Sociedade Brasileira de Farmácia Hospitalar e Serviços de Saúde

Rua Vergueiro, 1855 - 12º andar
Vila Mariana - São Paulo - SP
CEP 04101-000 - Tel./Fax: (11) 5083-4297
atendimento@sbrafh.org.br/www.sbrafh.org.br

Missão

Publicar artigos científicos que contribuam para o avanço do conhecimento da Farmácia Hospitalar e da assistência farmacêutica nos demais serviços de saúde, que apresentem tendências conceituais, técnicas, sociais e políticas que poderão ser utilizadas para fundamentar ações dos profissionais da área

Os artigos serão avaliados por, no mínimo, dois consultores com expertise e producao científica na área de conhecimento da pesquisa.

Periodicidade: Trimestral

Exemplares: 3.000

Acesso aberto pelo website http://www.sbrafh.org.br/rbfhss/index/edicoes/

Circulação é gratuita para os associados da SBRAFH.

Outros interessados em assinar a revista poderão efetuar seu pedido junto à Secretaria da SBRAFH – Telefone: (11) 5083-4297 ou pelo e-mail: atendimento@sbrafh.org.br.

Valores para assinaturas anuais (4 edições):

- Brasil: R$ 200,00
- Exterior: U$ 150

As normas para publicação de artigos técnicos estão na página principal.

Os artigos devem ser enviados através deste site após criar seu cadastro de autor e confirmá-lo através de email enviado.

Os artigos assinados são de inteira responsabilidade de seus autores e não refletem necessariamente a opinião da Sociedade Brasileira de Farmácia Hospitalar e Serviços de Saúde.

Os anúncios publicados também são de inteira responsabilidade dos anunciantes.

Esta Revista é impressa com apoio cultural do Laboratório Cristália de Produtos Químicos Farmacêuticos LTDA.

Editorial

PHARMACOPEIA AND ANVISA: A NECESSARY SYMBIOSIS

DOI: 10.30968/rbfhss.2017.084.001

Luís Mauricio T. R. Lima

A basic principle supporting for the use of prescription drugs is the assurance of their quality, safety and efficacy. New drug products require double blind, multicentric randomized controlled clinical trials. Any single adverse effect observed during the use of a giving prescription medicine must be registered and reported during trials intended for new drug/indications application and during post-marketing surveillance (PMS) pharmacovigilance. Generic and follow-on biologic product must be subjected to detailed evaluation in comparison to the reference product, including safety and non-inferiority clinical evaluation, along with the pharmacovigilance.

Any company that manufacture, prepare, propagate, compound, or process pharmaceutical ingredients or new or generic, similar or follow-on biologic product intended to be registered in Brazil are requested to provide a detailed description of the manufacturing process, formulation, component, quality and characterization of the active and adjunctive pharmaceutical ingredients and any potential impurity (1–3). This robust inventory of information concerning quality of the final formulated product and their components is, therefore, made available to the Brazilian National Health Surveillance Agency (ANVISA) which upon its evaluation will grant the registration or not. The analytical monograph must be provided to the ANVISA even in case it is available in any accepted pharmacopeia (4).

According to the Brazilian Pharmacopeia committee (5),

"the Brazilian Pharmacopoeia is the Official Pharmaceutical Code of the Country, which establishes, among other things, the minimum quality requirements for drugs, supplies, plant drugs, medicines and health products. Its purpose is to promote the health of the population, establishing requirements for quality and safety of the pharmaceutical products, in particular medicines, supporting health regulatory actions and inducing national scientific and technological development". Moreover, "the Brazilian Pharmacopoeia, so far, does not have its own laboratory. His research, preparation of monographs, laboratory tests, validation and certification of products are carried out by accredited universities and by official quality control agencies of medicines".

Despite high standard of technical and scientific qualification of the participating members of the Brazilian Pharmacopoeia and researchers, there could be a certain dissociation between the analytical knowledge and the actual productive processes of the pharmaceutical ingredients and finished drug product. It would be ideal if the Brazilian Pharmacopoeia - like any pharmacopoeia – could ensues from actual information from products and their processes, including its impurities of origin. Considering that the major manufactures of pharmaceutical ingredients and drug products are likely to remain outside the national industrial scenario, that the construction of an own headquarters (not currently available) for the Brazilian Pharmacopeia and hiring consultants for the preparation of pharmaceutical monographs is unlikely, one oversee as possible strategies in quality assurance of pharmaceutical products: i) the extension of the endorsement of other international official compendia (pharmacopoeias), and / or ii) to guarantee to the Brazilian Pharmacopoeia the access, in the character of confidentiality, of data from the archives of pharmaceutical ingredients and drug products registration from ANVISA, enabling the preparation and revision of the Brazilian Pharmacopoeia in full compliance with the actual pharmaceutical products currently available and registered in Brazil.

The adoption of simple strategies such as these would allow the rapid and desired establishment of rigorous reference standards for the quality of pharmaceutical ingredients and drug products, raising the Brazilian Pharmacopoeia to a high reference level in the international scenario. Furthermore, it would provide the highest standards of quality, safety and efficacy of pharmaceuticals, as desired by all, from patients to health professionals

---

Luís Maurício Trambaioli da Rocha e Lima is Associate Professor at School of Pharmacy at Rio de Janeiro Federal University.

School of Pharmacy, Federal University of Rio de Janeiro – UFRJ, CCS, Bss24, Ilha do Fundão, 21941-902, Rio de Janeiro, RJ, Brazil. Phone/Fax: (+55-21) 3938-6639

REFERENCES

1. Agencia Nacional de Vigilância Sanitária, ANVISA. Resolução da Diretoria Colegiada - RDC no 55 de 16/12/2010 [Internet]. ANVISA; 2010 [cited 2017 Jun 2]. Available from: http://portal.anvisa.gov.br/legislacao#/visualizar/28623

2. Agencia Nacional de Vigilância Sanitária, ANVISA. Resolução da Diretoria Colegiada - RDC no 60 de 10/10/2014 [Internet]. ANVISA; 2014 [cited 2017 Jun 2]. Available from: http://portal.anvisa.gov.br/legislacao#/visualizar/29265

3. Agencia Nacional de Vigilância Sanitária, ANVISA. Resolução da Diretoria Colegiada - RDC no 53 de 04/12/2015 [Internet]. 2015 [cited 2017 Jun 2]. Available from: http://portal.anvisa.gov.br/legislacao#/visualizar/29446

4. Agencia Nacional de Vigilância Sanitária, ANVISA. Resolução da Diretoria Colegiada - RDC no 37 de 06/07/2009 [Internet]. ANVISA; 2009 [cited 2017 Jun 6]. Available from: http://portal.anvisa.gov.br/legislacao#/visualizar/28346

5. Farmacopéia Brasileira. HotSite da Farmacopéia Brasileira [Internet]. [cited 2017 Jun 6]. Available from: http://www.anvisa.gov.br/hotsite/farmacopeiabrasileira/saiba_mais.htm