The Review Panel

Annual Report 2013

Medicines and Healthcare Products Regulatory Agency

The Review Panel

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Appendices

FOREWORD FROM THE CHAIRMAN OF THE MHRA

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

This relatively newly formed body plays the important role of hearing the views of those applicants and licence holders who disagree with a decision made by the MHRA where legislation allows. 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 the public service they provide and whose professional expertise, commitment and hard work, plays a role to ensure the medicines we take continue to be safe.

Professor Sir Gordon Duff
MHRA Chairman

THE REVIEW PANEL ANNUAL REPORT 2013

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, 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 On 21st May 2013 the MHRA appointed Mr Neil Mercer LLB (Hons) BA (Hons) as Chair of the Review Panel.

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

4. MEETINGS

4.1. The Panel met on one occasion on 22nd November 2013 and advised on three cases:

- The Panel considered written representations from the Licensing Authority and 'The Natural Health Practice Ltd' in relation to the product 'Black Cohosh'. The disputed facts related to the product's indication. The product was aimed at a discrete group: women with the menopause and presented as a food supplement. The Panel advised the Licensing Authority that it agreed with its provisional determination, that 'Black Cohosh' was a medicinal product under Article 1 of Directive 2001/83/EC as amended.

- The Panel considered written representations from the Licensing Authority and 'Health Aid Ltd' in relation to the product 'Health Aid Diaglucoforte.' The disputed facts related to the product's indication. The product is a herb extract aimed at adults and children over the age of 16 as a food supplement to balance and support healthy blood sugar levels. The Panel advised the Licensing Authority that it agreed with its provisional determination, that 'Health Aid Diaglucoforte' was a medicinal product under Article 1 of Directive 2001/83/EC as amended.

- The Panel considered written representations from the Licensing Authority and 'Nature's Best Health products Ltd' in relation to the product 'Prostex Saw Palmetto.' The disputed facts related to the product's indication. The product was aimed at men with prostate problems. The Panel advised the Licensing Authority that it agreed with its provisional determination, that 'Prostex Saw Palmetto' was a medicinal product under Article 1 of Directive 2001/83/EC as amended.

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.

Appendix I

MEMBERSHIP OF THE REVIEW PANEL

Chair

Mr Neil Mercer[1] 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
Non-Executive Director, Health Protection Agency

Mr Richard Crossley 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 Sommerville 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 PhD
Business Consultant; Former Managing Director of Smith and Nephew Healthcare and Chairman of the Community Services Committee of East Riding PCT

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

[1] Appointed 21/05/13-20/05/16

Appendix II

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

Appendix III

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

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Mr Neil Mercer Professor Peter Aggett	Pfizer Consumer Products (Probiotic Advisory Board)	Consultancy on research conduct on pre biotics	None	None	No	Member of the Labour Party
	New Zealand Diary Goat Co-Operative (Scientific Advisory Panel)	Design and conduct of clinical trial				
	Department of Health: PhE	Chair - scientific advisory committee on nutrition and subgroup on maternal and child nutrition				
	European Food Safety Authority (working groups on GMOS and on dietary intakes of minerals	Expert member				
	Food Standards Agency: Committee on Toxicity	Co-opted member from SACN				

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
Mrs Elizabeth Bamford	GlaxoSmithKline	Shares and options pensions	None	None	No	None
	Pfizer	Shares	None	None	No	
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 UK	Educational Grants awarded to the Tuberous Sclerosis Association during current financial year (2013/14) totaling £26k	Yes	None
Dr Stephen Waring	None	None	None	None	No	None
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	Phynova Ltd G W Pharm plc Omedica 3 Ltd	Shareholder, Consultant Shareholder Shareholder, Director	None	None	No	None

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	Essential Drug Co Ltd	Shareholder, Director				
	Nuique Ltd	Shareholder, Director				
	Encap Nutrition Ltd	Shareholder				

Contact for information about this report:

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