



Medicines & Healthcare products
Regulatory Agency

MHRA performance

Assessment of New Marketing Authorisation Applications and Variations

January 2023 - December 2023



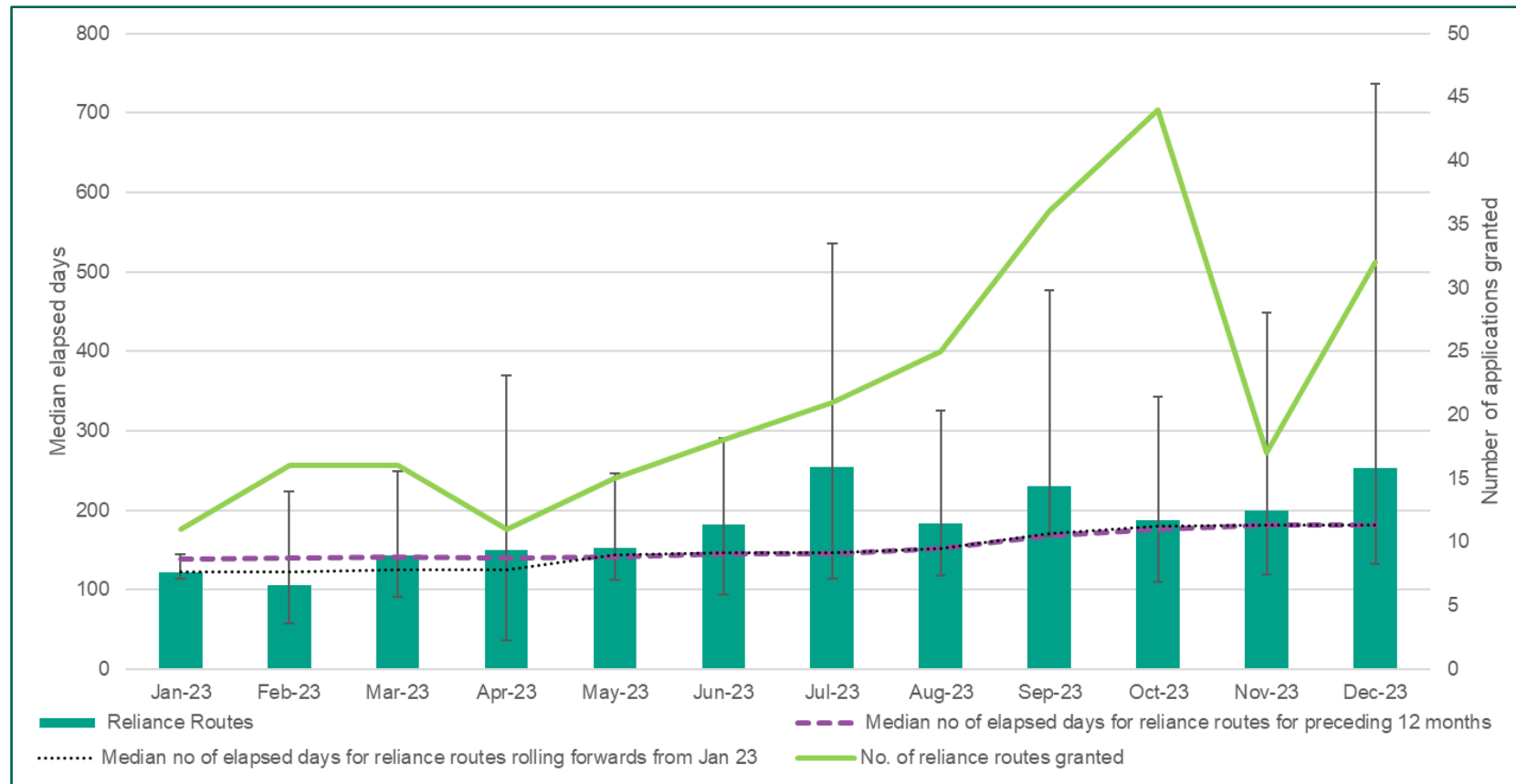
December summary

Work type	Median time in days*	Numbers Granted	% in target
Type IA variations – national	6	656	100%
Type IB variations – national, reliance	26	894	86%
Type II variations – national, reliance, Project Orbis	102	331	77%
Initials – established medicines national MAA	496	26	26%
Initials – established medicines reliance MAA	253	32	0%

Work on hand	
Overdue individual Product Licences (past the 210 days as at 4 January 2024)	1167

*Median elapsed days from validation to determination

Figure 1. Established medicines reliance initial licences granted - median time to determination (total elapsed days since validation) & number of applications for Jan –Dec 2023, median elapsed days for preceding 12 months, and median elapsed days rolling forwards from Jan 23



Key features

- Reliance routes include ECDRP and MRDC reliance
- This graph shows lines for the median elapsed days for reliance route granted applications for the preceding 12 months at each time point as well as the accumulative median at each time point from January 2023 onwards. The number of applications granted for each month is also shown.
- This includes applications which are being worked through from the queue, which is not truly able to be trended and median times are showing an extension.

Figure 2. Initial national established licences - median time to first RFI (total elapsed days from received) & number of applications with first RFI for Jan - Dec 2023



- **Key features**
- This graph shows the median number of elapsed days from application received to first RFI.
- This includes applications which are being worked through from the queue, which is not truly able to be trended.

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