



Medicines & Healthcare products  
Regulatory Agency

# MHRA performance

Assessment of New Marketing  
Authorisation Applications  
and Variations

April 2024



# April summary

Work type	Average time to validation in days	Numbers validated	% validated within statutory time
Validation for new MAAs – all submission routes	7	72	92
Validation for variations – all submission routes	5	884	97
Work type	Average time to determination days*	Numbers granted	% granted within statutory time
Type IA variations – national	10	232	99
Type IB variations – all submission routes	35	659	71
Type IB IRP variations	7	130	100
Type II variations – all submission routes**	69	178	76
Type II IRP variations	9	51	100
Initials – established medicines MAA***	430	82	5
Initials – established meds IRP route A	56	11	100
Initials – NAS IRP route A	55	1	100
Work type	Average assessment time in days	Numbers assessed	% assessed within statutory time
PIQU	52	73	100
Compliance – national MAAs only	30	61	92

Work on hand	
Overdue individual Product Licences from backlog of 1167 at 9 Jan 2024 (past the 210 days) as at 30 April 2024****	805

- \* 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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