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Choices and challenges in developing biosimilars in the MENA region

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Biosimilars are those biologics which are developed after patent expiration of innovator biopharmaceuticals. They are known as similar biologics, follow-on biologics, subsequent-entry biologics and second-entry or off-patent biotechnology in different countries. Furthermore, they require separate marketing approval since they are not generic versions of biologics which is new in the MENA region. They establish a group of new molecules owing to a number of heterogeneities as compared to the reference innovator biologics. Moreover, this presentation will also discusses the major challenges involved in the manufacturing of Biosimilars and the required documentation on quality, safety and efficacy including comparability exercises as well as the single most important factors affecting the Bio-manufacturing capacity in the region. Moreover, Biologics are one of the most important growth drivers for global pharmaceutical market but several challenges impede the way of growth of Biosimilars in the emerging markets. However, we will also take into consideration some trends that promise the bright future of Biosimilars in the MENA region. Finally, we will throw light on the regulatory guidelines of different countries especially in the MENA region and their impacts on the development of Biosimilars.

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Conception of *Ayurveda* adverse drug reaction and pharmacovigilance: An overview

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Drug safety is a very basic and fundamental concept in medical practice. ADRs play an important role in assessing patient safety in any system of medicine. Pharmacovigilance study is thus significant to understand treatment outcomes. Current raised issue with respect to complementary and alternative system medicine (CAM) like *Ayurveda* is increased in number of safety reports along with report misinterpretation; this generates the negative impact on system. Although, *Ayurveda* which is holistic system of medicine from India has elaborated the causes and methods of drug induced consequences along with preventive measures the available data in classical texts is scattered. The compilation and analysis along with modern concept drug safety is need of the hour. Present literature review was conducted from various compendium of *Ayurveda* and electronic data base with search terms of *'Vyapad', 'Viruddha', 'Ahita', 'herb-herb interaction', 'idiosyncrasy', 'Prakritiviruddha'* etc. The reported information was analyzed for the possible correlation on concept of ADR and Pharmacovigilance of current science. Overall review demonstrated that drug interaction, iatrogenic, over dose, administration of unsuitable drugs, reprehensive drug administration with respect to disease, complication from five procedural therapies (*Panchakarma*) and reprehensible preparation of mineral drug are nearer to the modern causes of ADR. Thus, concept of drug safety and ADR is not new to the *Ayurveda*. The concept "Drug which is not appropriate to be used as medicine" (*Abheshaja*) of *Ayurveda* sounds similar as that of modern pharmacovigilance.

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