List of transitional WLAs
(in alphabetical order) as of May 2024

The ultimate responsibility and decision for use of tWLA and WLA lists resides with the users (e.g., regulatory authorities, procurement agencies) and will depend on the specific context of its intended use. In no event shall the World Health Organization be liable for any damages arising from its use.

<table>
<thead>
<tr>
<th>National Regulatory Authority</th>
<th>Origin of transition</th>
<th>Scope of tWLA designation</th>
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</thead>
</table>
|                              | as per WHO interim list at 31/03/2022 | ☐ Medicines
|                              | A ML3/ML4 NRAs (medicines and/or vaccines)³ | ☐ Vaccines
|                              | B SRA (medicines)⁴ | ☐ Vaccines
|                              | C Highly performing NRA (vaccines)⁵ | ☐ Vaccines
|                              | D NRAr of the Americas (medicines and/or vaccines)⁶ | ☐ Vaccines
|                              | E Functional NRA (vaccines)⁷ | ☐ Vaccines
| 1. Argentina ANMAT            | D                     | Medicines
|                              |                       | Vaccines
| 2. Australia TGA             | B, C, E               | Medicines
|                              |                       | Vaccines
| 3. Brazil ANVISA             | D, E                  | Medicines
|                              |                       | Vaccines
| 4. Canada Health Canada      | B, C, D, E            | Medicines
|                              |                       | Vaccines
| 5. Chile ISP                 | D                     | Medicines
|                              |                       | Vaccines
| 6. China NMPA                | E                     | Medicines
|                              |                       | Vaccines
| 7. Colombia INVIMA           | D                     | Medicines
|                              |                       | Vaccines
| 8. Cuba CECMED               | D, E                  | Medicines
|                              |                       | Vaccines
| 9. Egypt EDA                 | A (ML3)               | Medicines
|                              |                       | Vaccines
| 10. Ghana FDA                | A (ML3)               | Medicines
|                              |                       | Vaccines
| 11. India CDSCO              | A (ML3)               | Medicines
|                              |                       | Vaccines
| 12. Indonesia BADAN POM      | A (ML3)               | Vaccines
| 13. Iran (Islamic Republic of) IFDA | E                     | Vaccines
| 14. Japan PMDA               | B, E                  | Medicines
|                              |                       | Vaccines
| 15. Mexico COFEPRIS          | D, E                  | Medicines
|                              |                       | Vaccines
| 16. Nigeria NAFDAC           | A (ML3)               | Medicines
| 17. Russian Federation Ministry of Health | E | Vaccines
| 18. Serbia ALIMS             | A (ML3)               | Vaccines
| 19. Thailand Thai-FDA        | A (ML3)               | Vaccines
The time-limited WHO interim list of National Regulatory Authorities was established in September 2019 as part of the planned transformation from the term Stringent Regulatory Authorities (SRAs) to WHO-Listed Authorities (WLA).

Precise scope of designation for tWLAs (new medicines, multisource, biotherapeutics, biosimilar products) will be further defined in agreement with each Regulatory Authority as part of the roadmap to listing.

National Regulatory Authorities (NRAs) operating at maturity level 3 (ML3) and maturity level 4 (ML4), as benchmarked against the WHO Global Benchmarking Tool (GBT)

Stringent Regulatory Authorities (SRAs) as defined in the WHO Technical Report Series 1003

NRAs exhibiting high level of performance of WHO’s six recommended regulatory functions and exercising full regulatory oversight of any given vaccine (WHO Technical Report Series 978 Annex 6)

Regional Reference Authorities for medicines in the Americas in the Americas (AMRO/PAHO), as assessed against WHO Regional Office for the Americas (AMRO)/Pan American Health Organization (PAHO) standardized evaluation procedure and AMRO/PAHO data collection tool

National Regulatory Authorities (NRAs) benchmarked against the WHO vaccine assessment tool and announced as “functional NRAs” before introduction of the Global Benchmarking Tool (GBT) in 2016