MHRA to present keynote address on UK regulator’s experience of PV and RMP for biosimilars | Biosimilars and Biobetters

This year's conference will address regulatory updates, pharmacovigilance of biosimilars, patent litigation, market access and EU & global market developments.

LONDON, ENGLAND, UNITED KINGDOM, May 19, 2015 /EINPresswire.com/ -- Several new high strength fixed combination and biosimilar insulin products are now on the market and draft guidance has been published which summarises ways to minimise the risk of medication errors. Further such insulin products will come to market over the next few years, as such the Medicines and Healthcare Products Regulatory Agency (MHRA) are encouraging those applicable to comment on the risk minimisation strategy for high strength and fixed combination insulin products, which is being developed by the European Medicines Agency (EMA).
(Source: 'High strength, fixed combination and biosimilar insulin products: minimising the risk of medication error', Medicines and Healthcare Products Regulatory Agency, 29 April 2015)

Against this backdrop, SMi's 6th annual Biosimilars and Biobetters conference, taking place on 30 September - 1 October 2015 in London, will feature the MHRA's Senior Scientific Assessor, Shahin Kauser presenting on Day Two: "UK regulator’s experience of PV and RMP for biosimilars". She will be discussing the following topics:
• What’s new in the overarching biosimilar guideline regarding pharmacovigilance?
• How traceable are ADRs for biosimilars reported to the UK Pharmacovigilance database?
• What types of post authorisation studies (e.g. registries) are requested?
• What other enhanced pharmacovigilance activities may be necessary?
• What types of additional risk minimisation measures may be necessary?

The two-day conference programme also features senior industry decision makers who are pioneering the way in biosimilars and biobetters with companies present including GfK, Teva, Harvest Moon Pharmaceuticals USA, as they share the latest developments on key areas including regulatory landscape, pharmacovigilance of biosimilars, patent litigation, market access and EU & global market developments.

Speaker Panel includes:
• Richard DiCicco, Chairman, Harvest Moon Pharmaceuticals USA, Inc
• Shahin Kauser, Senior Scientific Assessor, MHRA
• Chris Teale, Vice President Europe, GfK NOP Ltd
• Bracha Timan, Director, Israel Site Head, Global Bioassays & Technology, Global R&D, Teva
• Takashi Kei Kishimoto, Chief Scientific Officer, Selecta Biosciences
• Karsten Roth, Director Clinical Operations, Cinfa Biotech GmbH
• Alan Sheppard, Principal, Global Generics and Biosimilars, IMS Health

• Steinar Madsen, Medical Director, Norwegian Medicines Agency

To view the full speaker line-up and complete conference agenda, visit http://www.biosimilars-biobetters.co.uk/einpresswire

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