Medicines & Healthcare products Regulatory Agency

MHRA performance

Assessment of New Marketing Authorisation Applications and Variations

October 2024

October summary

Work type	Average time to validation in days	Numbers validated	% validated within statutory time
Validation for new MAAs – all submission routes	10	60	83
Validation for variations – all submission routes	6	1012	99
Work type	**Average time to determination in days***	**Numbers granted**	**% granted within statutory time**
Type IA variations – national	13	598	98
Type IB variations – all submission routes	13	620	98
Type IB IRP variations	3	186	96
Type II variations – all submission routes**	82	214	66
Type II IRP variations	17	70	93
Initials – NAS MAA national	298	4	25
Initials – established medicines MAA***	560	141	5
Initials – established meds IRP route A	54	9	100
Initials – established meds IRP route B	101	2	50
Initials – NAS IRP route A	39	5	100
Initials – NAS IRP route B	-	-	-
Work type	**Average assessment time in days**	**Numbers assessed**	**% assessed within statutory time**
PIQU	46	161	93
Compliance – national MAAs only	29	135	73
Work on hand as of 4 November 2024 ****			
Total overdue individual Product Licences			362

- * 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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