| No. | Area | Target description | Target | Q1 | Q2 | Q3 | Q4 | 2019/20 total | | Rating (RAG) | Comments |
|---|---|---|---|---|---|---|---|---|---|---|---|
| PM1 | Medicines licensing – validation of applications | a) For Type IB and Type II variations, 97% of scientific validation process completed within 14 days of case creation | 97% | 100% | | | | 100% | % validated within 14 days of case creation. | On track | |
| | | b) For new Marketing Authorisation applications, 97% of validation reports produced within 14 days of case creation. | 97% | 100% | | | | 100% | % of validation reports produced within 14 days. | On track | |
| | | c) 97% of Change of Ownership applications validated or Request For Information (RFI) issued within 42 days of receipt. | 97% | 100% | | | | 100% | % granted within 42 days of receipt. | On track | |
| PM2 | Medicines licensing – assessment of applications | a) The assessment of applications for new Marketing Authorisations for UK only: 97% assessed in 150 days | 97% | 100% | | | | 100% | % in 150 days | On track | |
| | | b) The assessment of applications for new Marketing Authorisations in European (MRP, DCP & CP) procedures: 97% assessed within the designated time* 95% of CP assessed within the | 97% | 100% | | | | 100% | % DCP RMS in 70 days | On track | |
| | | | 97% | 100% | | | | 100% | % DCP CMS in 100 days | On track | |
| | | | 97% | 100% | | | | 100% | % MR in 30 days | On track | |
| | | | 95% | n/a | | | | n/a | % Centralised Rap/Co-Rap in 80 days | | EMA no longer allocates rap/co-rap work to the UK |
| | | c) The assessment of Type IB minor and Type II major variation applications in National and European (MRP, CP) procedures: 97% assessed within the designated time | 97% | 99% | | | | 99% | Type II % in 90 days | On track | |
| | | | 97% | 98% | | | | 98% | Type IB % in 30 days | On track | |
| PM3 | Assessment of clinical trials and investigations | a) The assessment of applications for clinical trials of medicines in the UK: 98% in 30 days (all trial phases) and an average time of 14 days (Phase I trials) | 98% | 100% | | | | 100% | % of all authorisations within 30 days | On track | |
| | | | 14 day average | 12.91 | | | | 12.91 | average days for Phase I trials | On track | |
| | | b) Timescales for clinical investigation notifications for medical devices: maximum of 60 days | within 60 days | 100% | | | | 100% | % handled within 60 days | On track | |
| PM4 | Capturing and analysing adverse event reports –making reports available, issuing alerts and acting on signals | b) Medical Device Alerts will be issued: 95% within 10 days, 100% within 15 days | 95% | 80% | | | | 80% | % published within 10 days | Risk of missing target | |
| | | | 100% | 100% | | | | 100% | % published within 15 days | On track | |
| | | c) For fatal UK adverse drug reactions: 90% within 24 hours, 100% within 72 hours | 90% | 100% | | | | 100% | % within 24 hours | On track | |
| | | | 100% | 100% | | | | 100% | % within 72 hours | On track | |
| | | d) For serious UK adverse drug reactions: 95% within 72 hours, 100% within 5 days | 95% | 100% | | | | 100% | % within 72 hours | On track | |
| | | | 100% | 100% | | | | 100% | % within 5 days | On track | |
| | | e) Ensure all UK potential signals (relating to medicines) from whatever source are acted on promptly: 85% initially evaluated within 5 working days | 85% | 96% | | | | 96% | % within 5 working days | On track | |
| PM5 | Publication of UK assessment reports for new Marketing Authorisations | Publish 98% of UK assessment reports within 60 net calendar days of grant of new authorisations | 98% | 100% | | | | 100% | % PARs completed within 60 days | On track | |
| PM6 | Standards and control | a) Batch release activity – 99% of all requested official control authority batch release (OCABR) and non-EU testing completed within agreed timelines: | 99% | Met | | | | 99% | % within 8 days for Plasma Pools | On track | |
| | | | 99% | Met | | | | 99% | % within 10 days for Molecular Immunology | On track | |
| | | | 99% | Met | | | | 99% | % within 15 days for Haemostasis | On track | |
| | | • 8 days for Plasma Pools<br>• 10 days for Molecular Immunology<br>• 15 days for Haemostasis<br>• 95% of all requested official control authority batch release (OCABR) and non-EU testing completed within agreed timelines: 60 days for vaccines | 95% | Met | | | | 99% | % within 60 days for vaccines | On track | |
| PM7 | CPRD activity | a) 90% of research applications to receive initial feedback from ISAC review within 30 working days | 90% | 96% | | | | 96% | % of research applications to receive initial feedback from ISAC review within 30 working days | On track | |
| | | b) Expand CPRD database coverage to 20% of the total UK population | 20% | 17% | | | | 17% | Currently registered patients at CPRD contributing practices | On track | |
| | | c) 3 new routine linkages available for observational research studies | 3 | 0 | | | | 0 | number of routine linkages available for observational research studies | On track | |
| PM8 | Answering Freedom of Information requests, letters and Parliamentary Questions | a) Respond to all requests under the Freedom of Information Act within 20 working days (or within permitted extension). | 100% | 99% | | | | 99% | % replied to within 20 working days (inc. public interest test extensions) | On track | |
| | | b) Aim to return all responses to Parliamentary Questions (PQs) to the DHSC by noon on the date specified | 100% | 96% | | | | 96% | % answered on time | Risk of missing target | 28 PQs were answered in Q1 of which 1 was returned late (returned to DHSC within minutes of the 12 noon deadline) |
| | | c) Return Ministerial correspondence (POs) drafts to the DHSC within 4 working days of receipt in at least 90% of cases | 90% | 100% | | | | 100% | % answered on time | On track | 21 POs were answered all were returned on time |
| PM9 | Summary Evaluation Report reviews – TSE | a) In relation to Medical Devices utilising starting materials for which a TSE certificate of suitability is available – An opinion must be provided within 4 weeks from the date in which the Notified Body informed the MHRA | 100% | 100% | | | | 100% | % of opinions provided within 4 weeks from the date in which the Notified Body informed the MHRA | On track | |
| | | b) In relation to Medical Devices utilising starting materials for which a TSE certificate of suitability is not available – an opinion must be provided within 12 weeks from the date in which the Notified Body informed the MHRA | 100% | 100% | | | | 100% | % opinion provided within 12 weeks from the date in which the Notified Body informed the MHRA | On track | |
| | | c) For Summary Evaluation reports received from other Member States – responses must be provided within the required timeframe to ensure timely response back to the Notified Body. | 100% | 100% | | | | 100% | % provided within the required timeframe to ensure timely response back to the Notified Body. | On track | |
| PM10 | IT Operations | a) 10% reduction in major incidents (Category - Priority 1 and 2) | 10% | | | | | 10% | % reduction in the number of Category P1 and P2 incidents | On track | |
| | | b) Fewer than 5 major incidents (Categories: Priority 1 and 2 caused by change) | less than 5 | | | | | | number of P1 and P2 incidents caused by changes to the production systems | On track | |
| | | c) No major problem tickets open for more than 6 weeks | 0 | | | | | 0 | number of helpdesk service requests open for more than 6 weeks | On track | |
| PM11 | Information Management | a) Cybersecurity: Information Security Incidents resolved within 15 days of being reported | 95% | 75% | | | | | % resolved within 15 days of being reported | Risk of missing target | Target missed because of an unusually high number of complex incidents; an increase in reporting security incidents, and Information Security Officer vacancy. |
| | | b) Data: Subject Access Requests provided with a response within one month of receipt | 95% | 100% | | | | | % SARs provided with a response within GDPR timescales.<br>Standard SARs: one month deadline<br>Complex SARs: initial response within 1 month, plus upto 2 month extension to deadline | On track | |

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| On track |
| Risk of missing target |
| Significant risk of missing target |