THE GEORGE WASHINGTON UNIVERSITY
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Strengthening Regulatory Systems Through Convergence, Reliance, and Recognition

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International Collaborative Efforts Among Regulatory Agencies

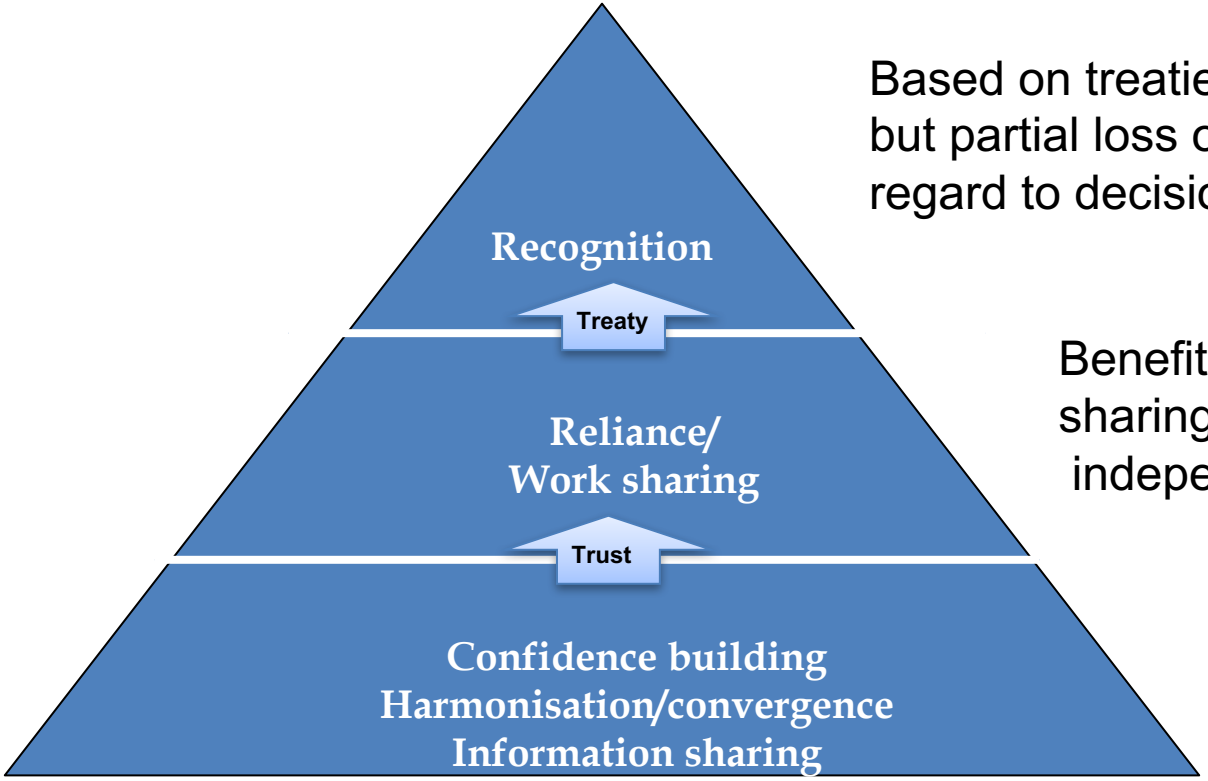
"In an increasingly globalised pharmaceutical market, ***collaboration between medicines' regulators is essential***," explains the EMA's Executive Director Guido Rasi. "Medicines' regulators are inter-dependent: any action taken in one territory has repercussions on the rest of the world. International cooperation is a key area of work for the Agency."

http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2014/02/news_detail_002028.jsp&mid=WC0b01ac058004d5c

International Collaborative Efforts Among Regulatory Agencies

"The work of protecting the health and safety of the American people cannot be done in isolation," says Janet Woodcock, M.D., Director of the FDA's Center for Drug Evaluation and Research. "***It is part of a larger collaborative global effort between the FDA and its international regulatory partners to ensure the health and safety of all our citizens.***"

How Regulators Collectively Can Make a Difference –
Strengthening Systems Through Convergence, Reliance, and Recognition



Based on treaties; «maximal benefit» but partial loss of authority with regard to decision-making

Benefit for regulators; sharing of workload, but independent decisions

Equivalence of requirements; establishing trust

- Luigetti, Riccardo, et al. *Collaboration, not competition: developing new reliance models, WHO Drug Information* 30.4 (2016) 558-566.
- de Brito Anabela Correia et al. *The contribution of mutual recognition to international regulatory co-operation,* OECD Pub. No. 2 **2016**, 1-90.

Why Convergence, Reliance, or Recognition?

- Today's drug development and commercialization processes are increasingly complex. They often require a multi-national supply chain involving multiple regulatory authorities.

- Increased awareness and acceptance of reliance and work-sharing concepts among regulators *("even the largest agencies cannot do everything themselves").*

- Overlaps and duplications of efforts (e.g., inspections) represent a major burden on resources.

- Benefit for industry, regulators, and patients *(equivalence of requirements enables trust).*

Examples

Recognition
Examples: Mutual Recognition Agreements (EU, ASEAN); marketing authorisation procedures (EU, GCC); unilateral recognition of marketing authorisations (Mexico);…

Reliance/Work-sharing
Examples: Abridged application routes/reference country model; WHO Pre-Qualification; EAC/MRH; ZAZIBONA(S), IGDRP; ACSS Consortium (HSA, TGA, HPFB, Swissmedic); …

Confidence building/harmonisation/convergence
Examples: AMRH; PIC/S; ICH; IPRF; IMDRF; RHIs/RECs; WHO trainings and networks, ICDRA; GRPs; Bilateral agreements; …

Mutual Recognition Agreements US/EU

- Provides significant resource benefits for both industry and regulators
  - Recognition of pre- & post-approval manufacturing facility inspections
  - Potential to rely on inspections in third countries
  - Waiver of import testing of products imported from the US into the EU

- The MRA applies to APIs, intermediates (EU) / in-process materials (US) and marketed finished pharmaceuticals including biological products

https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/UCM544394.pdf

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