



Medicines & Healthcare products
Regulatory Agency

MHRA performance

Assessment of New Marketing Authorisation Applications and Variations

October 2024



September summary

Work type	Average time to validation in days	Numbers validated	% validated within statutory time
Validation for new MAAs – all submission routes	3	55	83
Validation for variations – all submission routes	5	679	99
Work type	Average time to determination in days*	Numbers granted	% granted within statutory time
Type IA variations – national	13	618	96
Type IB variations – all submission routes	13	584	97
Type IB IRP variations	2	160	99
Type II variations – all submission routes**	139	180	57
Type II IRP variations	39	47	87
Initials – NAS MAA national	208	3	33
Initials – established medicines MAA***	578	78	1
Initials – established meds IRP route A	55	12	75
Initials – established meds IRP route B	104	2	100
Initials – NAS IRP route A	-	-	-
Initials – NAS IRP route B	110	1	100
Work type	Average assessment time in days	Numbers assessed	% assessed within statutory time
PIQU	42	83	100
Compliance – national MAAs only	25	76	82
Work on hand as of 1 October 2024 ****			
Total overdue individual Product Licences			353

- * 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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