medicines for europe
better access. better health.

IGBA
INTERNATIONAL GENERIC AND BIOSIMILAR MEDICINES ASSOCIATION

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JOINT

24th Medicines for Europe
21st IGBA Annual Conference

Global Generic, Biosimilar and Value Added Medicines Conference

HOTEL HILTON BUDAPEST, BUDAPEST

#IGBAMedicinesforEU

MARKETING DRAFT PROGRAMME

Introduction

The Joint 24th Medicines for Europe and 21st IGBA Annual Conference will bring together over 300 experts including medicine manufacturers, stakeholders and governments to evaluate market trends, innovative commercial strategies, challenges for the pharmaceutical sector and new opportunities to improve access to medicines for patients. At this unique event, the participants will not only gain new information, but will also have the opportunity to network in the beautiful capital of Hungary, Budapest!

Why you should attend the conference!

- Get updates on the latest development and market trends in the Generic, Biosimilar and Value Added medicines industry
- Meet high-level speakers from Europe, Brazil, US, Japan, Taiwan, Russia, Canada, Malaysia, South Africa, India and many more countries to understand the global relevance of Generic, Biosimilar and Value Added Medicines
- Network with policy-makers, regulators, payers and peers
- Discover business opportunities in pharmaceutical markets across the world

Session Topics will cover:

- Sustainability of the off-patent markets
- Political decisions impacting the supply of medicines
- The fight against counterfeit medicines
- How to keep up in providing data, recognising its value and making the best use of it
- How to manage selective transparency, commoditisation, shortages
- The impact of international agreements on access to medicines
- Models to bring better medicines to patients
- Defining a future where trust and regulatory efficiency translate into patient access
- Increasing patient access to specialty medicines

1. Markets

Sustainability of the off-patent markets

In order to develop a sustainable healthcare market, predictability is a key element. Payers require predictability to balance their healthcare budgets, but the generic and biosimilar medicines industry also requires a predictable market environment that allows companies to define their business plans and manufacturing capacities. In this session we will discuss the removal of barriers that limit competition in the market, therefore limiting patient access to medicines, and the sustainability of the healthcare systems. In addition, the introduction of incentives to promote the use of the most cost effective therapeutic options after day 1 of patent expiry is also an element of major importance for the sustainability of National Healthcare systems.

2. External Factors

New challenges in the pharmaceutical industry

The pharmaceutical industry is strongly influenced by factors that often are not strictly related to scientific considerations. This session will identify and discuss the key challenges emerging from the current political climate which may have a medium and long term impact on the business, with particular focus on the risks to the supply of Active Pharmaceutical Ingredients.

3. Fighting the Fakes

The fight against counterfeit medicines

Patient health and safety is of the utmost importance to Medicines for Europe and the IGBA. Consequently, we support initiatives and encourage streamlining efforts to support, cooperate and (co-)lead on various initiatives that are fighting counterfeit medicines. The session will give an overview on how different stakeholders fight counterfeit medicines, the tools they have to do so and the challenges they foresee.

4. Dealing with Data

How to keep up in providing data, recognising its value and making the best use of it

The importance of managing data is getting the recognition it deserves in the healthcare sector. The pharmaceutical industry, regulators and other stakeholders are dealing with enormous amounts of data. However due to high volumes, limited quality, complex processes and working without a clear EU/global strategy, its value and potential are not fully seized. In this session, we will tackle the value of data from three perspectives: 1 – how to make the best use of data that companies and regulators have in different databases; 2 – how to extract knowledge from the vast amount of real-world data and use it in decision-making processes and 3 – how to protect our own personal data and what our sector can do in this regard.

5. How to survive

How to manage selective transparency, commoditisation, shortages

This session will tackle the risks of further commoditisation of the prices of generic medicines. Generic medicines are used as a treatment for 80% of disease areas while only accounting for 20% of the medicine budgets. Medicines cannot just be sold at cost of goods. The medicines industry is one of the highest regulated industries

and fulfilling such regulatory requirements comes at a cost. In addition, new regulations, such as the falsified medicines directive, add more costs while payers seek only to further reduce the prices of medicines.

6. International cooperation

The impact of international agreements on access to medicines

International agreements related to pharmaceuticals have a huge impact on business development for pharmaceutical companies as well as on the level of patient access to medicines worldwide. This session will address the impact of regulatory convergence on the business and how patient access is affected.

7. Value added medicines

Models to bring better medicines to patients

Health delivery models are being challenged by a rising ageing patient population and current healthcare economic constraints, threatening the sustainability of healthcare systems. There is a need for a new value proposition for patients, healthcare professionals and healthcare systems, especially to address clinical (adherence, quality of life) and economic inefficiencies. Value added medicines can address these challenges by improving patient adherence and quality-of-life issues, while addressing medicine-related healthcare inefficiencies and improving healthcare provision and organisation, thereby contributing to the sustainability of healthcare systems.

8. Biosimilar medicines

Defining a future where trust and regulatory efficiency translate into patient access

In this session, we will discuss the key success strategies to deliver on the promise of access to biologic medicines, and the essential role regulatory convergence plays on enabling benefits for patients and the sustainability of the healthcare budgets. In this, there are 2 main features:

- *Confidence and trust: Converging regulatory and scientific approaches, accessibility and dissemination of information in support of policy making.*
- *Regulatory and Operational simplification and efficiency gains: removing the unnecessary complexity for robust and fast biosimilar medicines development and availability.*

9. Future strategies

Increasing patient access to specialty medicines

In this session, we will discuss how our industry needs to adapt to ensure patient access to specialty medicines. Not only does this lead to more complex R&D and manufacturing but also to a change in mind-set from an industry which is focussed on operational excellence to a position that also considers product leadership and customer intimacy. Going into the specialty market means, for many products, a commercial strategy shift from GPs or pharmacists to Key Opinion Leaders and hospitals or even other supply chains.