



Medicines & Healthcare products  
Regulatory Agency

# MHRA performance

## Assessment of New Marketing Authorisation Applications and Variations

January 2023 – January 2024

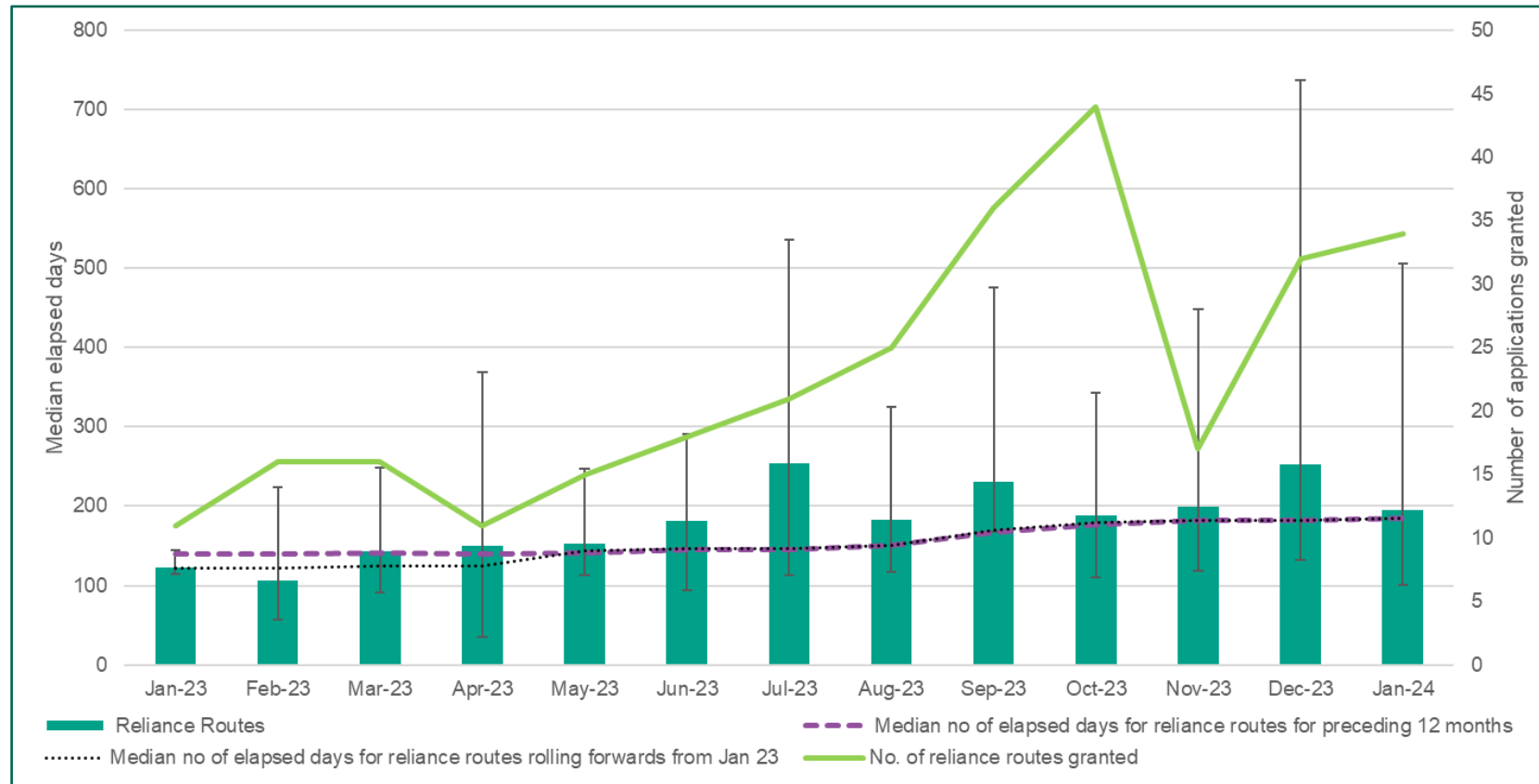


# January summary

Work type	Median time in days*	Numbers granted	% in target
Type IA variations – national	1	625	100%
Type IB variations – national, reliance	21	1038	88%
Type II variations – national, reliance, Project Orbis**	98	439	46%
Initials – established medicines national MAA	333	33	39%
Initials – established medicines reliance MAA	195	34	6%
Work on hand			
Overdue individual Product Licences (past the 210 days, as at 5 February 2024)***			1136

- \*Median elapsed days from validation to determination.
- \*\*Type II variations – 201 of 439 granted in time 46%.
- \*\*\*Overdue individual Product Licences (past the 210) days shows all pending abridged (biologicals removed) national licences (which current clock on or off) over regulatory clock on days over 210.

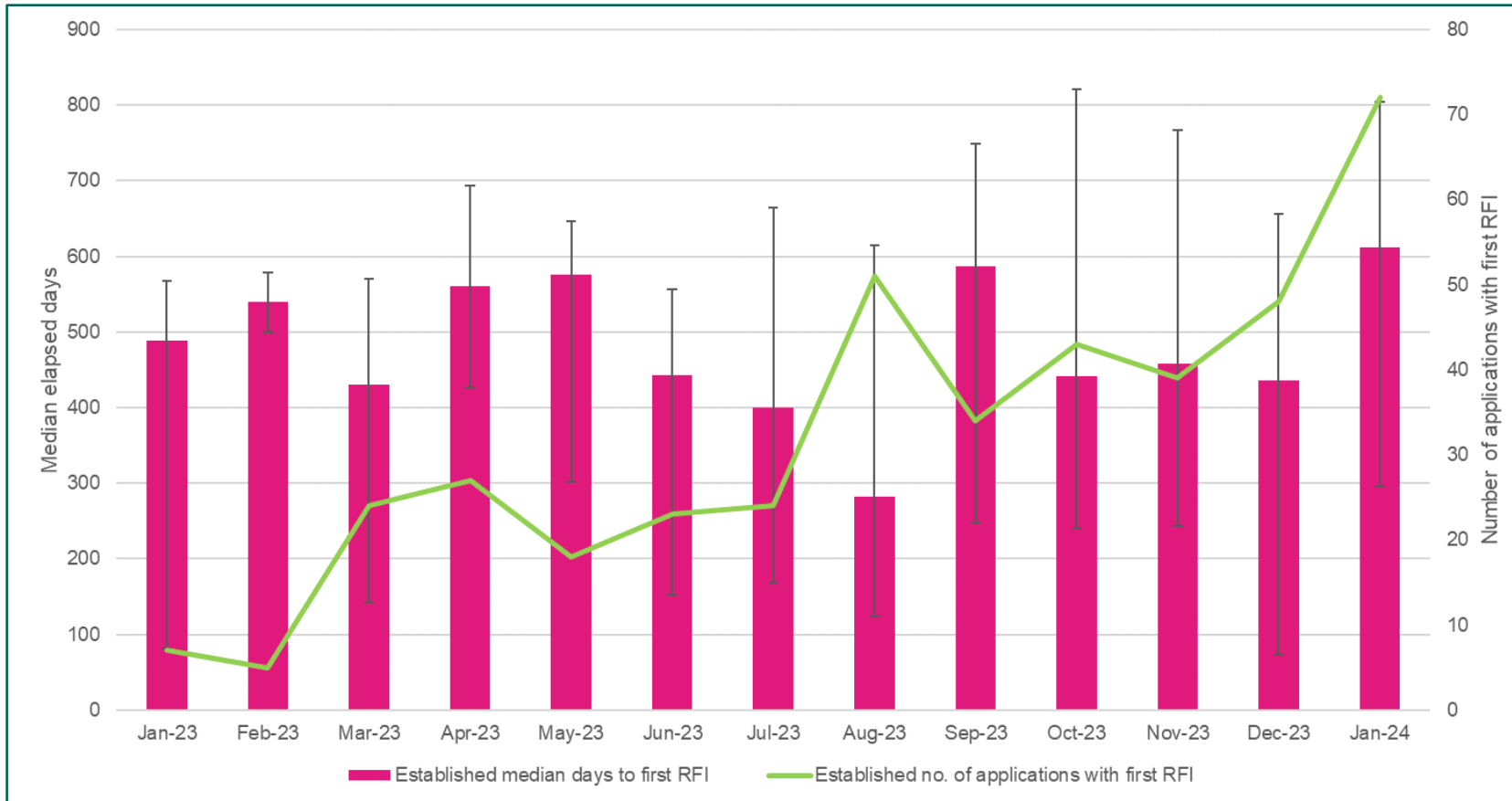
**Figure 1. Established medicines reliance initial licences granted - median time to determination (total elapsed days since validation) & number of applications for Jan 2023 – Jan 2024, median elapsed days for preceding 12 months, and median elapsed days rolling forwards from Jan 23**



**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 2023 – Jan 2024**



**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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