



The Review Panel

Annual Report 2018

Medicines and Healthcare Products Regulatory Agency

The Review Panel

Annual Report 2018

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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

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INTRODUCTION

1. The Review Panel was established 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.
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.

THE REVIEW PANEL'S ROLE AND TERM OF REFERENCE

3. 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
4. The Licensing Authority is required to appoint a panel to conduct the review and the Review Panel is in place to fulfil this function.
5. The Review Panel's terms of reference are:
 - a) 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
 - b) 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, 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

CHAIRMAN AND MEMBERS

6. A list of the Panel's membership is at Appendix I.
7. The Secretariat is based at the Medicines and Healthcare products Regulatory Agency (MHRA). Contact details are provided in Appendix II.

MEETINGS

8. The Panel did not meet in 2018.

COSTS

9. Members are entitled to claim an attendance fee of £200 per day (Chairman's fee £325). Travel and subsistence are also payable within Department of Health and Social Care 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 Jayne Spink BSc PhD
Chief Executive of the Tuberous Sclerosis Association

Dr W. Stephen Waring PhD FBPharmS FRCP
Consultant Physician in Acute Medicine and Clinical Toxicology, York Teaching Hospitals NHS Trust; 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 A Whittle¹ BPharm MSc PhD
Consultant in Pharmaceutical Development

¹ Passed away May 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.

Ms L Gear
Unit Manager

Ms M Guler
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 Professor Peter Aggett	Doh/Phe: Scientific Advisory Committee on Nutrition Food Standards Agency: Committee on Toxicity Royal College of Physicians London European Food Safety Authority; Nda Panel. Working Group Member. European Food Safety Authority; Member Of	Vice- chair of scientific advisory committee Cot: co-opted member from sacn/smcn. Chair of nutrition committee Working group on dietary reference vales; minerals Review of approved additives and appraisal of new substances. Member of a working	None	None		None

MEMBER	PERSONAL INTERESTS		NON-PERSONAL INTERESTS		WHETHER CURRENT	ADDITIONAL INFORMATION
	NAME OF COMPANY	NATURE OF INTERESTS	NAME OF COMPANY	NATURE OF INTERESTS		
	Panel On Additives And Nutrient Sources Added To Food.	group on phosphates and one on applying risk assessments to infants under 12 weeks of age.				
	European And Developing Countries Clinical Trials Partnership (Edctp)	Member of panel on research ethics and governance. Review of protocols for and conduct of collaborative research between European centres and developing countries into management of infectious diseases.				
	American Heart Association & Ilsi North America	Discussion of the risk analysis of substituting sodium-based food additives with potassium based additives				
Mrs Elizabeth Bamford	GLAXOSMIT HKLINE PLC PFIZER PLC	Pension Share Holding Share Holding (Very Small)	None	None		None
Mr Michael Carroll	None	None	None	None		None
Mr Richard Crossley	None	None	None	None		None

MEMBER	PERSONAL INTERESTS		NON-PERSONAL INTERESTS		WHETHER CURRENT	ADDITIONAL INFORMATION
	NAME OF COMPANY	NATURE OF INTERESTS	NAME OF COMPANY	NATURE OF INTERESTS		
Mrs Pamela Goldberg	None	None	None	None		None
Professor Nicola Robinson	None	None	None	None		None
Dr Jayne Spink	None	None	Actelion Pharmaceuticals AKCEA Alexion Amicus Amryt Bio Marin Bio Products Laboratory Biogen Bluebird Bio Chiesi Congenica EGAN Pharmaceuticals Illumina IPSEN IQUVIA Kyowa Kirin Ltd Leadiant Biosciences Ltd. Medical Research Network Medopad MiRagen Novartis Orchard	GRANTS AND PROJECT SPONSORSHIP - pooled funding	Yes	Details of all funding is published in our annual reports and statutory accounts which can be downloaded from the Charity Commission website.

MEMBER	PERSONAL INTERESTS		NON-PERSONAL INTERESTS		WHETHER CURRENT	ADDITIONAL INFORMATION
	NAME OF COMPANY	NATURE OF INTERESTS	NAME OF COMPANY	NATURE OF INTERESTS		
			Perkin Elmer Pfizer PTC Therapeutics Roche Sanofi Genzyme Sarapeta Santhera Shire SOBI SPARK Therapeutics UCB Vertex			
Dr W. Stephen Waring	None	None	None	None		None
Dr David Webster	Smith & Nephew plc	Shares, Medical Insurance benefit, Pension Trustee	None	None		My wife owns shares in Smith & Nephew and is a beneficiary of my medical insurance provided by the company.



**Contact for information about this report:
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Medicines & Healthcare products Regulatory Agency
10 S Colonnade, Canary Wharf, London E14 4PU**

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