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MODULE 8

Place: Semmelweis University, Department of Pharmacology and Pharmacotherapy
Floor 4, Knoll (formerly Issekutz) Room – No. 404
1089 Budapest, Nagyvárad tér 4.

Date: May 16-19, 2019

MODULE 8: FOLLOW-ON DRUGS: GENERIC, BIOSIMILAR & NON-BIOLOGICAL SIMILAR MEDICINAL PRODUCTS

Module Leader: Dr. Sándor Kerpel-Fronius and István Antal

LEARNING OUTCOMES
At the end of this Module the student should be able to demonstrate an understanding of:
1. Compare the scientific and regulatory basis for the definitions of the various types of follow-on drugs: generic, biosimilar and non-biological similar medicinal products, define their significance in the life-cycle management of medicines.
2. Choose the right timing of pharmacokinetic studies during follow-on drug development.
3. Assess the appropriate *in vitro and in vivo* methods to establish equivalent bioavailability of generic drugs.
4. Analyze the diversity caused by the development of independent formulations for the same active ingredients by the follow-on producer.
5. Comprehend and appreciate the causes leading to the diversity of the biosimilar medicinal products manufactured by different producers.
6. Appreciate the complex non-clinical and clinical comparative study requirements needed to evaluate the biological and immunogenic properties of biosimilar medicinal products including biosimilar monoclonal antibodies
7. Appreciate the specific properties of different complex non-biological similar medicinal products
8. Analyze, comprehend and assess the complexity and international diversity of regulatory requirements for evaluating the efficacy and safety of follow-on non-biological similar products
9. Evaluate the public health significance of follow-on drugs on the market. Comprehend the differences in the pricing principles of follow-on generic, biosimilar and non-biological medicinal products
10. Assess the clinical pharmacological problems associated with reference pricing
11. Appraise the various clinical pharmacological issues related to the clinical interchangeability of generic, biosimilar and non-biological similar products drugs.
12. Appraise the international significance of quality assurance of follow-on products.
13. Assess the international medical significance of counterfeiting drug.
14. Appreciate the factors influencing the adoption of follow-on drugs in the everyday practice.

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Day 1 – May 16, 2019 - Thursday

Time	Name of Lecturers Titles and topics of the lectures and cases Please list the topics to be covered by the lectures	Syllabus reference numbers	Learning outcomes reference number
9:00-9:50	**Klebovich, Imre** Generic medicinal products. Physical-chemical characterization of generic medicinal products. Biopharmaceutical Classification System. Comparative pharmacokinetic approach for the evaluation of bioequivalence	4.1, 4.4, 5.7, 13.8	3
10:00-10:50	**Kovács-Kiss, Dorottya** Industrial development of generic medicinal products. The development of added value generics. The importance of generics, branded generics and added value in the life cycle management of drugs.	6.2, 6.5, 6.7	1, 2
11:00-11:50	**Bogsch, Erik** Development and production of biosimilar medicinal products. Worldwide manufacturing of follow-on biological products, successes and pitfalls. Future perspectives.	10.6,	5, 6
12:00-12:50	**Pálfi-Goóts, Herta** Marketing authorization of generic and added value generic medicinal products. Differences of the EMA and FDA regulatory process of generics.	6.2, 6.5, 6.7	1
13:00-14:30	**Lunch**		
14:30-15:15	**Mollet, Annette** The clinical development of biosimilar products	5.7, 11.4, 13.8	6
15:30-16:15	**Baader, Ekkehard** Marketing authorization of biosimilar medicinal products. Differences of the EMA and FDA regulations	10.6, 10.12	1, 6
16:30-17:15	**Antal, István** The significance of biopharmaceutical formulation aspects in the development of generic products.	4.1, 4.3, 10.5, 13.8	4
17:30-18:15	**Mollet, Annette** The clinical development of radiopharmaceuticals and their follow-on products	3, 4, 5, 6	1, 4, 6, 11, 12

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Day 2 – May 17, 2019 - Friday

Time	Name of Lecturers Titles and topics of the lectures and cases Please list the topics to be covered by the lectures	Syllabus reference numbers	Learning outcomes reference number
9:00-9:50	**Mühlebach, Stefan** Types and properties of complex non-biological medicinal products. Development of similar non-biological medicinal products	4.1, 4.3, 4.4, 5.7, 10.12	1, 7, 8
10:00-10:50	**Mühlebach, Stefan** Nanomedicines, definition, physical-chemical properties	4.1, 4.3	7
11:00-11:50	**Sütő,Tamás** Sustaining the product life cycle	13.4, 13.6	6, 9, 10, 11
12:00-13:00	**Gross, Jens** Development of a biosimilar mAb. A case presentation	5.7, 11.4, 13.8	3, 6,11, 12
13:00-14:30	**Lunch**		
14:30-15:20	**Riba, Pál** Bioequivalence trials: design, evaluation, regulatory requirements	5.7, 9.8, 9.11, 10.12	1,2, 3
15:30-16:20	**Soroncz-Szabó,Tamás** Information provided to the health care payers, health care professionals and patients on follow-on drugs. Probable causes of slow uptake of follow-on drugs.	10.22, 12.4, 12.6, 12,7, 12.8, 12.9, 13.5,	9, 12, 13
16:30-17:20	**Kerpel-Fronius, Sándor** Interchangeability of follow-on products. Extrapolation to additional indications	5.7, 10.16, 13.8	6, 9, 11

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Day 3 – May 18, 2019 - Saturday

Time	Name of Lecturers Titles and topics of the lectures and cases Please list the topics to be covered by the lectures	Syllabus reference numbers	Learning outcomes reference number
9:00-10:00	**Szücs, Thomas** The role of drug expenditure within the health market and health care insurance	13.5, 13.4, 13.9	8, 9
9:45-11:00	**Szücs, Thomas** Various reimbursement strategies of follow-on medicinal products	13.5, 13.8	9, 10, 11
11:15-11:50	**Inotai, András** Health and economic aspects of pharmaceutical policies related to off-patent medicines	13.5, 13.4, 13.8, 13.9	9, 10, 11
12:00-13:00	**Inotai, András** Health and economic aspects of pharmaceutical policies related to off-patent medicines.	13.5, 13.4, 13.8, 13.9	9, 10, 11
13:00-14:30	**Lunch**		
14:30-15:20	**Caroli, Sergio** Quality control of follow-on medicinal products, with special reference to biosimilars	2.2	12
15:30-16:20	**Caroli, Sergio** The problems of counterfeiting and falsifying of medicinal products	2.2	12, 13

Day 4 – May 19, 2019 - Sunday

Time	Name of Lecturers Titles and topics of the lectures and cases Please list the topics to be covered by the lectures	Syllabus reference numbers	Learning outcomes reference number
9:00-9:50	MCQ test		
10:00-10:50	MCQ test		
11:00-11:30	Discussion of the MCQ test		
11:30-13:00	**Kerpel-Fronius, Sándor and Students** Overview and discussion of the course program and achievements. Program of the final examination and defense of the thesis		