. There are no areas for discussion at this point in the year.

Brexit Day 1 preparedness

5. In the second half of the last business year, the Corporate Executive Team and the Board agreed to de-prioritise a number of business plan objectives in order to free up resources to deliver critical Brexit day 1 preparedness activities, and to allow for Divisional discretion on targets. This approach was agreed with DHSC sponsors. Most of this re-prioritisation was done by deferring work on objectives which were desirable rather than business critical.
6. The impact of this de-prioritisation activity for this business plan was that at year end,
- we had fully completed or closed 60 of 72 objectives
 - 4 further objectives were largely met, with some activity postponed by agreement,
 - a further 8 objectives were postponed completely,
 - 36 of 41 business plan targets were fully met, with 2 nearly met, 2 not met, and one closed by previous agreement.
7. It seems right that the Corporate Executive Team and Board should again review whether there are objectives/ deliverables in the business plan which may need to be de-prioritised to ensure that we are resourcing critical Brexit work for 31 October. Subject to Board views, the team will engage with individual Directors to identify work which can be de-prioritised.

Conclusion / next steps

8. The Board is invited to
- discuss by exception any areas of concern on delivery against the business plan in Quarter 1; and
 - agree that we should look at options for de-prioritisation of business plan objectives to ensure business critical Brexit work is resourced.