First Asia-Pacific educational workshop on non-biological complex drugs (NBCDs), Kuala Lumpur, Malaysia, 8 October 2013

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Introduction: In recent years a new category of medicinal products, the non-biological complex drugs (NBCDs) emerged. They are distinct from both the small molecules and the biological therapeutics by being composed of non-homomolecular large structures, some of which may be nanoparticulate, and by not being a biological product or being chemically synthesized. Approval of their follow-on copies is problematic because like biologicals they are impossible to be fully characterized by only their physiochemical properties and both their structure and function are sensitive to small changes in the laborious and difficult to control manufacturing process. Today, requirements for authorization of follow-on NBCDs are unclear and handled on a case-by-case basis.

Methods: An educational workshop was held in Kuala Lumpur, Malaysia, in an attempt to identify current and best practices for the approval, use and post-approval monitoring of follow-on NBCDs. The workshop consisted of didactic presentations, case studies, and interactive sessions designed to present background information and evidence on NBCDs. The focus was on intravenous (IV) iron sucrose products where a series of data on differences between the innovative and follow-on versions have been published. Participants included practising clinicians, academics, drug regulators, and scientists from industry who were sent a reading list and a pre-workshop questionnaire about current and best practices concerning the regulation, use and monitoring of follow-on NBCDs. Two separate breakout sessions, one for clinicians and one for regulators were held to discuss the results of the questionnaires and to come to consensus about unmet regulatory and clinical needs and best practices.

Results: Both the questionnaire results and workshops confirmed that although awareness was partially raised, there remains a lack of uniformity in US/EU as well as Asia-Pacific regulations of follow-on NBCDs. There was consensus that there is a need for education of regulators and clinicians about these products as well as a need to develop better and more consistent regulatory practices for handling follow-on NBCDs. Clinicians expressed their concerns about the adequacy of current regulatory approval processes and the concomitant information provided for healthcare practitioners leading to the inappropriate substitution by pharmacists of products without informing or obtaining permission from treating clinicians.

Conclusions: There is a need to identify improved, best practices for the regulation, use and post-approval monitoring of NBCDs. Approval and substitution must consider clinically important product differences and more effectively involve clinicians.

Keywords: follow-on drugs, nanomedicines, non-biologic complex drugs, regulatory practice

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