



The Review Panel

Annual Report 2015

Medicines & Healthcare products Regulatory Agency

The Review Panel

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FOREWORD BY PROFESSOR SIR MICHAEL RAWLINS, CHAIRMAN OF THE MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

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

The purpose of this body is to hear representations, where legislation allows, from those applicants and licence holders who disagree with a decision made by the MHRA. It is able to operate in such way as it considers necessary to ensure fairness and, as with the work of all our advisory bodies, the Review Panel aims to meet the highest standards.

I would like to thank the Chair, Neil Mercer, and all the Review Panel Members for making their professional expertise available for a public service role that ensures the medicines we take continue to be safe.

Professor Sir Michael Rawlins
MHRA Chairman

THE REVIEW PANEL ANNUAL REPORT 2015

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 2015.

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 Bamford MRPhS
Former Director of Regulatory, Medical & Consumer Affairs, GlaxoSmithKline
Healthcare UK

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

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

Mrs Pamela Goldberg OBE FRSA
Past Master, Needlemakers
Membership Secretary, Lady Masters Association

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

Dr Marion Sommerville¹ 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 Whittle BPharm MSc PhD
Consultant in Pharmaceutical Development

¹ Stepped down 30 December 2015

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

Mr F Huckle
Secretary

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

MEMBER	PERSONAL INTERESTS		NON-PERSONAL INTERESTS		WHETHER CURRENT	ADDITIONAL INFORMATION
	NAME OF COMPANY	NATURE OF INTERESTS	NAME OF COMPANY	NATURE OF INTERESTS		
Mr Neil Mercer	None	None	None	None	No	None
Professor Peter J Aggett	Scientific Advisory Committee on Nutrition Food Standards Agency	Vice-Chair of Advisory Committee COT: co-opted member from SACN. Chair of Data Monitoring Committee for a clinical trial	None	None	No	Member of the Labour Party
	Royal College of Physicians London European Food Safety Authority	Chair of Nutrition Committee Member of Working Groups on Copper content of animal feed; Nutrition and Toxicology of GMOs, and on Dietary Reference Values				
Mrs Elizabeth Bamford	GlaxoSmithKline plc	Shares, Pension	None	None	No	None
Mr Michael Carroll	Pfizer	Shares				
Mr Richard Crossley	None	None	None	None	No	None
Mrs Pamela Goldberg	None	None	None	None	No	My daughter works for Novartis in Basel, Switzerland. My son-in-law works for Actelion in Basel, Switzerland

MEMBER	PERSONAL INTERESTS			NON-PERSONAL INTERESTS			WHETHER CURRENT	ADDITIONAL INFORMATION
	NAME OF COMPANY	NATURE OF INTERESTS		NAME OF COMPANY	NATURE OF INTERESTS			
Professor Nicola Robinson	None	None		None	None		No	None
Dr Jayne Spink	None	None		Novartis	Everolimus - Educational grants totaling £31,629		No	None
Dr William Stephen Waring	None	None		GW Pharma	Epidiolex - Conference Sponsorship £5,000		No	None
Dr Marion Sommerville	None	None		None	None		No	None
Dr David Fitzgerald Webster	Smith & Nephew Plc	Shares, Medical Insurance benefit, Pension Fund Trustee		None	None		No	My wife owns shares in Smith & Nephew and is a beneficiary of my medical insurance provided by the company.
Dr Brian A Whittle	GW pharmaceuticals plc Phynova Ltd Nutraceuticals Ltd	Sativex - Shareholder, consultant Shareholder, consultant Shareholder, director						



Contact for information about this report:

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