World Health Organization

List of transitional WLAs
(in alphabetical order) as of December 2025

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.

tWLA				
National Regulatory Authority			**Origin of transition** *As per WHO interim list at 31/03/2022* [1] **A** ML3/ML4 NRAs (medicines and/or vaccines)[3] **B** SRA (medicines)[4] **C** Highly performing NRA (vaccines)[5] **D** NRAr of the Americas (medicines and/or vaccines)[6] **E** Functional NRA (vaccines)[7]	**Scope of tWLA designation** ☐ **Medicines** [2] ☐ **Vaccines**
1.	Argentina	ANMAT	D	Medicines Vaccines
2.	Brazil	ANVISA	D, E	Medicines Vaccines
3.	Chile	ISP	D	Medicines
4.	China	NMPA	A (ML3), E	Vaccines
5.	Colombia	INVIMA	D	Medicines
6.	Cuba	CECMED	D, E	Medicines Vaccines
7.	Egypt	EDA	A (ML3)	Vaccines
8.	Ghana	FDA	A (ML3)	Medicines
9.	India	CDSCO	A (ML3)	Vaccines
10.	Iran (Islamic Republic of)	IFDA	E	Vaccines
11.	Japan	PMDA	E	Vaccines
12.	Mexico	COFEPRIS	D, E	Medicines Vaccines
13.	Nigeria	NAFDAC	A (ML3)	Medicines
14.	Russian Federation	Ministry of Health	E	Vaccines
15.	Serbia	ALIMS	A (ML3)	Vaccines
16.	Thailand	Thai-FDA	A (ML3)	Vaccines
17.	United Republic of Tanzania	TMDA	A (ML3)	Medicines
18.	Viet Nam	DAV	A (ML3)	Vaccines

[1] 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).

[2] 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.

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

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

[5] 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)

[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

[7] 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