Informa Life Sciences' 2nd Annual

The **global biosimilar market is estimated to reach US$19.4 billion by 2018** - stay on top of global regulations and market access strategies and grab your share of this rapidly growing area!

Biosimilars in Turkey, MENA, Southeast Asia, India & Russia

Wed 6 - Thurs 7 November 2013 | Istanbul | Turkey

Co-located with Biological Production Strategies in Turkey and MENA
Bringing together both technical and regulatory departments

Explore industry's only event focused on the market access and regulatory challenges for successful biosimilar development in Turkey, MENA, Southeast Asia, India and Russia

Gain critical knowledge from your global speaker panel:


Dr Ferhat Farsi, *RD and BD Director,* **Abdi Ibrahim Pharmaceuticals,** Turkey


Paul Thomas, *Associate Vice President - Business Strategy & Prog Mgmt, Biosimilar mAbs,* **Biocon,** India


Dr Moustapha El-Amine, *Senior Director, Scientific Services Dep. Strategic Investments Group,* **Emergent BioSolutions,** USA


Oleg Syarkevych, *Business Development Director,* **JSC Farmak,** Ukraine


Şeyda Çaşkurlu, *Director, Strategic Alliances,* **Merck,** Turkey


Leonard Ariff Abdul Shatar, *Chief Executive Officer,* **CCM Duopharma Biotech Berhad,** Malaysia


Ali Atta, *Medical, Pharmacovigilance and Compliance Manager,* **Sandoz Middle East Regional,** UAE


Richard Dicicco, *Chairman,* **HarvestMoon Pharmaceuticals,** USA

New for 2013!

- Hear new talks from **Iran, Algeria, Saudi Arabia, Malaysia, South Korea** & **India!**
- Expanded focus on **market access strategies** in these regions
- New topic on **protective national policies and their role in technology transfer**
- More interactive discussion sessions on **Selling Biosimilars in MENA** and **Global Biosimilar guidelines**

Industry's only Turkey/MENA biosimilars meeting

- Hear case studies exploring successful commercialisation **and market access strategies** from the Turkey and MENA region with updates from **Merck, Abdi Ibrahim, Jordan Pharmaceutical Association, Cinnegan, UCB, Biocon** and much more
- Discover how **the biosimilar market is rapidly growing in Southeast Asia, South Korea and India** – how can you penetrate these regions?
- Why are the US interested in the Middle East and what can we learn from **successful market penetration stories in Europe?**
- How to achieve **successful technology transfer deals** and what are the **local policies** on this?
- Join our **dedicated speed partnering session** to network with an international audience of biosimilar developers in just one venue

Hear From Your Expert Speaker Panel:

- ✔ **Dr Hasan Ersin Zeytin,** *Director, Medical Investigations,* **Nobel Pharmaceuticals,** Turkey
- ✔ **Dr Haleh Hamedifar,** *CEO,* **CinnaGen Co.,** Iran
- ✔ **Lina Emil Bajjali,** *Head of registration department,* **Jordan Food and Drug Administration,** Jordan
- ✔ **Ahcene Haddad,** *Head Manager,* **Biovital,** Algeria
- ✔ **Bulent Yildirim,** *Medical Manager,* **UCB,** Turkey
- ✔ **Prof Dongsoon Lim,** *Department of Economics,* **Dong Eui University,** South Korea
- ✔ **Zakia Kurdi,** *Licensing Director,* **JPM,** Jordan
- ✔ **Gihan Hamdy El-sisi,** *Team leader of HPA, Central Administration for Pharmaceutical Affairs,* **Ministry of Health & Population,** *Egypt*
- ✔ **Dr Steinar Madsen,** *Medical Director,* **Norwegian Medicines Agency,** Norway
- ✔ **Roman Ivanov,** *Vice President, Research & Development,* **Biocad,** Russia
- ✔ **Moutassem Sharaf,** *Managing Director,* **EMPA Middle East FZCO,** UAE
- ✔ **Sandra Frantzen,** *Intellectual Property Attorney,* **McAndrews, Held & Malloy, Ltd.,** USA

Make the most of your time out of the office with these essential training courses!

Pre-Conference Workshop: Tuesday 5th November 2013

Introduction to Biosimilars: From Development to Market

Leader: **Dr Cecil Nick,** *Vice President,* **Parexel,** UK

Evening Seminar: Wednesday 6th November 2013

Perception, Challenges and the Realities of Registering Biosimilars in the MENA region

Leaders: **Salim El Labban,** *Director, Business Development,* **BroadMed,** Lebanon
Iyad Ayoub, *Assistant Professor,* **The University of Jordan,** Jordan
and joined by **Richard Dicicco,** *Chairman,* **HarvestMoon Pharmaceuticals,** USA

Register online: www.informa-ls.com/biosimilarsmena

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PRE - CONFERENCE WORKSHOP W: TUESDAY 5TH NOVEMBER 2013

Introduction to Biosimilars: From Development to Market

Registration 11.30 – Start 12.00 – End 18.00 – Workshop material, refreshments and an evening meal will be provided

Developing a biosimilar is not a simple process but one that requires significant investment, technical capability and clinical trial expertise. Average cost estimates are extremely high and even higher when manufacturing plant development is needed. This symposium aims to identify the hurdles which the generic and pharmaceutical industries will face and how to successful implement strategies to overcome them. This workshop will help to develop an expert understanding of biosimilars including development requirements, strategies, costs, and timelines.

Specifically this workshop will cover:

- Introduction to Biosimilars: Identifying the key differences between small molecules and biologics development
- EU biosimilar experience and successful development plans to date
- Preparing your own development plan
- Define a target product profile
- Understand the market and competition?
- Who is already targeting that product? What stage of development are they in?
- Select an appropriate cell line and manufacturing platform
- Evaluate biosimilarity, and to evaluate the value of non-clinical studies
- Plan and execute clinical studies
- Apply for extrapolation of indications
- Use data from global sourced reference products
- Design a pharmacovigilance plan and post-authorisation follow-up

Dr Cecil Nick
Vice President
Parexel, UK

DAY 1: Wednesday 6th November 2013

08.00 Registration and Morning Coffee

08.55 Opening Remarks from the Chairman

Why Get Into Biotech and Biosimilars

09.00 **Keynote presentation**
Why biologics are of increasing interest to emerging markets
- Global pharma outlook
- Drivers and opportunities for pharma companies
- Increasing role of emerging markets
- Biotechnology based products
- Growing importance of biosimilars
- Future directions
- Sustainable growth for pharma or not?

Dr Ferhat Farsi, *RD and BD Director,* **Abdi Ibrahim Pharmaceuticals,** Turkey

Successful Commercialisation and Market Access Strategies in MENA & Turkey

09.35 **What is required to achieve successful market penetration in MENA: Overview analysis**
- A look at the biosimilars market in MENA & Turkey - where is now good to invest?
- How can you come to the region? How should you do it?
- What is the realistic market uptake of biosimilars in these regions?
- How to approach the payers and drivers in these regions?

Moutassem Sharaf, *Managing Director,* **EMPA Middle East FZCO,** UAE

10.10 **Speed Networking Session and Morning Coffee**

- With HIGH SPEED NETWORKING you can make more new business contacts in one session than most people will make in 6 months!
- Network with other professionals, one-on-one, a few minutes at a time working specifically in the biosimilars and biotech field
- Leave with a pocket full of business cards and numerous new business connections

Be quick, ...the clock is ticking!
Register on the morning registration

SAUDI ARABIA

11.15 **KEYNOTE PRESENTATION**
Case study: Successfully penetrating the Saudi Arabian market
- What is the potential of the Saudi Arabian Biosimilars market?
- What has been the market uptake to date?
- What is required to achieve market penetration?
- How can you successfully enter the SA market?

Ali Atta, *Medical, Pharmacovigilance and Compliance Manager,* **Sandoz Middle East Regional,** UAE

IRAN

11.50 **FEATURED PRESENTATION**
Case study: Successfully penetrating the Iranian market
- What is the potential of the Iranian Biosimilars market?
- What has been the market uptake to date?
- What is required to achieve market penetration?
- How can you successfully enter the Iranian market?

Dr Haleh Hamedifar, *CEO,* **CinnaGen Co.,** Iran

12.25 **This presentation will be given by GE Healthcare**
(please see website for further information)

12.55 Lunch and Networking Opportunities with Biological Production meeting

ALGERIA

14.00 **Case study: Successfully penetrating the Algerian market**
- What is the potential of the Algerian Biosimilars market?
- What has been the market uptake to date?
- What is required to achieve market penetration?
- How can you successfully enter the Algerian market?

Ahcene Haddad, *Head Manager,* **Biovital,** Algeria

TURKEY

14.35 **Success story from Turkey: Overcoming the guidelines and achieving market penetration**
- What were the difficulties encountered in registering biosimilars in Turkey?
- How was market penetration achieved?
- Who were the key drivers and players?

Şeyda Çaşkurlu, *Director, Strategic Alliances,* **Merck,** Turkey

15.10 **Protective national policies and their role in technology transfer**
- What are the national policies that must be considered for carrying out tech transfer?
- How do these policies impact the role of technology transfer?
- What are the best strategies to overcome these hurdles?

Zakia Kurdi, *Licensing Director,* **JPM,** Jordan

SPOTLIGHT PRESENTATION
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15.45 Afternoon Tea and Networking with Biological Production conference

16.10 **FEATURED PRESENTATION**
Case study: Why are US companies interested in the MENA region
- Why are US companies entering the MENA market?
- How to go from a regulated to a non-regulated region?
- What are the other major challenges to overcome?

Dr Moustapha El-Amine, *Senior Director, Scientific Services Dep. Strategic Investments Group,* **Emergent BioSolutions,** USA

16.45 **Case study: Lessons learned from Europe – how to achieve market access?**
- From approval to clinical use – obstacles and opportunities
- What were the lessons learned?
- Conclusions: How can we apply this knowledge in MENA

Dr Steinar Madsen, *Medical Director,* **Norwegian Medicines Agency,** Norway

How to Overcome Local Technology Transfer Barriers

17.20 **Protective national policies and their role in technology transfer**
- What are the national policies that must be considered for carrying out tech transfer?
- How do these policies impact the role of technology transfer?
- What are the best strategies to overcome these hurdles?

Zakia Kurdi, *Licensing Director,* **JPM,** Jordan

Selling Biosimilars in MENA

17.55 **Discussion Panel with session speakers: Selling Biosimilars in MENA, when, how and why?**
- What are the key take home messages from the earlier presentations?
- What are the most appropriate points to consider in entering the MENA region?
- Understanding the when, how and why of selling biosimilars in MENA

Panelists:
- **Bulent Yildirim,** *Medical Manager,* **UCB,** Turkey
- **Dr Hasan Ersin Zeytin Director,** *Medical Investigations,* **Nobel Pharmaceuticals,** Turkey
- **Richard Dicicco,** *Chairman,* **HarvestMoon Pharmaceuticals,** USA

18.15 Closing remarks from the Chair

18.20 End of conference day 1 and Networking Drinks with Biological Production Turkey Meeting

"A highly focused, intense and to the point meeting"
Caskurlu, MSD, 2012 Delegate

EVENING SEMINAR S: WEDNESDAY 6TH NOVEMBER 2013

Perception, Challenges and the Realities of Commercializing Biosimilars in the MENA region

Registration 18.30 – Start 18.45 – End 20.30 – Dinner and refreshments will be provided

The MENA region consists of diverse markets varying by their regulatory and commercial terms, but all markets have one thing in common that is: Multinational Pharma companies are legally required to have local partners, and unfortunately not all local companies have adequate experience in providing proper market access. That being said, to ensure optimal market access it is highly critical for Pharma manufacturers to have proper licensing strategies in place as well a sound knowledge in how the regulators, payers and drivers work in this region.

Specifically this workshop will cover:
- How to approach market access in these regions?
- What are the key challenges? What are the actual realities of companies that have tried to access these markets?
- Regional differentiation in disease treatment, and unmet needs
- Payer differences and the implications for pricing and reimbursement
- Outlining government requirements for local investment
- Current and future outlook for manufacturing Biosimilars in the MENA region
- Differences in data protection standards
- Realities and cultural consideration when partnering with regional (players)

Leaders:
Salim El Labban, *Director, Business Development,* **BroadMed,** Lebanon
Iyad Ayoub, *Assistant Professor,* **The University of Jordan,** Jordan and joined by
Richard Dicicco, *Chairman,* **HarvestMoon Pharmaceuticals,** USA

DAY 2: Thursday 7th November 2013

08.30 Morning Coffee

08.55 Opening remarks from the Chairman

Updated Snapshot on the Global Regulatory Pathways

09.00 **KEYNOTE PRESENTATION**
Regulatory and market overview of South East Asia with a focus on Malaysia
MALAYSIA
- What are the regulatory guidelines in the Southeast Asia?
- Overview of the biosimilar market in this region – what is the potential biosimilar uptake?
- Who are the key drivers and players in Malaysia?

Leonard Ariff Abdul Shatar, *Chief Executive Officer,* **CCM Duopharma Biotech Berhad,** Malaysia

09.35 **Biosimilar success stories from South Korea: Case studies of practical policies and experiences**
SOUTH KOREA
- Successfully manufacturing biosimilars in South Korea
- Guideline updates from the South Korean FDA and other Policy Authorities
- What are the representative and latest biosimilar products in the pipeline from South Korea
- Economic impacts of the biosimilars industry in Korea

Prof Dongsoon Lim, *Department of Economics,* **Dong Eui University,** South Korea

10.10 **FEATURED PRESENTATION**
Case study: Overcoming the hurdles and manufacturing biosimilars in India
- Successfully manufacturing biosimilars in India
- Guideline updates from the Indian biosimilar pathway
- What are the latest biosimilar products in the pipeline from India?

Paul Thomas, *Associate Vice President - Business Strategy & Prog Mgmt,* **Biosimilar mAbs Biocon,** India

10.45 Morning Tea & Networking Time with BioProduction Turkey

11.15 **FDA: Update on the biosimilar guidelines in the US**
USA
- Update on the progress of the FDA biosimilar guidelines
- Have they received their first application?
- What are the critical considerations for entering the US market in terms of law and marketing perspectives?

Sandra Frantzen, *Intellectual Property Attorney,* **McAndrews, Held & Malloy, Ltd.,** USA

11.50 **Discussion Panel with session speakers: Global biosimilar regulations**
- This will be the opportunity to ask any outstanding questions to the session speakers
- What are the key take home messages from the earlier presentations?
- What are the key comparisons between the regulatory pathways discussed?

Panellists:
Lina Emil Bajjali, *Head of registration department,* **Jordan Food and Drug Administration,** Jordan
Sandra Frantzen, *Intellectual Property Attorney,* **McAndrews, Held & Malloy, Ltd.,** USA

12.25 **SPOTLIGHT PRESENTATION**
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13.00 Lunch with the BiolProduction Turkey delegates

"The speed networking was really effective, I loved it!!"
Medac, 2012 delegate

Successful Commercialisation and Market Access Strategies in Russia & Ukraine

14.15 **Case study: Successfully manufacturing biosimilars in Russia**
RUSSIA
- Manufacturing and characterising biosimilars in Russia: technical considerations
- How to successfully carry out comparability studies
- How can you successfully enter the Russian market?

Roman Ivanov, *Vice President, Research & Development,* **Biocad,** Russia

14.50 **Biosimilars in the Ukraine: current market and regulatory environment**
UKRAINE
- Update on the regulatory guidelines in the Ukraine
- What is the potential of the Ukraine Biosimilars market?
- What has been the market uptake to date?
- What is required to achieve market penetration?

Oleg Syarkevych, *Business Development Director,* **JSC Farmak,** Ukraine

15.25 Afternoon Tea

Pricing and Reimbursement in Turkey and MENA

15.45 **Success story in health economics: best practice from Egypt**
EGYPT
- Exploring reimbursement and coverage decisions in MENA
- What is required for local authorities to reimburse your product?
- What are the government incentives currently in place?

Gihan Hamdy El-sisi, *Team leader of HPA, Central Administration for Pharmaceutical Affairs,* **Ministry of Health & Population,** Egypt

Originator Positioning on Biosimilars

16.20 **Case Study: Originator positioning on Biosimilars**
- What is the authorised biosimilar and how may it impact these regions?
- What strategies have been employed to date to counteract biosimilars?
- Have they been successful?

Richard Dicicco, *Chairman,* **HarvestMoon Pharmaceuticals,** USA

16.55 Summary notes and Closing Remarks from the Chair

17.00 End of Conference Day 2

"An excellent opportunity to establish a network amongst companies developing biosimlars in Turkey, MENA and Russia"
Attendee 2012, *Business Development Expert,* **Menarini Biotech**

Meet the Key Players Driving the Turkey/MENA Biotech Industry Forward

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Reasons why you should choose this event:
- Promote your services to key regulatory and industry leaders from the biosimilar community in these new rapidly expanding markets.
- Educate the market and regulators on the benefits of your new technology
- Co-located with **Biotechnology Production in MENA & Pharmaceutical Law in Turkey & MENA** - Network and partner with 3 markets at the same time

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Conference	**CQ3504C**
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❑ Pre-Conference Workshop W: Introduction to Biosimilars: From Development to Market

❑ Evening Seminar X: Perception, challenges and the realities of commercializing Biosimilars in the MENA region

Select your pass:	Code	Book before Friday 16th August 2013	SAVE	Book between Friday 16th August 2013 & Friday 4th October 2013	SAVE	Book after Friday 4th October 2013	SAVE
2 Day Pass: Conference Only	CQ3504C	£1299	£200	£1399	£100	£1499	
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