BIOTHERAPEUTIC MEDICINES

Regulatory challenges and current practices. Approaches for harmonization.

15-16 MAY
MOSCOW

ORGANIZER:
IFPMA (International Federation of Pharmaceutical Manufacturers & Associations)

CO-ORGANIZER:
AIPM (Association of International Pharmaceuticals Manufacturers)

WITH SUPPORT AND PARTICIPATION OF:
- Ministry of Health of the Russian Federation
- Federal Service for Supervision of Health of the Russian Federation
- Eurasian Economic Commission
- Committee on Health Protection of State Duma
- Russian Academy of Medical Sciences

WITH EXPERT PARTICIPATION OF:
- World Health Organization
- National Regulatory Authorities from European Union & North America, CIS
- Professional associations and biopharmaceutical industry professionals

FORMAT:
2day workshop which joins health authorities representatives and biopharmaceutical industry experts from EU, North America, CIS and other regions to discuss the key aspects of biotherapeutic medicines, as regulatory pathways for biotherapeutic medicines and biosimilars; quality aspects of development; comparability and similarity exercises; preclinical and clinical data; immunogenicity; pharmacovigilance and safety tracking, interchangeability.
8.00 – 9.00 Registration of participants, welcome coffee.
SESSION 1
Approaches to regulation of biotherapeutic medicines. Global and regional perspective.
9.00 – 11.40
Chair – Dr. Ivana Knezevic, Scientist; Quality, Safety & Standards, World Health Organization.
Co-chair – Dr. Elena Maximkina, Head of Department of state regulation of medicines, Ministry of Health, Russian Federation.
Welcome word from organizers.
1. Experience and position of World Health Organization on the regulation of biotherapeutic medicines and biosimilars. Dr. Ivana Knezevic, Scientist; Quality, Safety & Standards, World Health Organization.
2. Key issues on biosimilars guidelines development and current revision trends in EU. Dr. Carlo Pini, Head of the National Center for Immunobiologicals Research and Evaluation, Superior Institute of Health (Italy).
3. Development vector of regulatory procedures of biotherapeutic medicines & biosimilars in Russia. Dr. Elena Maximkina, Head of Department of state regulation of medicines, Ministry of Health, Russian Federation.
5. Regulation of biotherapeutic medicines, including biosimilars in Ukraine. Latest changes in dossier assessment rules and requirements. Future perspectives. Yury Gamazin, State Center of Expertise, Ministry of Health, Ukraine.
Q&A, discussion.
11.40 – 12.00 Coffee break.
12.00 – 13.30
Chair – Marat Sakaev, Advisor to the Head of Eurasian Economic Commission.
Co-Chair – Dr. Carlo Pini, Head of the National Center for Immunobiologicals Research and Evaluation, Superior Institute of Health (Italy).
1. Approaches to regulation of biological medicinal products within the Customs Union & Common Economic Space. Larissa Pak, Deputy Head of Committee of pharmaceutical and medical activities, Ministry of Health of the Republic of Kazakhstan.
2. Regulatory experience with monoclonal antibody submissions in the EU. Dr. Alex Kudrin, Medical Assessor, Biologicals Licensing, Medicines and Healthcare Products Regulatory Agency, UK.
Q&A, discussion.
13.30 – 15.00 Lunch.
SESSION 2
Biosimilars. Regulatory framework and quality considerations — dynamics of international practices.
15.00 – 16.30
Chair – Dr. Alex Kudrin, Medical Assessor, Biologicals Licensing, Medicines and Healthcare Products Regulatory Agency, UK.
Co-chair – A.N. Mironov, Director of Scientific Centre of Medicines Assessment (FGBU NCESMP), Ministry of Health, Russian Federation.
2. Non-clinical evaluation of biosimilars according to current EMA guidelines. Dr. Hans-Karl Heim, Non-clinical Assessor, BfArM, Germany & Member of Biosimilars Medicinal Products Working Party, European Medicines Agency.
Q&A, discussion.
16.50 – 18.20
1. Biologicals and biosimilars pathway in the U.S. Expertise and regulatory requirements for biological product approval, interchangeability considerations (tbc).
2. Challenges to biosimilar product development and experience gained. Dr. Thomas Kirchlechner, Head of Regulatory RoW, Sandoz Biopharmaceuticals Development.
3. Comparability of biotherapeutic products following the manufacturing process improvement. Quality aspects and comparability issues. Dr. Inger Mollerup, Corporate Vice President, Regulatory Affairs, Novo Nordisk A/S.
Q&A, discussion.
18.20 – 20.00 Reception.
SESSION 1
Immunological safety, pharmacovigilance and risk minimization programs for the biological products.
9.00 – 11.00
Chair — Dr. Barry Cherney, IABS Human Biotherapeutics Scientific Committee.
Co-chair — Dr. Carlo Pini, Head of the National Center for Immunobiologicals Research and Evaluation, Superior Institute of Health (Italy).
1. Immunogenicity as a key issue for biotechnology-derived products. Dr. Carlo Pini, Research Director, Superior Institute of Health, Italy.
2. Immunogenicity testing of biotechnology products and the impact to biosimilars. Dr. Barry Cherney (Amgen), IABS Human Biotherapeutic Scientific Committee.
3. Approaches to assessment of different bio groups in Russia. Dr. Andrey Vasiliev, Scientific Centre of Medicines Assessment, Ministry of Health, Russian Federation.
Q&A, discussion.
11.10 – 11.30 Coffee break.
11.30 – 13.40
Chair – Dr. Shanthi Pal, Medicines Safety Program Manager, World Health Organization.
1. Pharmacovigilance and risk minimization programs for the biological products. Dr. Shanthi Pal, Medicines Safety Program Manager, World Health Organization.
3. Pharmacovigilance at national level in EU and EU Risk Management Plans, EudraVigilance, EMA. Niels Vermeer, Pharmacovigilance Assessor, Medicines Evaluation Board/ Pharmacoepidemiology Department, Utrecht University, Netherlands.
4. Pharmacovigilance system in Kazakhstan. Specificities of biotherapeutic medicines monitoring. Prof. Shynar Baidullaeva, Head of the Pharmaceutical expertise department of National Center for Medicines, Medical Devices and Medical Equipment Expertise, Republic of Kazakhstan.
5. Pharmacovigilance aspects of biotherapeutic medicines. Nowadays and perspectives. Dr. Peter DeVee, Qualified Person for Pharmacovigilance, F. Hoffmann-La Roche on behalf of IFPMA.
Q&A, discussion.
SESSION 2
Global and regional practices and approaches for interchangeability. Global regulatory discussion. Key challenges.
14.40 – 16.10
Chair – Dr. Elena Maximkina, Head of Department of state regulation of medicines, Ministry of Health, Russian Federation.
Co-chair – Dr. Raffaella Balocco, INN Program Manager, World Health Organization.
3. Traceability of biologicals in spontaneous reporting systems (EudraVigilance/AERS). Niels Vermeer, Pharmacovigilance Assessor, Medicines Evaluation Board/ Pharmacoepidemiology Department, Utrecht University, Netherlands.
Q&A, discussion.
16.40 – 18.10
6. Regulatory and medical aspects of Interchangeability of biological products. Dr. Jaap Venema, Senior Director Biotherapeutics, Global Head and US Lead, AbbVie.
Q&A, discussion.
18.10 – 18.30
Concluding speeches of the participants. Closure of the conference.