



La liste des autorités nationales de régulations pharmaceutiques reconnues par DMP en matière de libération de lots de vaccins :

Pays	Autorité de régulation	Statut OMS selon l'origine de la transition
Argentine	ANMAT	D
Australie	TGA	B C E
Belgique	FAMPH	B C E
Brésil	ANVISA	D E
Bulgarie	BDA	B E
Canada	Health Canada	B C D E
Chine	NMPA	E
Cuba	CECMED	D E
Danemark	DKMA	B E
Egypte	EDA	A (ML3)
France	ANSM	B C E
Allemagne	PEI	C E
Inde	CDSCO	A (ML3)
Indonésie	BADAN POM	A (ML3)
Iran (République Islamique de l')	IFDA	E
Italie	AIFA	B C E
Japon	PMDA	B E
Mexique	COFEPRIS	D E
Pays-Bas	MEB	B C E
Fédération de Russie	Ministry of Health	E
Serbie	ALIMS	A (ML3)
Suède	SMPA	B E
Thaïlande	Thai-FDA	A (ML3)
Royaume-Uni de La Grande-Bretagne et Irlande du Nord	MHRA	B C E
États unis de Amérique	US-FDA	B C D E
Viet Nam	DAV	A (ML3)
Réseau européen de réglementation des médicaments ¹	EMA	B C

A : ML3/ML4 ANR (médicaments et/ou vaccins)

B : Des autorités réglementaires strictes (SRA) (médicaments)

C : Très performant ANR (vaccins)



D : ANR des Amériques (médicaments et/ou vaccins)

E : ANR fonctionnel (vaccins)

1 : Celui-ci est composé de la Commission européenne, de l'Agence européenne des médicaments et des 30 États membres suivants :

L'Autriche, Belgique, Bulgarie, Croatie, Chypre, Tchéquie, Denmark, Estonie, Finlande, France, Allemagne, Grèce, Hongrie, Islande, Ireland, Italie, Lettonie, Liechtenstein, Lituanie, Luxembourg, Malta, Pays-Bas, Norvège, Pologne, Portugal, Romania, Slovaquie, Slovénie, Espagne, Suède

Document de Référence : Site OMS : Liste des WLA de transition (par ordre alphabétique) en octobre 2023

Signature de Monsieur le Directeur de Médicament et de la pharmacie :

Le Directeur du Médicament
et de la Pharmacie
Dr. Aziz MRABTI 15 AVR. 2024

Date de signature :

List of transitional WLAs (in alphabetical order) as of October 2023

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		Origin of transition <i>As per WHO interim list at 31/03/2022¹</i>	Scope of tWLA designation
National Regulatory Authority		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	<input type="checkbox"/> Medicines ² <input type="checkbox"/> Vaccines
1. Argentina	ANMAT	D	Medicines Vaccines
2. Australia	TGA	B, C, E	Medicines Vaccines
3. Austria	AGES	B	Medicines
4. Belgium	FAMPH	B, C, E	Medicines Vaccines
5. Brazil	ANVISA	D, E	Medicines Vaccines
6. Bulgaria	BDA	B, E	Medicines Vaccines
7. Canada	Health Canada	B, C, D, E	Medicines Vaccines
8. Chile	ISP	D	Medicines
9. China	NMPA	E	Vaccines
10. Colombia	INVIMA	D	Medicines
11. Croatia	HALMED	B	Medicines
12. Cyprus	MoH-PHS	B	Medicines
13. Cuba	CECMED	D, E	Medicines Vaccines
14. Czech Republic	SUKL	B	Medicines
15. Denmark	DKMA	B, E	Medicines Vaccines
16. Egypt	EDA	A (ML3)	Vaccines
17. Estonia	SAM	B	Medicines
18. Finland	FIMEA	B	Medicines
19. France	ANSM	B, C, E	Medicines

			Vaccines
20. Germany	BfARM	B	Medicines
21. Ghana	PEI	C, E	Vaccines
22. Greece	FDA	A (ML3)	Medicines
23. Hungary	EOF	B	Medicines
24. Iceland	OGYEI	B	Medicines
25. India	IMA	B	Medicines
26. Indonesia	CDSCO	A (ML3)	Vaccines
27. Iran (Islamic Republic of)	BADAN POM	A (ML3)	Vaccines
28. Ireland	IFDA	E	Vaccines
29. Italy	HPRA	B	Medicines
30. Japan	AIFA	B, C, E	Medicines
31. Latvia	PMDA	B	Vaccines
32. Liechtestein	ZVA	B	Medicines
33. Lithuania	Office of Health	B	Medicines
34. Luxembourg	VVKT	B	Medicines
35. Malta	MoH	B	Medicines
36. Mexico	Medicines Authority	B	Medicines
37. Mexico	COFEPRIS	D, E	Vaccines
38. Netherlands	MEB	B, C, E	Medicines
39. Nigeria	NAFDAC	A (ML3)	Vaccines
40. Norway	NOMA	B	Medicines
41. Poland	URPL	B	Medicines
42. Portugal	INFARMED	B	Medicines
43. Romania	ANMDMR	B	Medicines
44. Russian Federation	ALIMS	E	Vaccines
45. Serbia	Ministry of Health	A (ML3)	Vaccines
46. Slovakia	SUKLO	B	Medicines
47. Slovenia	JAZMP	B	Medicines
48. Spain	AEMPS	B	Medicines
49. Sweden	SMPA	B, E	Vaccines
50. Thailand	Thai-FDA	A (ML3)	Vaccines
51. United Kingdom of Great Britain and Northern Ireland	MHRA	B, C, E	Medicines
52. United Republic of Tanzania	TMDA	A (ML3)	Vaccines
53. United States of America	US-FDA	B, C, D, E	Medicines
54. Viet Nam	DAV	A (ML3)	Vaccines

Regional Regulatory System		
European Medicines Regulatory Network ⁸	B, C	Medicines 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

⁸ This is composed of the European Commission, the European Medicines Agency and the following 30 member states: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czechia, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Liechtenstein, Lithuania, Luxembourg, Malta, the Netherlands, Norway, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden