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Sharing regulatory data as tools for strengthening health systems in the region of the Americas

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Backgrounds: Regulatory transparency is an imperative characteristic of a reliable National Regulatory Authority. In the region of the Americas, the building process of an open government is still fragile and fragmented on Health Regulatory Agencies (HRA) even on Regional Reference Authorities (RRA).

Purpose: This paper assesses the transparency status of RRA, focusing on some medicine life-cycle documents (Medicine Dossier, Clinical Trial Report, and Inspection report), as tools for strengthening health systems.

Methods: Through a qualitative and descriptive evaluation of regulatory transparency on RRA, it was portrayed in two different branches: information public disclosure and inter-agency data and work sharing.

Results: The risk benefits of information public disclosure were assessed considering the involvement and roles of multi-stakeholders (healthcare professionals, regulators, industry, community, and academics) bearing in mind the protection of commercially and personally confidential data. Inter-agency data and work sharing were inserted in the context of harmonization and co-operation projects that focus on regulatory convergence.

Conclusions: Technical and practical engagements are proposed to improve and strengthen health systems in the region of the Americas through establishment of an openness directive over pharmaceutical regulatory environment. To successfully address these challenges is crucial that regional leadershipssteer and support collaborative regional alliances toward the development and establishment of a trustful regulatory environment as well as a sustainable public health system in the Latin America and the Caribbean, using as reference international successful initiatives besides taking into account domestic characteristics and experiences of each single country.

Biography

Varley Dias Sousa is a Pharmacist (2003), post-graduated on health surveillance (2007) and international health systems (2006), and has completed his MSc (2010). Currently he is performing PhD studies at the University of Brasilia. He is a senior Auditor on Brazilian Health Surveillance (ANVISA) since 2005, been certified in Good Manufacturing Practices (inspecting international facilities in almost 10 different countries) and Good Clinical and Laboratory Practices (Inspecting more 30 international CROs). He has evaluated more than 150 bioavailability and bioequivalence (BA/BE) studies and more than 150 Medicine Applications. Also, he is member of the commission in charge of confidentiality classification on Medicine Dossier. Dâmaris Silveira is a Pharmacist (1986), with PhD in Natural Product Chemistry (1999). Currently she is Associate Professor at the University of Brasilia, and coordinator of Laboratory of Quality Control as well as of the Pharmaceuticals – Regulation and Public Policies research group.

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