

THE BORDERLINE BETWEEN MEDICINES AND FOODS

12 December 2014, Conf. No. A12-4314



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Registration Information

Dates
12 December 2014
Start: 09.30 – Finish: 16.45

Registration & Coffee
12 December 2014 09.00

Venue and Accommodation
The Rembrandt Hotel, 11 Thurlow Place,
London SW7 2RS
Hotel Tel: +44(0)20 7589 8100
Hotel Fax: +44(0)20 7225 3476
Email: reservations-rembrandt@sarova.co.uk
Subject to availability, a limited number of bedrooms have been reserved at the hotel at a special rate.

All bookings should be made directly with the hotel or online at www.sarova.com/rembrandt quoting promo code 'manforum'.

Directions
Opposite V&A Museum. Nearest underground station: South Kensington.
www.sarova-rembrandthotel.com/location-local-attractions

Fee
£575 + VAT if applicable. The fee includes course documentation as well as mid-session refreshments and lunch. Invoice and confirmation will be forwarded to you.

Conference No. A12-4314

Discounted Rates
Available on application for personnel from non-profit making organisations and registered charities.
Group discount available on request

Cancellation Policy:
Over 14 days prior to the Seminar: Cancellation fee of £75. 7/14 days prior to the Seminar: 50% of the fee. Fewer than 7 days or if no notification received: Registrant liable to pay FULL seminar fee.
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THE BORDERLINE BETWEEN MEDICINES AND FOODS



Topics to be covered at this seminar:

- Where is the Borderline and on which Side does my Product Fit?
- Complying with Medicines Legislation and the Traditional Herbal Medicinal Products Directive
- Understanding and Working with Legislation on Nutrition and Health Claims for Foods
- Health Claims in Europe: Implications for Marketing and Research and Development Strategies
- Borderline Products – Practical Issues of Labelling and Advertising
- EU Borderline Law – Key Aspects

Chair

Penny Viner Vice President, Health Food Manufacturers Association (HFMA)

Speakers

Dr Chris Jones Manager, Borderlines Section, MHRA

Gwyneth Massey Health Food Manufacturers Association (HFMA)

Professor David Richardson DPR Nutrition

Brian Kelly Covington and Burling LLP

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12 December 2014
The Rembrandt Hotel, London

INTRODUCTION

Medicines treat, cure or prevent illness. Foods provide nutrition. But are the distinctions so clear? Foods also have a physiological effect and a role in disease risk reduction - and substances whose purpose is nutritional may be presented as medicines. An understanding of where the borderline lies between medicines and foods is essential for the successful marketing of specialist health products; getting it wrong is a costly route to market failure. However, the regulatory framework is detailed and complex, requiring a knowledge of the relevant legislation. By addressing these topics, this seminar aims to assist delegates to an understanding of how the borderline may be defined and how best to tailor the presentation of their products to the regulatory structure appropriate to them.

CHAIR

Penny Viner - After initial careers in teaching and industry, (manufacturing natural medicines and cosmetics), from 1996 - 2003 Penny was Director of HFMA and remains its Vice-President. Currently, she consults on food/medicine regulation, chairs the UK Herbal Forum of herbal medicine associations, is Director/Secretary of the British Association of Homoeopathic Manufacturers, Director/ Secretary of the European Food Law Association (UK), a Project manager for the International Alliance of Dietary/ Food Supplement Associations (IADSA) (writing its monthly 'Newsflash' and co-ordinating its Scientific Group) and is a botanicals expert for the European Botanical Forum.

SPEAKERS

Dr Chris Jones is the Manager of the Medicines Borderline Section at the MHRA. The Section is responsible for determining the medicinal status of any product that contains a pharmacologically active substance or makes medicinal claims (claims to treat or prevent disease, or to interfere with the normal operation of a physiological function of the human body are regarded as medicinal). Chris has a PhD in microbiology and, prior to joining the MHRA, worked at the Food Standards Agency in the area of food innovation, specifically on the regulation and safety assessment of novel food ingredients.

SPEAKERS

David P. Richardson BSc MSc PhD FIFST FRSM RNutr (DPR Nutrition Limited) provides scientific and regulatory advice to trade associations, food and food supplement manufacturers and regulatory authorities worldwide. He is Visiting Professor at the Universities of Newcastle and Reading. He began his teaching and research activities at the University of London and the Massachusetts Institute of Technology and then embarked on an industrial career, which included his position as Group Chief Scientist at Nestlé UK Ltd. He has an active role in projects such as the scientific substantiation of health claims (PASSCLAIM author), the health benefits of cereal grains (HEALTHGRAIN partner) and BRAFO (nutritional benefit-risk analysis).

Gwyneth Massey is a Chartered Biologist and a Member of the Society of Biology. Having graduated from University College, Cardiff with an honours degree in Biochemistry, she spent several years as a Biochemist at the Royal Free Hospital, London, researching into various aspects of Haemophilia. For the last 18 years she has been a Code Administrator with the Health Food Manufacturers Association (HFMA) providing comprehensive advice on all aspects of the labelling and advertising of food, cosmetic and medicinal products within the UK

Brian Kelly is an Associate in the London Life Sciences group at Covington and Burling LLP, whose practice focuses on food and drug law, public and administrative proceedings, internal investigations, European Union law and product liability and safety. Mr Kelly's advice on general regulatory matters includes borderline determinations, tissue and stem cell regulation, adverse event and other reporting obligations, manufacturing controls, labelling and promotion, pricing and reimbursement/procurement, product life cycle management and anti-bribery and corruption advice. He has also advised on EU and national laws governing clinical research, data protection, the regulatory status of borderline products, regulatory aspects of mergers and acquisitions, licensing, and collaborative arrangements. He is an honorary lecturer at University College London.

Programme

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|-------|---|---|
| 09.30 | ▶ | Chairman's Welcome and Introduction |
| 09.35 | ▶ | Where is the Borderline? <ul style="list-style-type: none">• Why do borderlines matter and how do they affect my products?• Medicines Legislation and the Traditional Herbal Medicinal Products Directive• Food Legislation, the Regulation on Nutrition and Health Claims for Foods• National Lists; the Mutual Recognition Procedure Penny Viner, HFMA |
| 10.30 | ▶ | Health Claims in Europe: Implications for Marketing and Research and Development Strategies <ul style="list-style-type: none">• The European laws on nutrition and health claims - scope, provisions, global impact• The scientific substantiation of health claims including PASSCLAIM• Role of the European Food Safety Authority (EFSA)• Impact on existing and new product claims, formulations and recipes, commercial communications and product development and innovation Professor David P. Richardson, DPR Nutrition Ltd |
| 11.30 | ▶ | Coffee |
| 11.50 | ▶ | The Borderline: Food for Thought
Dr Chris Jones, MHRA |
| 12.45 | ▶ | Lunch |
| 14.00 | ▶ | EU Borderline Law on Medicines and Foods <ul style="list-style-type: none">• Background to health claims on foods• Primary legislative framework<ul style="list-style-type: none">- EU Regulation (EC) No 1924/2006• The Permitted List Regulation<ul style="list-style-type: none">- EU Regulation (EU) No 432/2012• EU case law on health claims and the borderlines<ul style="list-style-type: none">- HFMA and others v European Commission- Medicines borderline case law Brian Kelly, Covington & Burling |
| 14.45 | ▶ | Discussion |
| 15.00 | ▶ | Tea |
| 15.20 | ▶ | Borderline Products – Practical Considerations <ul style="list-style-type: none">• Food or medicine – how do I decide?• Labelling – how do I label my product?• Advertising – what claims can I make?• Consumer promotions – what is acceptable? Gwyneth Massey, HFMA |
| 16.15 | ▶ | Final Discussion |
| 16.45 | ▶ | End of Seminar |

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