



The theme of our third TOPRA Annual Medical Technologies Symposium addressed the question, 'Continual regulatory change: are we equipped for the challenge?', with four sessions providing a comprehensive forum for ongoing discussions

The 3rd TOPRA Annual **Medical Technologies Symposium** 2008

Reviewed by Karen Brown (Ciba Vision, UK), John Deavin (Deavin Associates, UK), Angela M Miller (Esai Ltd, UK), Amanda Spencer (MeddiQuest Ltd, UK)

Session 1: Medical Device Directive revisions and the consequences – how are they working in practice?

This opening session looked at the revisions to the Medical Device Directive (MDD) introduced in 2007, and considered whether the proposed recast announced this year was appropriate. The speakers for this session were **John Andrews (LRQA Ltd)**, **Anne O'Connor (Irish Medicines Board, Eire)** and **Roger Gray (Donawa Consulting)**, representing the Notified Body perspective, the Health Authority perspective and the Company perspective. As speaker for the Notified Body, John Andrews gave an overview of the revisions and provided background to the revision process, offering clarification to areas such as clinical evaluation and the new requirements for phthalates labelling. As Health Authority speaker, Anne O'Connor looked more closely at the borderlines with other legislation, software and classification anomalies as well as considering whether national authorities or the EMEA should be involved in the evaluation of drug-device combinations. She also explained the background into the revision of the New Approach before considering the recast of the MDD, concluding that the recast was believed to be premature. Roger Gray, representing industry's viewpoint, gave a thorough overview of the changes, indicating the impact and consequences seen in the industry following the revision. The MDD changes are due to come into effect in March 2010, but from an industry standpoint the areas which manufacturers need to be considering now are changes to the authorised representative, single use devices, ergonomic requirements, class IIa device registration, reclassification, clinical evaluation and the need for clinical investigations.

Session 2: Medical device vigilance – development and impact

The vigilance session covered the development and impact of medical device vigilance (MEDDEV) from the view of the Regulator, the Notified Body and Industry. These areas were covered by **Anne Tobin (Irish Medicines Board)**, **Neil Adams (BSI Product Services, UK)** and **Marianne van Maarschalkerweerd (ex-Sanofi Aventis, Germany)** respectively.

As the regulatory representative, Anne Tobin opened the session by discussing the reasons for the amendments to the MEDDEV. This was followed by an outline of the responsibilities of relevant parties involved in vigilance, and it was pointed out that cooperation is essential between all parties to ensure compliance. It was highlighted that more clarity is required on when incidents and FSCA should be reported and on the role of the coordinating competent authority.



The discussion was lively and challenging, with questions from the audience on problem products such as ophthalmics and injectables

The Notified Body speaker, Neil Adams, advised that there is a potential for incidents not to be reported to the notified body since the MDD requires the manufacturer to notify the competent authorities of adverse incidents but not the Notified Bodies. However the MEDDEV gives guidance on the manufacturer advising the Notified Body of post-market issues that could affect certification.

The industry speaker, Marianne van Maarschalkwerd, talked about the manufacturer's role in beginning the investigation, carrying out any corrective action and ensuring a good network and open communication is maintained with the Authorities.

Overall, the general feeling was that further clarity is needed on a number of issues in the MEDDEV, and that we must continue to learn from each other through open communication.

Session 3: Combination products and the drug-device interface – current and future challenges

Session 3 considered the regulatory challenges facing manufacturers and regulators in determining the regulatory strategy for combination products and also in deciding whether a healthcare product should be regulated as a medicine or a medical device.

The speakers for this session were **John Deavin (Deavin Associates)**, **Sharon Frank (Cordis division of Johnson & Johnson Medical Belgium**, previously with the European Commission) and **Geoff Fatzinger (ICON UK)**.

John Deavin gave an introductory critique on the legal definitions of medicinal product and medical device, highlighting the difficulties in deciding whether a healthcare product should be regulated as medicine or device.

Sharon Frank examined the EU regulatory environment for combination products by considering how combination products are regulated at community level, and a review of the changes introduced by the revised medical device directive 2007/47. She reviewed different types of combination products including active implantables and advanced therapy medicinal products.

Geoff Fatzinger considered combination products from an industry perspective and in particular the problems and pitfalls. He questioned why they are challenging, how they can be complicated or simple, setting new standards of requirements, why regulations may not cover the product, and how knowledge in both agencies and industry is in its infancy. He recommended that companies meet with agencies and be prepared to defend their product.

The discussion was lively and challenging, with questions from the audience on problem products such as ophthalmics and injectables. It was clear there is still a lack of understanding within the industry on what constitutes a medical device or medicinal product, despite all the guidelines.

Session 4: The international update

International developments were discussed in respect of the Global Harmonization Task Force, Global Medical Device Nomenclature, Japan and the US.

The speakers for this session were **Neil Armstrong (MeddiQuest)** and **Geoff Fatzinger (ICON UK)**.

Neil Armstrong, chairing the session, opened it by examining the background of the Global Harmonization Task Force, its achievements to date, the documents in progress and the new challenges posed by the development of global trade. This part of the session concluded with Neil giving a short review of the Global Medical Device Nomenclature and the need for a Unique Device Identifier.

Geoff Fatzinger looked at the changes that are continuing to occur within the Japanese regulatory system, noting how the number of reviewers is to be increased, as the User Fees are likely to be. This was followed by a discussion on the regulatory landscape and country perspective.

Neil then ended the session with a US update, considering the pressure on the FDA, inspection initiatives and submissions, as well as new general- and product-specific guidance notes.

The session was lively and humorous throughout.