



The Review Panel

Annual Report 2019

Medicines and 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 license holders who disagree with a decision made by the MHRA. It is able to operate in such a 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 Panels Members for making their professional expertise available for all public service role that ensures the medicines we take continue to be safe.

**Professor Sir Michael Rawlins
MHRA Chairman**

THE REVIEW PANEL ANNUAL REPORT 2019

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 2019.

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, Needleworkers
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

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 Lorraine Gear
Unit Manager

Mrs Munise 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			ADDITIONAL INFORMATION
	NAME OF COMPANY	NATURE OF INTERESTS	NAME OF COMPANY	NATURE OF INTERESTS	WHETHER CURRENT	
Mr Neil Mercer	None	None	None	None	No	None
Professor Peter Aggett	Department of Health/Public Health England: Scientific Advisory Committee on Nutrition	Vice Chair of Scientific Advisory Committee	None	None	Yes	None
	Food Standards Agency: Committee on Toxicity	Co-opted liaison from Scientific Advisory Committee on Nutrition, and its subgroup on maternal and child nutrition				
	Royal College of Physicians London	Chair of Nutrition Committee				
	European Food Safety Authority: NDA Panel working group	Working group on dietary reference values: minerals. Assessment of uncertainty factors to apply to assessed Upper Level for copper				
	European Food Safety Authority: member of	Review of approved additives and				

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	appraisal of new substances. Member of the working group on phosphates				
	European Food Safety Authority: Scientific Committee: working group	Review of approaches to determination of Health Based Guidance Values for Nutrients				
	European And Developing Countries Clinical Trials Partnership	Member of panel reviewing research ethics and governance of protocols for conduct of collaborative research between European centres and developing countries. The principal focus is on sub-Saharan Africa and infectious diseases.				
Mrs Elizabeth Bamford	GlaxoSmithKline PLC	Pension, Share holding	None	None	Yes	None
	Pfizer PLC	Share holding (very small)				
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	None

MEMBER	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			ADDITIONAL INFORMATION
	NAME OF COMPANY	NATURE OF INTERESTS	NAME OF COMPANY	NATURE OF INTERESTS	WHETHER CURRENT	
Professor Nicola Robinson	None	None	None	None	No	None
Dr Jayne Spink	None	None	Actelion Pharmaceuticals UK Ltd/Janssen	None	No	None
			Aegerion Pharmaceuticals	Grant/Sponsorship		
			AKCEA Therapeutics UK Ltd	Grant/Sponsorship		
			Alexion Services Europe	Grant/Sponsorship		
			Amicus Therapeutics	Grant/Sponsorship		
			Avexis	Grant/Sponsorship		
			Bio Marin	Grant/Sponsorship		
			Biogen	Grant/Sponsorship		
			Bionical Limited	Grant/Sponsorship		
			Bluebird Bio	Grant/Sponsorship		
			Chiesi Limited	Grant/Sponsorship		
			Kyowa Kirin Ltd	Grant/Sponsorship		
			Illumina	Expenses to enable patient advocates to attend patient summit on genomics		
			Lupin Pharmaceuticals	Grant/Sponsorship		
			Novartis Pharmaceuticals UK Ltd	Grant/Sponsorship		

MEMBER	PERSONAL INTERESTS		NON-PERSONAL INTERESTS		WHETHER CURRENT	ADDITIONAL INFORMATION
	NAME OF COMPANY	NATURE OF INTERESTS	NAME OF COMPANY	NATURE OF INTERESTS		
			Orchard Therapeutics Ltd	Grant/Sponsorship		
			Pfizer	Grant/Sponsorship		
			PTC Therapeutics	Grant/Sponsorship		
			Roche Products Ltd	Grant/Sponsorship		
			Sanofi Genzyme	Grant/Sponsorship		
			Santhera	Grant/Sponsorship		
			Sarepta	Grant/Sponsorship		
			Shire/Takeda	Grant/Sponsorship		
			SOBI	Grant/Sponsorship		
			Spark Therapeutics Ltd	Grant/Sponsorship		
			UCB Celltech	Grant/Sponsorship		
			Vertex Illumina Dante Labs Open Health	Grant/Sponsorship		
Dr W. Stephen Waring	None	None	None	None	No	None
Dr David Webster	Smith & Nephew PLC	Shares, Pension Trustee, Medical Insurance	None	None	No	Family member owns shares in Smith & Nephew and is a beneficiary of this member's medical insurance provided by the company



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

ReviewPanel.Secretariat@mhra.gov.uk