

## EAHP ACADEMY SEMINARS 19 – 21 October 2018, Warsaw, Poland

# Medicines Shortages – Causation and Approaches to Improvements

ACPE Universal Activity Number (UAN): 0475-0000-18-032-L05-P/CEUs: 1.28



An ACPE application based activity

The European Association of Hospital Pharmacists (EAHP) is accredited by the Accreditation Council for Pharmacy Education as a provider of continuing pharmacy education.

## PROGRAMME

FRIDAY, 19 <sup>th</sup> OCTOBER 2018, SALON A	
08.30 – 08.40	<b>Invitational speech by the President of the European Association of Hospital Pharmacists</b> <i>Petr Horák, President of the EAHP, Czech Republic</i>
08.40 – 08.50	<b>Welcome – needs and objectives of the Academy Seminar</b> <i>Prof Dr Helena Jenzer, Bern University of Applied Sciences / University Hospital of Psychiatry Zurich, Switzerland (moderator)</i>
08.50 – 09.00	<b>Assessment of Learning success – SurveyMonkey® (Part-1 - pre-meeting baseline)</b> <i>Delegates</i>
09.00 – 09.45	<b>Hospital pharmacists as troubleshooters</b> <i>Dr Torsten Hoppe-Tichy, Ruprecht-Karls-University of Heidelberg, Germany</i> <ul style="list-style-type: none"> <li>Some typical cases as an inspiring start of the programme</li> </ul>
09.45 - 10.30	<b>An international bottom-up approach – analysis of causation of shortages</b> <i>Prof Dr Helena Jenzer, Bern University of Applied Sciences / University Hospital of Psychiatry Zurich, Switzerland</i> <ul style="list-style-type: none"> <li>Subject of COST Action CA15105 and other attempts</li> <li>Definitions, interpretations, positions, interests</li> <li>Stakeholders, causes, and erroneous incentives</li> <li>Vulnerabilities of the supply chain</li> <li>Intermediate results after 2 of 3 years life time of the Action</li> </ul>
<b>10:30 – 11.00</b>	<b>Coffee break (Foyer)</b>
11.00 – 11.45	<b>The clinical needs</b> <i>Nenad Miljković, Institute of Orthopaedic Surgery "Banjica", Serbia</i> <ul style="list-style-type: none"> <li>Clinical needs</li> <li>Shortages of life-saving medicines</li> <li>Anti-infectives shortages</li> <li>Risk considerations</li> </ul>
11.45 – 12.30	<b>Social and ethical aspects</b> <i>Prof Dr Tomasz Bochenek*, Medical College of the Jagiellonian University, Krakow, Poland</i> <ul style="list-style-type: none"> <li>Impact of shortages on clinical, economic and social outcomes</li> <li>Patients Interests (QoL)</li> <li>Development of the socio-financial situation</li> <li>Differences east-west</li> </ul>

12.30 – 14.00	<b>Lunch break (Restaurant Olive)</b>
14.00 – 14.45	<p><b>Simulation of a complex network using System Dynamics</b>  <i>Prof Dr Stefan Grösser, Bern University of Applied Science, Switzerland</i></p> <ul style="list-style-type: none"> <li>• Methods of prediction and foresight, e.g. qualitative and quantitative foresight</li> <li>• Simulation approaches for causal modelling and foresight</li> </ul>
14.45 – 16.15	<p><b>Workshop “Experimentation with simulation models”</b>  <i>Prof Dr Stefan Grösser, Bern University of Applied Science, Switzerland</i></p> <ul style="list-style-type: none"> <li>• Assumptions used in the models</li> <li>• Participants explore models</li> <li>• Participants experiment with a supply chain simulation about medicines shortages</li> </ul>
16.15 – 16.45	<b>Coffee break (Foyer)</b>
16.45 – 17.45	<p><b>Interactive plenary and podium discussion “Analysis of the worldwide medicines shortages problem”</b>  <i>Prof Dr Stefan Grösser</i>  Moderation: <i>Lene Juel Kjeldsen, Despoina Makridaki</i></p> <ul style="list-style-type: none"> <li>• Discussion about solutions by means of simulation modelling (what is more suitable for improvements than standard approaches?)</li> <li>• Opportunities to improve, structure and abate medicines shortages problems</li> <li>• Limitation and model boundary</li> </ul>
17.45 – 18.00	Summary – End of Day 1
19.30 – 22.30	<b>Dinner at the hotel (Restaurant Olive)</b>
<b>SATURDAY, 20<sup>th</sup> OCTOBER 2018, SALON A</b>	
08.30 – 09.15	<p><b>Pragmatic coping strategies in Hospital Pharmacies</b>  <i>Dr Torsten Hoppe-Tichy, Ruprecht-Karls-University of Heidelberg, Germany</i></p> <ul style="list-style-type: none"> <li>• Some typical examples of opening access to further resources</li> </ul>
09.15 - 10.00	<p><b>Systematic attempts at a solution</b>  <i>Prof Dr Helena Jenzer, Bern University of Applied Sciences / University Hospital of Psychiatry Zurich, Switzerland</i></p> <ul style="list-style-type: none"> <li>• Coping strategies</li> <li>• Supply contracts between the Swiss Federal Office for National Economic Supply and the pharmaceutical industry</li> <li>• The importance of being innovative, anticipative and of sharing responsibilities</li> </ul>
10:00 – 10.30	<b>Coffee break (Foyer)</b>
10.30 – 11.15	<p><b>How clinical needs could be met</b>  <i>Nenad Miljković, Institute of Orthopaedic Surgery "Banjica", Serbia</i></p> <ul style="list-style-type: none"> <li>• Proactive risk assessment</li> <li>• First risks – first treatments</li> </ul>
11.15 – 12.30	<p><b>Social and ethical framework and obligations to be met</b>  <i>Prof Dr Tomasz Bochenek*, Medical College of the Jagiellonian University, Krakow, Poland</i></p> <ul style="list-style-type: none"> <li>• The social need for access to medicines supply</li> </ul>
12.30 – 12.45	<p><b>Introduction to the workshops</b>  <i>Prof Dr Helena Jenzer, Bern University of Applied Sciences / University Hospital of Psychiatry Zurich, Switzerland</i></p>
12.45 – 14.15	<b>Lunch break (Restaurant Olive)</b>

14.15 – 15.45	<b>Parallel workshops World Café Style</b> <ul style="list-style-type: none"> <li>• “Vulnerabilities” (Despoina Makridaki, Lene Juel Kjeldsen)</li> <li>• “Manufacturing Options” (Torsten Hoppe-Tichy)</li> <li>• “Clinical needs” (Nenad Miljković)</li> <li>• “Social and ethical aspects of access to medicines supply” (Tomasz Bochenek)</li> <li>• “Measures against causes of supply chain disruptions” (Helena Jenzer)</li> </ul>
15.45 – 16.00	<b>Wrap-up and feedbacks of the workshops</b> <i>Helena Jenzer, Lene Juel Kjeldsen, Despoina Makridaki, Torsten Hoppe-Tichy, Nenad Miljković, Tomasz Bochenek</i>
<b>16.00 – 16.30</b>	<b>Coffee break (Foyer)</b>
16.30 – 16.45	<b>Assessment of Learning success – SurveyMonkey® (Part 2 – post-meeting assessment)</b> <i>Delegates</i>
16.45 – 17.00	<b>Wrap-up of the seminars and workshops, summary and closing remarks</b> <i>Prof Dr Helena Jenzer, Bern University of Applied Sciences / University Hospital of Psychiatry Zurich, Switzerland (moderator)</i>
17.00 – 17.10	<b>Closing speech by the President of the National Association of Hospital Pharmacists from Poland</b> <i>Ewa Steckiewicz-Bartnicka</i>
<b>19.30 – 22.30</b>	<b>Dinner at the hotel (Restaurant Olive)</b>
<b>SUNDAY, 21<sup>st</sup> OCTOBER 2018</b>	
08.15	Meet in the hotel lobby
08.30 – 12.00	City Tour. Departure by bus from the hotel
12.00	Return to the hotel

**Important note:** EAHP confirms that the Speakers and the Scientific Committee members responsible for the development of the Academy Seminar programme have signed and submitted the Conflict of Interest Disclosure forms.

\* Indicates speaker or SC member has stated a conflict of interest.

# “MEDICINES SHORTAGES – CAUSATION AND APPROACHES TO IMPROVEMENTS”

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## The Educational Need Addressed

Topics of EAHP events are fixed both in a **top-down** manner by the Scientific Committee and directly arising from the fields the members daily are moving in, such as:

- Politics
- Practice
- Education
- Current research and development
- New professional opportunities
- New technology
- New medicines
- New methodologies
- New treatments
- Research and development

and in a **bottom-up** manner by

- Proposals from members
- Surveys (responses at the Congress' Cyber Café) / Questionnaires (every five years)
- National associations based on their national strategies
- Focus groups
- Joint commissions
- Mandated members of the Scientific Committee.

This year's **Academy Seminar topics** are

- **Leadership and management**
- **Innovation**
- **Creativity**
- **Interpretation and anticipation of restricted medicines availabilities**
- **Workshops and Interactive Sessions**

Generally, topics will be approved by the EAHP Board. Educational need and gaps between best and current practice and actual versus desired skills respectively can be easily screened by the Scientific Committee from

- EC resolutions
- EAHP surveys (by Survey Monkey® or Adobe Acrobat® form generator)
- FIP statements
- Current agenda of the Board
- The Scientific Committee Meetings
- The General Assembly
- Evaluation of submitted abstracts for poster or oral presentation

- Past congresses' evaluations
- Existing data such as surveys, questionnaires, et cetera

The current educational event on Medicines Shortages is one of two events organised by EAHP in the course of the 2018 Academy. The events have been selected by the Scientific Board according to the criteria depicted above. They have been approved by the EAHP Board.

## **Medicines Shortages - Catalytic leverage and added values provided by hospital pharmacy**

Medicine shortages (also referred to as drug shortages) have become a global phenomenon and are recognized to affect all health systems. It is a problem that has grown to become a crisis in terms of delivering patient care. For example, over 1400 products were reported to be in shortage in the Netherlands between 2004 to 2011. This concern is known to affect all countries in Europe and beyond including the USA, Canada, and Australia. Medicines affected by shortages include those used to treat cancer, infections, emergencies, cardiovascular conditions, anaesthetic products, neurology and many more. The major challenge is that the economic incentive system in place is aligned in such a way that participating stakeholders are motivated to maneuver themselves into a deadlock situation. A critical issue today is that the key players do not collaborate sufficiently to guarantee a security of supply of essential medicines. What is needed is a system perspective to understand and loosen this deadlock situation as well as to create innovative incentives on a legal and regulatory level.

Shortages result in the suffering of individuals and negative consequences for an economy. An option to overcome shortage situations is to use a different medicine as a substitute. However, alternatives are not always feasible and available. When shortages arise, risk increases through substitution from other excipients, other concentrations, foreign language vials, or untranslated package leaflets. Such risks have not yet been quantified in a scientifically credible way. Thus, a decrease of the number of shortages as a result of the project will have a global economic and societal impact which is in the interest of careers, patients, public health, and of taxpayers.

Hospital pharmacists intend to contribute to how medicine shortage problems can be detected, reduced, or avoided respectively by employing a systemic ecosystems perspective taking into account strategic and quality issues along the supply chain. A collaborative community of relevant stakeholders is to be established to overcome these reasons.

This EAHP Academy Seminar is intended to:

- disclose and unravel restrictive legal, economic, or organizational frameworks and routines, erroneous incentives in the supply chain, conflicts of interest, and problematic cost-benefit ratios that serve to exacerbate or create shortages
- elucidate and approach the supply chain-inherent problems at every step from raw material up to the patient's need and outcome
- identify coping strategies
- provide tools to escape with threats from supply chain disruption

It covers in introductory lectures and in workshops the following parts

- Stakeholders
- Causes / Erroneous incentives
- Impacts on Outcomes

- Clinical outcomes
- Economic outcomes
- Patients Interests (QoL)
- Approach to improvements
  - Systems Dynamics
  - Manufacturing and preparation
  - Resolution, Guidelines or reglementation?

### Target audience

Delegates nominated by their national associations should fulfil specific requirements such as

- be hospital pharmacists recommended by each country's national association president;
- be hospital pharmacists who have experience with medicines shortages in their hospital;
- be fluent in English;
- attend all seminar sessions;
- complete seminar evaluation form;
- contribute, give presentation and/or demonstrate knowledge gained during workshops and seminar concluding session;
- must be able to accurately disseminate the knowledge obtained during the academy seminar within their country via seminars or workshops and provide documentation that dissemination was done (i.e. national workshop agendas). The national associations then need to report back on how this was accomplished to the EAHP via the country report which is presented each year during the EAHP General assembly.

### Links to the EAHP mission & goals and to the European Statements of Hospital Pharmacy

The main EAHP goal covered by the Academy Seminar on Medicines Shortages is to promote and facilitate activities to cope with shortages in the own hospital.

“Medicines Shortages” is covered by all sections of the European Statements of Hospital Pharmacy, i.e.

- Section 1: Introductory Statements and Governance (1.1, 1.2, 1.3, 1.5)
- Section 2: Selection, Procurement, and Distribution (2.1, 2.4, 2.5, 2.6)
- Section 3: Production and Compounding (3.1, 3.2, 3.3, 3.4)
- Section 4: Clinical Pharmacy Systems (4.1, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8)
- Section 5: Patient Safety and Quality Assurance (5.1)
- Section 6: Education and Research (6.2, 6.4)

### Assessment of Learning Success

To evaluate the learning success as requested by ACPE and as defined by teaching goals and learning objectives, a Survey Monkey® driven online questionnaire will be used. This form is answered on day 1 as a baseline snapshot of existing knowledge and can be completed online on day 2 after the Academy Seminar to assess the learning success. The link will be communicated to the delegates during the Seminar. A participation certificate will be delivered by link after anonymous submission of the completed questionnaire.

## ACADEMY AND WORKSHOP FACULTY

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### Presenters and Workshop coaches

(biographies are available on the website <http://www.eahp.eu>, section events)

#### Prof Dr Helena Jenzer



#### **AFFILIATION:**

Bern University of Applied Sciences / University Hospital of Psychiatry  
Zurich

#### **COUNTRY:**

Switzerland

**Current Status, Position.** Prof Dr Helena Jenzer has 2 job activities and affiliations: 50% as **past head** of applied Research and Development Nutrition and Dietetics at Bern University of Applied Sciences (Bern). 80% cover research activities and 20% teaching. 50% as **chief pharmacist** at the University Hospital of Psychiatry Zurich. The main activity actually is to develop the Quality Assurance system and to promote hospital pharmacy research for the Medical Faculty of the University of Zurich.

**Education.** Helena Jenzer is a specialist in hospital pharmacy, educated at the Universities of Fribourg and Bern Switzerland from 1978-1984. She got the Doctor of pharmacy Degree in 1987. She had then leading positions as head of a hospital pharmacy for more than 25 years, as well as positions as qualified person in producing hospital pharmacies and in a blood product manufacturing industry. She is specialised in all questions of quality assurance, manufacturing and quality control in a frame of cGMP and PIC/s guidelines. She has a CAS in Public Health Collaboration. She was a member of the board of the GSASA and is currently member of the Scientific Committee of the EAHP (European Association of Hospital Pharmacist). Her further activities were leading full-time a nutritional medicines research division at a University of Applied Sciences, which lead to a series of publications including supply chain related articles about the availability of medicines. In 2014 and 2015 she was main proposer and became chair of COST Action CA15105 (European Medicines Shortages Research Network - addressing supply problems to patients). Actually, she has two half time equivalents as head researcher and as chief hospital pharmacist.

**Research Area.** Starting from her thesis topic on biomolecular mechanisms of thyroid hormone biosynthesis, Helena Jenzer performed research on enzymology of cytochrome enzymes such as peroxidases, oxygenases, cyclooxygenases and Nitric Oxide Synthase (NOS) competing Arginase. Many of these enzymes are involved in nutritionally related diseases and metabolic pathways such as wound healing, angiogenesis, energy production (respiratory chain, oxidative phosphorylation). The latest activities have been focusing on the genomics based impacts of nutrients and pharmaca on obesity, physical performance, metabolism of antipsychotic drugs, aromatase, ethnicity-dependant nutritional disorders and many more.

**Conflict of interest: None**



## Dr Torsten Hoppe-Tichy



### **AFFILIATION:**

Ruprecht-Karls-University of Heidelberg

### **COUNTRY:**

Germany

**Current Status, Position.** Dr Torsten Hoppe-Tichy is currently **Chief Pharmacist** at Heidelberg University Hospital, **lecturer** at School of Pharmacy at Ruprecht-Karls-University of Heidelberg and at Duale Hochschule Baden-Wuerttemberg and **Member of the Scientific Committee of EAHP**.

**Education.** Dr. Torsten Hoppe-Tichy studied Pharmacy at School of Pharmacy at TU Braunschweig, Germany. He obtained a PhD (Dr. rer. nat.) in Pharmaceutical Chemistry. He is a Specialist in Clinical Pharmacy and Pharmaceutical Analytics. Before he took over the position as Chief Pharmacist at Heidelberg University Hospital he served as a Deputy Chief Pharmacist at University Hospital of Ulm.

**Research Area.** Dr Torsten Hoppe-Tichy's research area is focused on clinical pharmacy regarding drug safety and patient safety through safe administration of drugs, pharmacokinetics of antimicrobial agents, pharmacoconomics, organisation of hospital pharmacy and automatisisation of logistics and drug reconstitution and production.

**Conflict of interest: None**

## Nenad Miljković



### **AFFILIATION:**

Institute of Orthopaedic Surgery "Banjica"

### **COUNTRY:**

Serbia

**Current Status, Position.** Nenad Miljković is currently **the Head** of Hospital Pharmacy Services at the Institute of Orthopaedic Surgery "Banjica". He is also **a member** of Institute's Drug and Therapeutics Committee. Nenad is also responsible for International cooperation on behalf of Pharmaceutical Association of Serbia, Hospital Pharmacy Section, including COST Action 15105-European Medicines Shortages Research Network.

**Education.** Nenad Miljković studied Pharmacy at the University of Belgrade, where he graduated in 2004 and subsequently specialised in clinical pharmacy in 2014. In 2012, Nenad obtained a Dual Master Degree in European Public Health at the University of Sheffield in the UK, and at the University Sorbonne Paris Cite in France.

**Research Area.** Nenad Miljković's research focuses on pharmacy education and healthcare services, patient adherence to osteoporosis medications, medicines shortages including patient clinical needs assessment and prospective risk evaluation.

**Conflict of interest: None**



## Prof Dr Tomasz Bochenek



### **AFFILIATION:**

Medical College of the Jagiellonian University, Krakow, Poland

### **COUNTRY:**

Poland

**Current Status, Position.** Prof Dr Tomasz Bochenek is currently a **deputy director** of the Institute of Public Health of the Jagiellonian University Medical College in Krakow, and an **assistant professor** at the Department of Drug Management. He is responsible for teaching and research projects, including the analysis of problems associated with drug shortages in health care systems. Prof Dr Bochenek is an author of about 100 scientific publications and numerous conference presentations, a member of scientific council and an academic editor at scientific journals, and a reviewer of many scientific publications. Dr Bochenek worked in public administration, where his duties were associated with implementing pharmaceutical policy, pricing and reimbursement of medicines and medical devices, as well as utilization of health technology assessment for funding health care services. He was a director of the department responsible for reimbursement of medicines and medical devices at the Sickness Fund and the National Health Fund in Malopolska Province. He also worked as an expert to the Minister of Health, the Agency for Health Technology Assessment and Tariff System, and other institutions.

**Education.** Tomasz Bochenek studied medicine at the Medical College of the Jagiellonian University in Krakow, Poland, and became licensed physician in 1993. He studied also public health and obtained Master of Public Health at the Nordic School of Public Health in Gothenburg, Sweden, in 2006. In 2011 he obtained a PhD in medicine at the Jagiellonian University for his work in area of pharmacoconomics and health technology assessment.

**Research Area.** Prof Dr Tomasz Bochenek's professional interests and research are focused on pharmaceutical policy, pharmaceutical pricing and reimbursement, management of medicines and medical devices, pharmacoconomics and health technologies assessment.

**Conflict of interest: Prof Dr Tomasz Bochenek received speakers' fee and/or honoraria from Amgen.**

## Prof Dr Stefan Groesser



### **AFFILIATION:**

Bern University of Applied Science

### **COUNTRY:**

Switzerland

**Current Status, Position.** Prof Dr Stefan Groesser is currently **the head** of department, Industrial Engineering and Management Science. He is responsible for the study degrees of industrial engineering and management science (both bachelor and master).

**Education.** Prof Dr Groesser studied Management at the University of Stuttgart, at the Massachusetts Institute of Technology, the University of St. Gallen and the University of Bergen, Norway. In 2011 he obtained a PhD in Management at the University of St. Gallen for his work on innovation diffusion.

**Research Area.** Prof Dr Stefan Groesser' research focuses on simulation modelling of complex systems, especially on the digitalization of supply chains and **business models**.

**Conflict of interest: None**

## Dr Lene Juel Kjeldsen



### **AFFILIATION:**

Amgros I/S

### **COUNTRY:**

Denmark

**Current Status, Position.** Dr Lene Kjeldsen is a **senior researcher** in clinical pharmacy in Denmark. Dr Kjeldsen has conducted numerous national research project in collaboration with clinical pharmacists at hospitals throughout Denmark.

**Education.** Lene Kjeldsen graduated with a MSc (pharm) degree in Copenhagen, Denmark in 1997 and with a PhD in quality use of medicine from Department of Medicine, University of Queensland, Brisbane, Australia in 2002. She has completed a postgraduate course in clinical pharmacy and my professional career has primarily focused on research and development within the area of clinical pharmacy. Her current work involves conducting studies as well as providing support to projects within the area of clinical pharmacy by request from hospital pharmacies in Denmark. She has previously worked with clinical pharmacy projects within the primary care setting when employed by Pharmakon in Denmark. Other previous employments include organizations; The University of Southern Denmark, Odense University Hospital and The Danish Medicines Agency.

**Research Area.** Dr Lene Kjeldsen's area of interest include practice research testing clinical pharmacy interventions, medication adherence, drug-related problems, medication reviews and methodology.

**Conflict of interest: None**

## Despoina Makridaki



### **AFFILIATION:**

Sismanoglio - Amalia Fleming General Hospital of Attica

### **COUNTRY:**

Greece

**Current Status, Position.** Mrs Despoina Makridaki is currently the **Director of Pharmaceutical Services** in Sismanoglio-Amalia Fleming General Hospital of Attica.

**Education.** Despoina Makridaki received her Degree in Pharmacy by National and Kapodistrian University of Athens in 1987, an MSc in Clinical Pharmacy by the same School in 1999 and an MBA in Management of Healthcare Units by National School of Public Health in 2018. She has a 30-years experience in Hospital Pharmacy served in both Oncological (15 years) and General Hospital (15 years). She was appointed and served as 1<sup>st</sup> Vice president in National Organization for Medicines for 40 months (since April 2015 until 5<sup>th</sup> of June 2018) and joined EMA Management Board during the same period. She joins the COST-Action CA15105 on Medicines Shortages as delegate of Greece. Member of EAHP Board (Director of Professional Development) since June 2017 and member of the Scientific Committee of EAHP since September 2014. She is delegate from Greece for more than 10 years in ESOP. President of Panhellenic Association of Hospital Pharmacists (PEFNI) since 2013.

**Research Area.** Clinical and Oncology Pharmacy, Clinical Trials, Pricing, Procurement and Reimbursement Procedures (member of National Committee on monitoring Pharmaceutical Expenditure and Therapeutic Protocols at the Ministry of Health since 2015), IT applications in hospital pharmacy, Certification of Procedures, Quality Management, Falsified Medicines.

**Conflict of interest: None**

## Prof Dr Kees Neef



### **AFFILIATION:**

Maastricht University Medical Center+

### **COUNTRY:**

The Netherlands

**Current Status, Position.** Prof Dr Kees Neef is a retired **hospital pharmacist** in Maastricht and **professor emeritus** in Clinical Pharmacy at the Maastricht University. He is EAHP Board member and Director of Education, Science and Research.

**Education.** Kees Neef studied Pharmacy at the State University of Groningen and he became a licenced pharmacist in 1978. In 1983 he obtained a PhD in Pharmacology at the same institute of Pharmacology for his thesis on the structure pharmacokinetic relationship of quaternary ammonium compounds. He finished his education as a clinical pharmacologist in 1986 in the Antonius Hospital in Nieuwegein/Utrecht.

**Research Area.** Prof Dr Kees Neef 's research focusses on pharmacokinetic - pharmacodynamic modeling.

**Conflict of interest: None**

## **Programme Responsibility and Support**

- **Kees Neef**, EAHP Director of Education, Science & Research.  
EAHP Director of Education, Science and Research  
Professor of Clinical Pharmacy, clinical pharmacologist, PhD  
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- **Helena Jenzer**, EAHP Member of the Scientific Committee, PhD,  
Professor and Senior Researcher AR&D in Nutrition and Dietetics, Chief-Pharmacist  
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- EAHP Staff
  - **Jennie De Greef**, COO
  - **Henadzi Sobal**, Events Assistant
  - **Anne-Cécile Tanton**, Events Assistant
  - **Isabel Valero Guerrero**, Project Assistant

# EDUCATIONAL NEEDS, CONTENTS, AND LEARNING OBJECTIVES OF THE LECTURES

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The Academy Seminar and Workshops show a main track from a general overview to national clinical implications. The focus is put and centred on the patient and on processes.

Kind reminder: The second slide of each presentation will give the disclosure of conflicts of interest. The last slides of presentation should give a summary.

## DAY I

### Hospital Pharmacists as troubleshooters

*Dr Torsten Hoppe-Tichy, Ruprecht-Karls-University of Heidelberg, Germany*

#### Linked to EAHP Statements

- Section 1: Introductory Statements and Governance (1.1, 1.2, 1.3, 1.5)
- Section 2: Selection, Procurement, and Distribution (2.1, 2.4, 2.5, 2.6)
- Section 5: Patient Safety and Quality Assurance (5.1)

#### Abstract

Hospital Pharmacists are in the driver's seat of the pharmaceutical supply chain. They are mandated to provide the employer's patients with medicinal products and accompanying services. All troubleshooting and debugging actions arising from disruptions of the supply chain are a process which binds unnecessarily many human and technical resources. In this presentation some typical cases are presented as an inspiring start of the programme.

#### Learning objectives

At the end of this session, participants will be able to:

- know hospital pharmacist's challenges in situations of non-availability of registered products;
- recognise the extent of the global phenomenon;
- participate and provide actively inputs in professional task forces to improve the shortages situation.

#### Educational need addressed

To deal with medicine shortages has become a daily business of Hospital Pharmacists. In practice, pragmatic procedures to open further supply sources are most currently used. There might be useful hints to be communicated to others and space for capacity building by learning from colleagues.

**Keywords:** medicine shortages, global dimension, national patterns, hospital pharmacist's challenges, commonalities, improvement options, capacity building.

## **An international bottom-up approach – analysis of causation of shortages**

*Prof Dr Helena Jenzer, Bern University of Applied Sciences / University Hospital of Psychiatry Zurich, Switzerland*

### **Linked to EAHP Statements**

- Section 1: Introductory Statements and Governance (1.1, 1.2, 1.3, 1.5)
- Section 2: Selection, Procurement, and Distribution (2.1, 2.4, 2.5, 2.6)
- Section 3: Production and Compounding (3.1, 3.2, 3.3, 3.4)
- Section 4: Clinical Pharmacy Systems (4.1, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8)
- Section 5: Patient Safety and Quality Assurance (5.1)
- Section 6: Education and Research (6.2, 6.4)

### **Abstract**

For two decades already, the medicines shortages situation keeps on deteriorating. To deal with medicine shortages has become a daily business of Hospital Pharmacists. Many attempts for improvements have been undertaken, however seldom comprehensively over the whole supply chain. Professional association from the clinical frame collaborate as far as possible and against all odds of administration. There are different interpretations in definitions, different positions and interests and several dependencies from third parties which all favour disruptions of the vulnerable supply chain. Responsibilities for patients are voluntarily neglected and ranked inferior as compared to interests of business and returns on investment. In this situation, no leadership is seen from governments to provide incentives and to line up interests. The most promising approach and a true perspective for a success story lies in the comprehensive approach involving all stakeholders.

### **Learning objectives**

At the end of this session, participants will be able to:

- know about attempts to improve the shortages situation (COST Action CA15105 and other attempts);
- interpret definitions, positions, interests arising from different stakeholders;
- disclose erroneous incentives;
- identify vulnerabilities of the supply chain.

### **Educational need addressed**

A number of improvements for an undisrupted pharmaceutical supply chain has been proposed in the past years. Most of them shed light on a distinct step of the supply chain. None has been brought a breakthrough. Although there are different national challenges in the EAHP member countries, harmonised patterns and commonalities in the fight against supply chain disruptions are more likely to lead to global stabilisation and improvement.

**Keywords:** medicine shortages, global dimension, national patterns, definitions, interests, positions, dependencies, hospital pharmacist's challenges, commonalities, improvement options.

### The clinical needs

*Nenad Miljković, Institute of Orthopaedic Surgery "Banjica", Serbia*

#### **Linked to EAHP Statements**

- Section 2: Selection, Procurement, and Distribution (2.1, 2.4, 2.5, 2.6)
- Section 4: Clinical Pharmacy Systems (4.1, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8)
- Section 5: Patient Safety and Quality Assurance (5.1)

#### **Abstract**

There is a clinical need to avoid and manage risks to patient health arising from medicine shortages and associated with introducing replacement/alternative medicines. Success of a dedicated healthcare intervention is assessed by the outcome. Therefore, the clinical need represents an estimate of an appropriate treatment strategy. Medicines represent an essential part needed to fulfil the expectations of both healthcare professionals and a patient when it comes to desired health outcomes. Non-availability of the right medicines induces serious uncertainties and deviations from the established treatments. These threats are of a particular importance in case of life-saving medicines such as anti-infectives, vaccines, and immuno-therapeutics. In case of their non-availability a number of risks have to be considered along with the evaluation of substitute treatments.

#### **Learning objectives**

At the end of this session, participants will be able to:

- understand conflicts arising from not being able to fulfil clinical needs as for non-availability of medicines;
- estimate the optimal expected outcome related to a substitute medicine as compared to a medicine initially prescribed;
- recognise and forecast the threats to expected patients outcomes in case of non-availability of medicines;
- predict risks arising from lack of access to life-saving medicines.

#### **Educational need addressed**

Although there are different national challenges in the EAHP member countries, certain therapeutic groups such as anti-infectives or vaccines are more at risk to be out-of-stock. To understand the mechanisms leading to empty stocks of these groups is one of the keys to find coping strategies for all therapeutic groups.

**Keywords:** threads, risk factors and vulnerabilities, emergency medicines, life-saving medicines, risk of substitutions.

### Social and ethical aspects

*Prof Dr Tomasz Bochenek, Medical College of the Jagiellonian University, Krakow, Poland*

#### **Linked to EAHP Statements**

- Section 1: Introductory Statements and Governance (1.1, 1.2, 1.3, 1.5)
- Section 5: Patient Safety and Quality Assurance (5.1)
- Section 6: Education and Research (6.2, 6.4)

#### **Abstract**

Successful or less successful fulfilment of clinical needs bring with it satisfying or unsatisfying

outcomes. Benchmarks and statistics are assessed for clinical outcomes, for financial outcomes, and for quality-of-life outcomes. In times of economic restrictions, serious impacts are put on public health services, linked to ethical and payability of treatments. The conflict between different objectives of public health, business, finances, and humanity is a risk for social peace.

### Learning objectives

At the end of this session, participants will be able to:

- understand the balance between different outcomes;
- assess points of view of clinicians, hospital directors, governments, industry, and patients;
- reproduce differences in the health care potency in European countries.

### Educational need addressed

Outcomes are understood as clinical, financial, and quality-of-life results of patient cases. In all cases, outcomes are linked to sociological and ethical needs.

**Keywords:** medicine shortages, outcomes, ethics, sociological situation, payability of treatments, social peace.

### Simulation of a complex network – a Systems Dynamics

(followed after the workshop by an Interactive Plenary and Podium Discussion “Analysis of the worldwide Medicines Shortages Problem”)

*Prof Dr Stefan Grösser, Bern University of Applied Science, Switzerland*

### EAHP Statements

- Section 1: Introductory Statements and Governance (1.1, 1.2, 1.3, 1.5)
- Section 2: Selection, Procurement, and Distribution (2.1, 2.4, 2.5, 2.6)
- Section 6: Education and Research (6.2, 6.4)

### Abstract

System Dynamics is a recognised methodology for increasing the reliability of foresight. Instead of linear simulation, a non-linear growth curve is considered and simulated. Linear models are not satisfying in terms of precise prognostics. Unexpected events destroy calculations entirely. A more scientific approach of predicting growth curves is provided by the Systems Dynamics approach where not only single linear models are applied, but an interrelation between all stakeholders in a network.

In this session, the methodology of System Dynamics is transferred to the medicines shortages framework. Options to take measures for improvements of medicines supply will be outlined.

Future research bases on different methods of foresight.

### Learning objectives

At the end of this session, participants will be able to:

- explain the Systems Dynamics approach of foresight;
- introduce a simulation methodology of decision making in a complex network;
- understand the methodology of Systems Dynamics and its suitability to identify systems pitfalls in complex networks;
- derive conclusions from simulation to coping strategies of medicines shortages in the modelled system.



### Educational need addressed

Industry and (pre-)wholesalers calculate and plan budgets using several methods of foresight. Linear foresight is erroneous and unforeseen events cannot be anticipated. More reliable and sophisticated methods of foresight and future research are needed.

**Keywords:** system dynamics, foresight, future research, non-linear prediction.

## DAY 2

### Pragmatic coping strategies in Hospital Pharmacies

*Dr Torsten Hoppe-Tichy, Ruprecht-Karls-University of Heidelberg, Germany*

### Linked to EAHP Statements

- Section 1: Introductory Statements and Governance (1.1, 1.2, 1.3, 1.5)
- Section 2: Selection, Procurement, and Distribution (2.1, 2.4, 2.5, 2.6)
- Section 3: Production and Compounding (3.1, 3.2, 3.3, 3.4)
- Section 4: Clinical Pharmacy Systems (4.1, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8)
- Section 5: Patient Safety and Quality Assurance (5.1)
- Section 6: Education and Research (6.2, 6.4)

### Abstract

In practise, hospital pharmacists have learned to spontaneously deal with shortages. In most cases, exchange within regional networks is practised. Another current option is to import. This however switches the problem to an international level to the disadvantage of low-price countries suffering particularly from parallel exports. This presentation lists a couple of fast-track optional activities to bridge intermediate gaps in the supply chain irrespective of the long-term international situation.

### Learning objectives

At the end of this session, participants will be able to:

- know further options to bridge supply chain gaps;
- recognise that such actions only translocate the problem but do not resolve the global shortages problem.

### Educational need addressed

Pragmatic procedures to open further supply sources are most currently used. At the moment a shortage is encountered, it is not evident which one of the approaches is most effective. The patient case may be requesting the fastest option, although more expensive.

**Keywords:** effective coping strategies, improvement options, cost – benefit, cost – effectiveness.

### Systematic attempts at a solution

*Prof Dr Helena Jenzer, Bern University of Applied Sciences / University Hospital of Psychiatry Zurich, Switzerland*

### Linked to EAHP Statements

- Section 1: Introductory Statements and Governance (1.1, 1.2, 1.3, 1.5)
- Section 2: Selection, Procurement, and Distribution (2.1, 2.4, 2.5, 2.6)

- Section 3: Production and Compounding (3.1, 3.2, 3.3, 3.4)
- Section 4: Clinical Pharmacy Systems (4.1, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8)
- Section 5: Patient Safety and Quality Assurance (5.1)
- Section 6: Education and Research (6.2, 6.4)

### Abstract

In Switzerland, a nationally funded research projects maps the interests of the stakeholders and will clarify options for improvements. Major pitfalls in the system are the total absence of a leadership and of responsibility. Nevertheless, interviews have already brought insight into the willingness to contribute to a bottom-up approach and best and worst alternatives to negotiated agreements. BATNAs for industry might be a protection of trading and pricing liberty. WATNAs might be a regulation and further loss of return on investment. One of the main achievements obtained so far is a contract framework between the Swiss Federal Office for National Economic Supply (FONES) and those industries providing life-saving medicines. According to these contracts, industry keeps a minimal stock to warrant supply in times of particular politico-social and public health conditions.

### Learning objectives

At the end of this session, participants will be able to:

- acquire knowledge about first integral resolutions approaches;
- develop further resolution approaches for their own country and hospital;
- reconstruct to philosophy of stockpiling contracts with industry;
- animate responsibility sharing among the stakeholders in the supply chain.

### Educational need addressed

Whereas causes of shortages are widely known, prevention and bridging gaps are not so clear at the moment of action needed. Finding solutions depends on a serious analysis of each one of the shortages. The amendment of such a deviation may however not be fast enough to be helpful for a given patient case.

**Keywords:** interests, positions, (in-)dependence, BATNA, WATNA.

### How clinical needs could be met

*Nenad Miljković, Institute of Orthopaedic Surgery "Banjica", Serbia*

### Linked to EAHP Statements

- Section 4: Clinical Pharmacy Systems (4.1, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8)
- Section 5: Patient Safety and Quality Assurance (5.1)
- Section 6: Education and Research (6.2, 6.4)

### Abstract

This presentation will summarise a recent survey on risk considerations in the context of life-saving medicines supply.

### Learning objectives

At the end of this session, participants will be able to:

- recognise the particular importance of keeping the flow of life-saving medicines from industry to the patients;

- identify disruption risk and propose preventing measures to assure availability of life-saving medicines.

### **Educational need addressed**

Life-saving medicines and therapeutic groups such as anti-infectives or vaccines need an urgent improvement of the shortages situation. Surveys are useful to shed light on clinician's and patient's perspectives of non-availabilities of certain medicines to find flexible options for pharmacotherapies.

**Keywords:** survey, life-saving medicines, clinician's perspective, patient's perspective.

### **Social and ethical framework and obligations to be met**

*Prof Dr Tomasz Bochenek, Medical College of the Jagiellonian University, Krakow, Poland*

### **Linked to EAHP Statements**

- Section 1: Introductory Statements and Governance (1.1, 1.2, 1.3, 1.5)
- Section 4: Clinical Pharmacy Systems (4.1, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8)
- Section 5: Patient Safety and Quality Assurance (5.1)
- Section 6: Education and Research (6.2, 6.4)

### **Abstract**

Harmonisation in Europe not only concerns economic levelling, but also access to high quality of health services and coverage of medicines supply. This presentation gives an insight in attempts to improve harmonisation in general and medicines supply in particular, as far as the social framework is suitable to be subject for harmonisation and economic-cultural levelling.

### **Learning objectives**

At the end of this session, participants will be able to:

- assess the successful provision of equal medicines supply throughout Europe from a social point of view.

### **Educational need addressed**

Outcomes can be improved if discussions are reframed to ethical values and just matters. For this, social partners have to give up particular interests and positions and "negotiate at a round table".

**Keywords:** harmonisation, economic levelling, high quality of public health, social framework.

# CONTENTS AND LEARNING OBJECTIVES OF THE WORKSHOPS

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## WORKSHOP DAY 1

### Workshop “Simulation Experimentation”

*Prof Dr Stefan Grösser, Bern University of Applied Science, Switzerland*

#### Linked to EAHP Statements

- Section 1: Introductory Statements and Governance (1.1, 1.2, 1.3, 1.5)
- Section 2: Selection, Procurement, and Distribution (2.1, 2.4, 2.5, 2.6)
- Section 3: Production and Compounding (3.1, 3.2, 3.3, 3.4)
- Section 4: Clinical Pharmacy Systems (4.1, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8)
- Section 5: Patient Safety and Quality Assurance (5.1)
- Section 6: Education and Research (6.2, 6.4)

#### Abstract

In a partly interactive workshop, delegates get familiar with the previously presented software Vensim® by studying a business model case. Delegates experiment with a supply chain simulation about medicines shortages and explore a model.

Recommended Reading for the workshop:

Schaffernicht/Groesser 2018, Wiley Publishing.

E-book (at a price of 16€, in German only)

[https://www.amazon.de/Qualitative-Modellierung-mit-System-Dynamics/dp/1540707024/ref=sr\\_1\\_1?ie=UTF8&qid=1523077527&sr=8-1&keywords=stefan+groesser+qualitative+modellierung](https://www.amazon.de/Qualitative-Modellierung-mit-System-Dynamics/dp/1540707024/ref=sr_1_1?ie=UTF8&qid=1523077527&sr=8-1&keywords=stefan+groesser+qualitative+modellierung)

#### Learning objectives:

At the end of this workshop, participants will be able to:

- use Vensim® for strategic foresight;
- experiment with a supply chain simulation about medicines shortages;
- assess the impact of assumptions used in the simulated model;
- explore what modification are to be expected following changes in decisions taken by stakeholders.

#### Educational need addressed

A number of improvements for an undisrupted pharmaceutical supply chain has been proposed in the past years. Most of them shed light on a distinct step of the supply chain. None has been brought a breakthrough. System Dynamics is one of the promising innovative approaches to improve the supply chain by more precise non-linear foresight.

**Keywords:** vensim®, foresight, future research.

## WORKSHOP DAY 2

### Parallel workshops World Café Style

#### Linked to EAHP Statements

- Section 1: Introductory Statements and Governance (1.1, 1.2, 1.3, 1.5)
- Section 2: Selection, Procurement, and Distribution (2.1, 2.4, 2.5, 2.6)
- Section 3: Production and Compounding (3.1, 3.2, 3.3, 3.4)
- Section 4: Clinical Pharmacy Systems (4.1, 4.3, 4.4, 4.5, 4.6, 4.7, 4.8)
- Section 5: Patient Safety and Quality Assurance (5.1)
- Section 6: Education and Research (6.2, 6.4)

#### Abstract

There will be 5 parallel workshops in a World Café Style. This means that doors will be open for delegates to move from one room to the other to contribute with ideas to a common output. Workshop leaders will stay in the rooms and manage the steadily growing afflux of contributions.

The five workshops and the leaders are:

- “Vulnerabilities” (Despoina Makridaki, Lene Juel Kjeldsen)
- “Manufacturing Options” (Torsten Hoppe-Tichy)
- “Clinical needs” (Nenad Miljković)
- “Social and ethical aspects of access to medicines supply” (Tomasz Bochenek)
- “Measures against causes of supply chain disruptions” (Helena Jenzer)

An initial attribution of delegates to one of these five working groups is done according to their professional activity. After this organised start, delegates are free to move from one workshop to the other and place their contributions.

The declared aim of the parallel World Café Style workshops is to acquire knowledge and experiences of delegates as related to coping with the medicines shortages situations. To prevent a loss of time for organisation of the groups, the workshop leaders submit a first set of working documents such as brainstorming items, keywords and/or discussion issues extracted from their presentations as follows:

- A poster of a mind-map showing a classification of causes of shortages (“vulnerabilities of the supply chain”) (to be submitted by Helena Jenzer)
- A poster of coping strategies and approaches to counter the causes of disruptions of the supply chain (to be submitted by Helena Jenzer)
- A poster of options to activate the manufacturing pathway (to be submitted by Torsten Hoppe-Tichy)
- A poster of life-saving medicines at risk for frequent supply disruption (to be submitted by Nenad Miljković)
- A poster of financial and socio-ethical arguments needing an intensified fight against the shortages (to be submitted by Tomasz Bochenek)

Delegates contribute with their creative proposals to an improvement of the medicines shortages situation. They place their inputs directly into the mind-maps, flow-charts, or bulleted lists.

### Learning objectives:

At the end of this workshop, participants will be able to:

- use the medicines shortages causes mindmap in their own hospital;
- use the medicines shortages coping strategies mindmap in their own country;
- contribute further to a harmonised international approach to find solutions for the steadily worsening flow in the pharmaceutical supply chain.

### Educational need addressed

All elements of analysis of supply chain disruptions are useful for quality improvements in terms of plan – do – check – act cycles or structure, process, and outcome qualities. These kinds of quality need to be lived rather than only to be run through. A comprehensive overview over the elements is needed.

**Keywords:** medicine shortages, global dimension, national patterns, hospital pharmacist's challenges, commonalities, improvement options.