Medicines & Healthcare products Regulatory Agency

MHRA performance

Assessment of New Marketing Authorisation Applications and Variations

January 2025

January summary

Work type	Average time to validation in days	Numbers validated	% validated within statutory time
Validation for new MAAs – all submission routes	17	93	26
Validation for variations – all submission routes	5	703	99
Work type	**Average time to determination in days***	**Numbers granted**	**% granted within statutory time**
Type IA variations – national	30	632	42
Type IB variations – all submission routes	14	814	99
Type IB IRP variations	8	273	100
Type II variations – all submission routes**	73	314	86
Type II IRP variations	37	180	98
Initials – NAS MAA national	286	3	0
Initials – established medicines MAA***	648	24	8
Initials – established meds IRP route A	57	28	100
Initials – established meds IRP route A extended	96	7	100
Initials – established meds IRP route B	-	-	-
Initials – established meds IRP route B extended	103	3	100
Initials – NAS IRP route A	-	-	-
Initials – NAS IRP route A extended	-	-	-
Initials – NAS IRP route B	107	3	100
Work type	**Average assessment time in days**	**Numbers assessed**	**% assessed within statutory time**
PIQU	36	158	100
Compliance – national MAAs only	29	19	90
Work on hand as of 3 February 2025 ****			
Total overdue individual Product Licences			166

- * Regulatory clock on days from validation to determination
- ** Type II variations – This is a crude estimation of 90 days as there are different work types and different procedure types grouped together
- *** Includes national and reliance route conversions
- **** Overdue individual Product licences (past the 210) days shows all pending abridged (biologicals removed) national licences (with current clock on or off) with regulatory clock on days over 210

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