



The Review Panel

Annual Report 2014

Medicines & Healthcare products Regulatory Agency

The Review Panel

Annual Report 2014

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FOREWORD FROM THE CHAIRMAN OF THE MHRA

It gives me great pleasure to present the 2014 Annual Report of the Review Panel.

This appeal panel has been established to hear the views of those applicants and licence holders who disagree with a decision made by the Licensing Authority where legislation provides for a review. It is set up to operate in such a way as is considered necessary to ensure the fairness of the review and, as with the work of all our advisory bodies, the Review Panel aims to ensure that medicines meet the appropriate standards of safety, quality and efficacy in compliance with the legislative framework under which the Licensing Authority operates.

Although the panel has not met in 2014, I would like to thank the Chair, Neil Mercer, and all the Review Panel Members for their continued willingness to serve on the panel, and their commitment to the public service to ensure that the medicines we take continue to be of appropriate standards of safety, quality and efficacy.

Professor Sir Michael Rawlins
MHRA Chairman

THE REVIEW PANEL ANNUAL REPORT 2014

1. INTRODUCTION

1.1 The Review Panel was created on 1st November 2012. It performs the functions undertaken before that date by:

- the Independent Review Panel on the Advertising of Medicines (IRPAM)
- the Independent Review Panel on the Classification of Borderline Products (IRPCBP)
- the Regulation of Medicines Review Panel.

1.2 The panel performs statutory and non-statutory reviews of proposals, decisions and provisional decisions taken by the MHRA on behalf of the Licensing Authority or Ministers where legislation provides an applicant or Marketing Authorisation Holder with the opportunity to review upon representation.

2. THE REVIEW PANEL'S ROLE AND TERM OF REFERENCE

2.2 Legislation provides that an applicant who disagrees with a proposal or decision of the Licensing Authority may choose to make a representation about the proposal or decision by submitting a request for a review of the proposal

2.3 The Licensing Authority is required to appoint a panel to conduct the review and the Review Panel is in place to fulfil this function.

2.4 The Review Panel's terms of reference are:

- to perform the functions of "the reviewers" under regulations 162 and 163 of the Human Medicines Regulations 2012 (the Regulations) in relation to provisional determinations made by the MHRA, on behalf of the Licensing Authority, that a product is a medicinal product under regulation 159 of the Regulations
- to perform the functions of "the reviewers" under Schedule 5 to the Regulations in relation to decisions or proposals of the MHRA, taken on behalf of the Licensing Authority, to (a) suspend, vary or revoke a manufacturer's or wholesale dealing licence under regulation 26 of the Regulations; (b) to grant, refuse, renew, revoke, vary or suspend a UK marketing authorisation, certificate of registration or traditional herbal under paragraphs 10 or 12 of Schedule 11 to the Regulations; (c) to refuse or grant in terms outside the terms of application a variation application under paragraph 22 of Schedule 11 to the Regulations; and (d) to refer an applicant to the Committee on Herbal Medicinal Products under paragraph 29 of Schedule 11 to the Regulations

- to consider any written and/or oral representations made by a person or body notified under regulation 305 of the Regulations that the MHRA are minded to make a determination that their advertisement is incompatible with the prohibitions; and/or to advise the Ministers prior to their making a final determination under regulation 306 of the Regulations.

3. CHAIRMAN AND MEMBERS

3.1 A list of the Panel's membership is at **Appendix I**.

3.2 The Secretariat is based at the Medicines & Healthcare products Regulatory Agency (MHRA). A list of the secretariat is at **Appendix II**.

4. MEETINGS

4.1. The Panel did not meet in 2014.

5. COSTS

5.1 Members are entitled to claim an attendance fee of £200 per day (Chairman's fee £325). Travel and subsistence is also payable within Department of Health guidelines.

MEMBERSHIP OF THE REVIEW PANEL

Chair

Mr Neil Mercer LL.B. (Hons) B.A. (Hons)
Practising Barrister, Thomas Bingham Chambers, London

Members

Professor Peter Aggett OBE MSc FRCPCH FRCP
Emeritus Professor of Child Health and Nutrition

Mrs Elizabeth Bamford¹ MRPhS
Former Director of Regulatory, Medical & Consumer Affairs, GlaxoSmithKline
Healthcare UK

Mr Michael Carroll BSc (Hons) MBA CSci CChem FRSC MIQA
Non-Executive Director, Health Protection Agency

Mr Richard Crossley² LLB
Non-Executive Director, Fundraising Standards Board

Mrs Pamela Goldberg OBE
Independent Consultant

Professor Nicola Robinson BSc (Hons) PhD DipHE LicAc
Professor of Traditional Chinese Medicine (TCM) and Integrated Health, Faculty of
Health and Social Care, London South Bank University

Dr Marion Sommerville³ PhD R.D.
Registered Dietitian; Member of the British Dietetic Association and Registered with the
Health Professions Council

Dr Jayne Spink BSc PhD
Chief Executive of the Tuberous Sclerosis Association

Dr Stephen Waring PhD FRCP
Consultant Physician in Acute Medicine and Clinical Toxicology, York Hospital;
Honorary Senior Lecturer Hull York Medical School

Dr David Webster
Retired Business Consultant; Non-Executive Director of Compass, former Non-
Executive Director of East Riding NHS Primary Care Trust and Managing Director of
Smith and Nephew Healthcare

Dr Brian Whittle⁴ BPharm MSc PhD
Consultant in Pharmaceutical Development, Nutraceuticals Ltd

¹ Re-appointed 01 February 2014 – 31 January 2018

² Re-appointed 01 February 2014 – 31 January 2018

³ Re-appointed 01 February 2014 – 31 January 2018

⁴ Re-appointed 01 February 2014 – 31 January 2018

MEMBERS OF THE PANEL'S ADMINISTRATIVE SECRETARIAT

Administrative support to the Panel is provided by a Secretariat made up from MHRA staff. They are selected on a case by case basis to ensure they have at no time been involved with any of the processes or any decision-making connected with an application being considered for review.

Mr R Fraser
Unit Manager

Ms E Paik
Secretary

REVIEW PANEL: MEMBERS HAVE DECLARED CURRENT PERSONAL AND NON-PERSONAL INTERESTS IN THE PHARMACEUTICAL INDUSTRY AS FOLLOWS:

MEMBER	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
	NAME OF COMPANY	NATURE OF INTERESTS	NAME OF COMPANY	NATURE OF INTERESTS	WHETHER CURRENT	ADDITIONAL INFORMATION
Mr Neil Mercer	None	None	None	None	No	None
Professor Peter Aggett	Pfizer Consumer Products: Probiotic Advisory Board New Zealand Dairy Goat Co-operative: Scientific Advisory Panel	Consultant to advise on design of and conduct of clinical trials of pre and probiotics Scientific Panel discontinued March 2014. Lecture on Causal Inference and Health Claims relating to nutritional and safety evaluation of Breast Milk Substitutes	None	None	No	None
	Dept of Health: Scientific Advisory Committee on Nutrition & Subgroup on Maternal & Child Nutrition	Vice Chair of Advisory Committee				
	Food Standards Agency: Committee on Toxicity	Co-opted from SACN/SMCH; Chair of Data Monitoring Committee for a clinical trial				

MEMBER	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			ADDITIONAL INFORMATION
	NAME OF COMPANY	NATURE OF INTERESTS	NAME OF COMPANY	NATURE OF INTERESTS	WHETHER CURRENT	
	European Food Safety Authority	External Expert for Working Groups on GMOs and on Dietary Reference values for minerals				
Mrs Elizabeth Bamford	GlaxoSmithKline	Shares and pension	None	None	No	None
	Pfizer	Shares (very small holding)				
Mr Michael Carroll	None	None	None	None	No	None
Mr Richard Crossley	None	None	None	None	No	None
Mrs Pamela Goldberg	None	None	None	None	No	An immediate family member works for Actelion in Basel, Switzerland and another works for Novartis in Basel, Switzerland.
Professor Nicola Robinson	None	None	None	None	No	None
Dr Marion Sommerville	CIGNA Healthcare Insurance Company	Consultancy	None	None	No	None
Dr Jayne Spink	None	None	Novartis	Everolimus - Educational Grants awarded to the Tuberous Sclerosis Association during current financial year (2013/14)	Yes	None
Dr Stephen Waring						

MEMBER	PERSONAL INTERESTS		NON-PERSONAL INTERESTS		WHETHER CURRENT	ADDITIONAL INFORMATION
	NAME OF COMPANY	NATURE OF INTERESTS	NAME OF COMPANY	NATURE OF INTERESTS		
Dr David Webster	Smith & Nephew Plc	Shares, medical insurance benefit, Pension Fund Trustee	None	None	No	An immediate family member owns shares in Smith & Nephew and is a beneficiary of my medical insurance provided by the company.
Dr Brian Whittle	G W Pharmaceuticals PLC Phynova Ltd Omedica 3 Ltd Encap Nutrition Ltd Nutraceuticals Ltd	Sativex ® Shareholder, Consultant Shareholder, Consultant Shareholder, Director Shareholder Shareholder, Director	None	None	No	None



Contact for information about this report:

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