Quarter 2 2026-27:
Performance & Results Report

November 2026

Quarter 2 performance at a glance



Written scientific advice delivered on time



National medicines licence applications determined on time



Quality of scientific advice service score



Time to deliver formal written scientific advice (30-working-day target)



New manufacturing licences (90-day target)



Vaccine batch testing (43-working-day target)



Customer enquiries handled



Parliamentary questions responded to on time

Confidence in performance – our KPIs



Clinical trials and investigations assessed on time



Recognition of international medicines licences determined on time



Adverse incidents processed within 24 hours



Vaccines and blood products certified on time



National variations determined on time



Scientific advice requests – written advice delivered on time



National medicines licence applications determined on time



Decisions on manufacturing and distribution authorisations made on time



End of the year 2025–26

Q2 2026–27

Timely decisions on clinical trials and investigations

		Time target (max days)	Median time Q2 (days)	5th percentile Q2 (days)	95th percentile Q2 (days)
Clinical trial authorisations	Initials	30	29	10	30
	Modifications	35	34	6	35
Clinical investigations	Initials	60	57	36	60
	Modifications	21	5	0	43

Quality scientific advice

Scientific advice	Time target (max working days)	Median time Q2 (working days)	5th percentile Q2 (working days)	95th percentile Q2 (working days)
Time to offer a meeting	10	4	0	10
Time to offer written advice*	30	24	6	29
End-to-end timeline across regulatory services	N/A	68	42	100

Quality of advice service score:



Overall experience with MHRA:



*We aim to deliver the formal written advice within 30 working days of the meeting date or, if no meeting is required or requested, within 30 working days of receiving company documentation.

Reliable licensing timelines

		Time target (max days)	Median time Q2 (days)	5th percentile Q2 (days)	95th percentile Q2 (days)
National marketing authorisations granted	Established medicines	210	200	101	210
	New active substances	210	136	58	185
IRP marketing authorisations granted	Route A	60	60	50	109
	Route B	110	105	63	132

Robust variations timelines

Measure	Time target (max days)	Median time Q2 (days)	5th percentile Q2 (days)	95th percentile Q2 (days)
Type Ib – National	30	15	1	30
Type Ib – Safety	30	16	5	29
Type II – National	90	58	8	112
Type II – Safety	90	61	14	90

Consistent timelines for wholesale dealer and manufacturing licences

		Time target (max days)	Mean time Q2 (days)
Wholesale Dealer Licences	New application	90	50
	Variation: Inspection	90	39
	Variation: No inspection	30	13
Manufacturing Licences	New application	90	48
	Variation: Inspection	90	50
	Variation: No inspection	30	11

Responsive batch control testing delivery

	Number batches tested	Time target (max working days)	Median time Q2 (working days)	5th percentile Q2 (working days)	95th percentile Q2 (working days)
Blood products	177	15	5	1	10
Vaccines	204	43	2	0	15

Transparent and timely responses

Category	Parliamentary questions	Customer enquiries	Complaints	Freedom of Information requests
Number received	42	11,341	61	277
Responded on time in Q2	100%	90%	84%	97%
Target for on-time responses	85%	90%	90%	90%

Forecast for quarter 3 (October - December 2026)



Launch our Strategy to 2030, setting the direction for a modern, innovative and internationally connected regulator



Provide long-term certainty for the medical devices sector through confirmation of indefinite CE-marking recognition



Publish guidance to support the development and regulation of mRNA medicines



Clarify the evidence requirements for using trial data generated in non-OECD countries



Confirm the outcome of fees reform proposals designed to support higher-value regulatory services

Forecast for quarter 3 (October - December 2026)



Bring together global leaders at the DIA–MHRA Global Summit



Launch the MHRA Patient and Public Involvement and Engagement Plan and the Women's Health Programme



Take forward first recommendations of the National Commission into AI in Healthcare



Support developers in earlier advice on manufacturing quality (GMP) requirements



Advance steps towards a new cutting-edge framework for gene therapies

Days reported are calendar days unless specified as working days.

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