RIS Appendix One: Comparison of medicines regulators' timeframes

	New Zealand	Australia	EU	Singapore	UK	US
Name of regulator	Medsafe	Therapeutics Goods Authority	European Medicines Agency -	Health Sciences Authority	Medicines and Healthcare products Regulatory Agency	US Food and Drug Administration
Use of reliance	Yes *Abbreviated New Medicines Application process (3.3)* It recognizes AU, US, CAN, UK, EU, Switzerland and Singapore for high or immediate risk	Yes – 3 reliance pathways identified (here) (1) Comparable Overseas Regulator pathway (2) Work sharing Australia, Canada, Singapore, Switzerland, UK (ACCESS) pathway. (3) Project Orbis, a work sharing procedure (FDA)(oncology)	Outside of the centralised procedure – there are: - Mutual recognition (auth granted in one state can be recognized in another) - Decentralised – a medicines not yet auth'd in EU can be auth'd simultaneously in EU states Note there are mutual recognition agreements for certain areas (GMP) with other countries to varying degrees	Use reliance in the following routes - '**Abridged** evaluation': new medicines approved by another regulator - **Verification**: approved by reference drug agencies (CAN, AUS, USA, EU, UK) - **Verification CECA**: manufactured in India and approved by ref agencies. [only Generics]	• Fast track decisions via recognition route. (Recently implemented) • Two recognition pathways proposed (A, B) based on when medicine was approved	
Approval timing under reliance	No legislated timing for abbreviated new medicines process but targets and performance, measured in calendar days. *Initial evaluation* • Abbreviated (120) • Full application (200) If sponsor responds to RFI within 28 days, the EAI (eval of additional info) target timeframe is 28 days.	Comparable Overseas Regulator pathway (1) < 120 working days (COR - A)(legislated) (2) < 175 working days (COR-B) (legislated) Work sharing (ACSS) pathway. Project Orbis (FDA) (3) Noted that the priority review pathway is shorter eval time and flexible	Unclear if there is a time differential for reliance.	Time differential Screening (working days) **Abridged: 50** **Verification: 50** Evaluation **Abridged: 180** **Verification: 60**	• Recognition A: 60-day timetable • Recognition B: 110-day timetable	No changes to the approval time for mutual recognition agreement
Reliance Timing approach	Calendar days (includes holidays and weekends) Clock starts from payment of application. Does not have stop clock for a pre application or recognition submission. Does not have a stop clock for sponsors response times.	Working days (does not include holidays or weekends) Clock starts when TGA accepts the submission (i.e. after Medsafe) Stops clock ramps exist depending on supplier responses to rolling questions or triggering a s31 request for further information for evaluation.	Active days (working days) Unclear if there is a difference for reliance – i.e. there is only a standard v accelerated assessment	Working days	Calendar days Have to apply 6 weeks before a designated start time. Starts once the recognition submission has been validated by MHRA A: No stop clock but will switch from A to B pathway if major objections identified B: 1 stop clock at 70 days and allows up to 60 days for response. reverts to national 210 timeline if major objections.	NA
General timing approach	Medsafe does categorise based on reliance but distinguishes between abbreviated and non abbreviated.	*For non-reliance type reviews.* *TGA target times* Standard: 220 TGA working days Priority: 150 TGA working days	Full process Standard: 210 'active days' (working days) Accelerated assessment: 150 days Note this does not include the 2 stop clocks after the first evaluation (3-6 months) and second eval (1 -2 months)	Full process if not been approved by another regulator	Calendar days 210 day timetable Clock stop: excluding time taken to provide any additional information or data required by the MHRA	Once a New Drug Application is received, FDA have 60 days to make a decision on whether it will be reviewed, review team has 6 to 10 months to make a decision on whether to approve the drug