

Regulatory Pathways
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Pre-reading references

References

- Dellepiane, N, Pagliusi, S, Regulatory Experts Working Group. Challenges for the registration of vaccines in emerging countries: Differences in dossier requirements, application and evaluation processes. N. Dellepiane, S. Pagliusi and Registration Experts Working Group. Vaccine 2018; 36(24): 3389-3396
- Dellepiane, N, Pagliusi, S, Regulatory Experts Working Group. Opportunities for improving access to vaccines in emerging countries through efficient and aligned registration procedures: An industry perspective. Vaccine 2019; 37: 2982-2989.
- World Health Organization. Procedure for assessing the acceptability, in principle, of vaccines for purchase by United Nations agencies. WHO Technical Report Series 978, Annex 6; 2013.
- EMA procedural advice for medicinal products intended exclusively for markets outside the European Union under Article 58 of Regulation (EC) No 726/2004 in the context of co-operation with the World Health Organisation (WHO) https://www.ema.europa.eu/en/documents/regulatory-procedural-guideline/european-medicines-agency-procedural-advice-medicinal-products-intended-exclusively-markets-outside/2004-context-cooperation-world-health_en.pdf

References

- Collaborative procedure between the World Health Organization (WHO) Prequalification Team and national regulatory authorities in the assessment and accelerated national registration of WHO-prequalified pharmaceutical products and vaccines. WHO TRS 996, Annex 8 : 2016
- Emergency Use Assessment and Listing Procedure (EUAL) for candidate vaccines for use in the context of a public health emergency: 2015
<http://apps.who.int/medicinedocs/es/m/abstract/Js21987en/>
- POLICY- Evaluating and publicly designating regulatory authorities as WHO listed authorities: 2019 Draft for comments
https://www.who.int/medicines/areas/quality_safety/quality_assurance/QAS19_82_8_Policy_on_WHO_Listed_Authorities.pdf?ua=1