

Annexure-1: List of Reference Regulatory Authorities for Marketing Authorization

Followings are reference regulatory authorities for matters related to registration of vaccines & biological products:

Sl	Country	Regulatory Authority	Registration of Vaccine & Biological Product
1	USA	Food and Drug Administration (FDA)	√
2	Europe	European Medicines Agency (EMA)	√
3	Australia	Therapeutic Goods Administration (TGA)	√
4	Japan	Pharmaceuticals and Medical Devices Agency (PMDA)	√
5	UK	Medicines and Healthcare Regulatory Agency (MHRA)	√
6	Germany	Federal Institute for Drugs and Medical Devices	√
7	Switzerland	Swissmedic	√
8	France	France NRA	√

And WHO PQ products/vaccines case to case consideration.

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