WHO Listed Authorities (WLAs)

Unit B5 - Medicines: policy, authorisation and monitoring

European Commission
Directorate-General for
Health and Food Safety

84th Pharmaceuticals Committee,
7 November 2019, Brussels

Health and Food Safety

Overview

- Short background
- State of play
- Considerations/next steps

Background (I)

- WHA Resolution 67.20 on *Regulatory system strengthening for medical products*

- mandates WHO to apply evaluation tools to generate and analyze evidence of regulatory system performance (Global Benchmarking Tool)

- objective: assist countries to have effective, efficient and transparent oversight
  - ✓ Promote regulatory cooperation, convergence through networking, work-sharing and reliance

Background (II)

- May 2019: WHO concept note on a framework for evaluating and publicly designating regulatory authorities as WHO-Listed Authorities

…to provide a transparent and evidence-based pathway for regulatory authorities or regional regulatory systems to be globally recognized as meeting international recognized standards and practices, replacing the concept of Stringent Regulatory Authorities (SRAs)

- Sept 2019: international consultative meeting with WHO Members and stakeholders on WLAs

State of play

- WHO is currently working on an updated draft **policy document** that will be published soon for comments (statement, definitions, operating principles)

- Important for the EU to speak with one voice – our aim is to have both the EU as a single entity as well as the individual regulatory authorities that are part of that system listed as WLA

Next steps from WHO side

- Update draft policy on WLAs and publish for comments
- Develop proposed timelines, resourcing estimates and advocacy and communication plan
- Develop working draft of operational guidance, including performance evaluation framework
- Engage with experts to further develop operational guidance and publish for comment
- Conduct limited number of pilots to test and refine framework (second half of 2020)