No.	Area	Target description	Target	Q1	Q2	Q3	Q4	2016/17 total		Rating (RAG)	Comments	Division/ Centre	Information Lead
PM1	Medicines licensing – validation of applications	a) For Type IB15 and Type II16 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		IMD	Shaun Fiddes
		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		IMD	Shaun Fiddes
		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		IMD	Shaun Fiddes
PM2	Medicines licensing – assessment of applications	a) The assessment of applications for new Marketing Authorisations for UK only: 97% assessed in 150 days	97%	98%				98%	% in 150 days	On track		Licensing	Colm Reddington
		b) The assessment of applications for new Marketing Authorisations in European (MR, DC & centralised) procedures: 97% assessed within the designated time	97%	91%				91%	% DCP RMS in 70 days	Risk of missing target	A single procedure involving multiple strengths missed the target.	Licensing	Colm Reddington
			97%	100%				100%	% DCP CMS in 100 days	On track		Licensing	Colm Reddington
			97%	96%				96%	% MR in 50 days	Risk of missing target	A single procedure missed the target by 1 day.	Licensing	Colm Reddington
			97%	100%				100%	% Centralised Rap/Co-Rap in 80 days	On track		Licensing	Colm Reddington
		c) The assessment of Type IB minor and Type II major variation applications in National and European (MR, centralised) procedures: 97% assessed within the designated time.	97%	95%				95%	Type II % in 90 days	Risk of missing target	Largely the result of resource constraints resulting from the time necessary to train new assessors.	Licensing	Colm Reddington
			97%	97%				97%	Type IB % in 30 days	On track		Licensing	Colm Reddington
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%	99%				99%	% of all authorisations within 30 days	On track		Licensing	Martin O'Kane
			14 day average	12.7				12.7	average days for Phase 1 trials	On track		Licensing	Martin O'Kane
		b) Timescales for clinical investigation notifications for medical devices: maximum of 60 days with an overall average of 54 days or less	within 60 days	100%				100%	% handled within 60 days	On track		Devices	Clare Headley
			average 54 days or <	47%				47%	average days in total	On track		Devices	Clare Headley
		a) Maximum timescales between receipt	95%	100%				100%	% made available within 2 working days	On track		Devices	Philip Grohmann

No.	Area	Target description	Target	Q1	Q2	Q3	Q4	2016/17 total		Rating (RAG)	Comments	Division/ Centre	Information Lead
PM4	Capturing and analysing adverse event reports –making reports available, issuing alerts and acting on signals	of reports and making them available for evaluation and analysis: For fatal and serious device adverse incidents: 95% within 2 working days and 100% (fatal and serious only) within 3 working days	100%	100%				100%	% available within 3 working days	On track		Devices	Philip Grohmann
		b) Medical Device Alerts will be issued: 95% within 10 days, 100% within 15 days	95%	100%				100%	% published within 10 days	On track		Devices	Philip Grohmann
			100%	100%				100%	% published within 15 days	On track		Devices	Philip Grohmann
		c) For fatal UK adverse drug reactions: 90% within 24 hours, 100% within 72 hours	90%	100%				100%	% within 24 hours	On track		VRMM	Mick Foy
			100%	100%				100%	% within 72 hours	On track		VRMM	Mick Foy
		d) For serious UK adverse drug reactions: 95% within 72 hours, 100% within 5 days	95%	100%				100%	% within 72 hours	On track		VRMM	Mick Foy
			100%	100%				100%	% within 5 days	On track		VRMM	Mick Foy
		e) Ensure all UK potential signals (relating to medicines) from whatever source are acted on promptly: 85% initially evaluated within 5 working days	85%	91%				91%	% within 5 working days	On track		VRMM	Mick Foy
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		Licensing	Ajmal Afzal
PM6	Standards and control	a) Biologics standards supply - 93% of all materials supplied within 6 working days	93%	85%				85%	% of all materials supplied within 6 working days	Risk of missing target	There has been a large turnover of staff in the standards sales area resulting in a heavy reliance on temporary staff for the last 6 months. This is causing difficulties in meeting the turnaround target.	NIBSC	Adrian Bristow
		b) Batch release activity – 99% of all requested official control authority batch release (OCABR) and non-EU testing completed within agreed timelines: • 10 days for Plasma Pools • 10 days for Parenterals • 15 days for Haemostasis • 60 days for vaccines	99%	100%				100%	% within 10 days for Plasma Pools	On track		NIBSC	Ian Feavers
			99%	100%				100%	% within 10 days for Parentals	On track		NIBSC	Ian Feavers
			99%	100%				100%	% within 15 days for Haemostasis	On track		NIBSC	Ian Feavers
			99%	100%				100%	% within 60 days for vaccines	On track		NIBSC	Ian Feavers
PM7	CPRD activity	a) Support 260 new observational research studies in 2016/17	260	65				65	total new observational research studies support in 2016/17	On track		CPRD	Jon Ford
		b) Drive the increase of CPRD GP coverage from 600 to 1000 GP practices	1000	599				599	increasing the number of GP practices contributing data to CPRD	On track		CPRD	Jon Ford
		a) Respond to all requests under the Freedom of Information Act within 20 working days (or within permitted extension).	100%	99.4%				99.4%	% replied to within 20 working days (inc. public interest test extensions)	On track		Policy	Gareth Newman

No.	Area	Target description	Target	Q1	Q2	Q3	Q4	2016/17 total		Rating (RAG)	Comments	Division/ Centre	Information Lead
PM8	Answering Freedom of Information requests, letters and Parliamentary Questions	b) Return responses to Parliamentary Questions (PQs) to the Department of Health by noon on the date specified in at least 90% of cases with less than 5% returned to MHRA by the Department for rewriting.	5%	5.5%				5.5%	% returned for rewriting	Risk of missing target	One of the 18 PQs in Q1 needed a rewrite. This was not requested by DH, but division noticed a minor factual error and took action to correct it.	Policy	Gareth Newman
		c) Return Ministerial correspondence (POs) drafts to the Department of Health within 4 working days of receipt in at least 90% of cases with less than 5% returned to MHRA by the Department for rewriting.	90%	90%				90%	% answered on time	On track		Policy	Gareth Newman
			5%	0.0%				0.0%	% returned for rewriting	On track		Policy	Gareth Newman
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		Devices	Dhruti Patel
		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		Devices	Dhruti Patel
		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		Devices	Dhruti Patel

RAG status

- Completed
- On track
- Risk of missing target
- Significant risk of missing target