The Review Panel

Annual Report 2020

Medicines and Healthcare products Regulatory Agency

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FOREWORD BY STEPHEN LIGHTFOOT
CHAIR OF THE MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

I am pleased to present the Annual Report of the Review Panel for the last year.

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. Importantly, the Review Panel continues to operate with the highest standards of conduct, independence and fairness to help ensure that the medical products we use are safe.

I would also like to take this opportunity to express my sincere thanks to the Chair and Members for their professional expertise, commitment and focus on protecting or improving patient health whilst they have been performing their public duties on the Review Panel.

Mr Stephen Lightfoot
Chair
MHRA

THE REVIEW PANEL ANNUAL REPORT 2020

INTRODUCTION

1. The Review Panel was established on 1 November 2012. It performs the functions as set out in the Human Medicines Regulations 2012 (SI 2012/1916) (as amended) ("the Regulations") and 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. The Regulations provide 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 of at least two reviewers to conduct the review.

5. The Review Panel's terms of reference are:

    a) to perform the functions of "the reviewers" under regulations 162 and 163 of 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:
        - suspend, vary or revoke a manufacturer's or wholesale dealing licence under regulation 26 of the Regulations;
        - suspend or vary a broker's registration or remove a person from the register under regulation 45G of the Regulations;
        - suspend or vary an active substance registration or remove a person from the active substance register under regulation 45Q of the Regulations

- suspend or vary a person's entry on the list of authorised sellers of medicinal products at a distance or remove the person's entry on the list under regulation 256I of the Regulations
- to grant or renew the UK marketing authorisation, certificate of registration, traditional herbal registration under paragraph 10 or 12 of Schedule 11 to the Regulations
- to grant or renew the authorisation, certificate or registration in accordance with the application under paragraph 10 or 12 of Schedule 11 to the Regulations
- to revoke, vary or suspend the authorisation, certificate or registration under paragraph 10 or 12 of the Regulations
- to decide that the orphan criteria are not met in relation to a medicinal product which is the subject of a UK marketing authorisation under paragraph 10 or 12 of Schedule 11 to the Regulations
- to refuse or grant in terms outside the terms of application a variation application under paragraph 22 of Schedule 11 to the Regulations; and
- to refuse to agree a paediatric investigation plan or to agree otherwise than in accordance with the request for agreement under paragraph 13A of Schedule 11 of the Regulations
- to refuse to a modification to a paediatric investigation plan or to agree otherwise than in accordance with the request for modification under paragraph 13A of Schedule 11 of the Regulations
- to impose, revoke or refuse to grant a waiver of the obligation under regulation 50A(3) to provide the Licensing Authority the results of all studies performed or
- to revoke a waiver which was agreed as part of an agreed paediatric investigation plan

CHAIR 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 met on one occasion on 30 January 2020 and advised on one case:

    - The Panel considered written and oral representations from the applicant and the Licensing Authority for a medicine indicated for the treatment of pain and inflammation in adults, which has been refused a Marketing Authorisation by the Licensing Authority following consideration by the Commission on Human Medicines (CHM).
    - The disputed facts related to the quality in relation to safety and efficacy of the product. The Panel agreed with the decision of the CHM and advised the

Licensing Authority that, the applicant had not demonstrated sufficiently that bioequivalence could be assured (assurance was essential for product efficacy and safety) and it agreed with its refusal of the application.

COSTS

9. Members were entitled to claim an attendance fee of £200 per day (Chair'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[1] 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[2] 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[3] 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[4] BSc PhD
Chief Executive of the Tuberous Sclerosis Association

Dr W. Stephen Waring[5] PhD FBPharmS FRCP
Consultant Physician in Acute Medicine and Clinical Toxicology, York Teaching Hospitals NHS Foundation Trust; Honorary Senior Lecturer, Hull York Medical School

Dr David Webster[6]
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

[1] End of appointment 31/01/2020
[2] End of appointment 31/01/2020
[3] End of appointment 31/01/2020
[4] End of appointment 31/01/2020
[5] End of appointment 31/01/2020
[6] End of appointment 31/01/2020

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 Geear
Regulatory Scientific Business Support Unit Manager

Mrs Munise Guler[7]
Secretary

Ms Vivian Chu[8]
Secretary

[7] Until 31 May 2020
[8] From 1 June 2020

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	NIL	NIL	NIL	NIL	N/A	NIL
Professor Peter Aggett	Department of Health/Public health England: Scientific Advisory Committee on Nutrition	Vice Chair of Scientific Advisory Committee	NIL	NIL	YES	NIL
	Food standards agency: Committee on Toxicity	Co-opted liaison from Scientific Advisory Committee on Nutrition, and its subgroup on maternal and child nutrition			YES	
	Royal College of Physicians London	Co-opted liaison from Scientific Advisory Committee on Nutrition, and its subgroup on maternal and child nutrition			YES	
	European Food Safety Authority: NDA panel working group	Working group on dietary reference values: minerals			YES	

	PERSONAL INTERESTS		NON-PERSONAL INTERESTS			
MEMBER	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**NAME OF COMPANY**	**NATURE OF INTERESTS**	**WHETHER CURRENT**	**ADDITIONAL INFORMATION**
	European Food Safety Authority: member of panel on additives and nutrient sources added to food	Review of approved additives and appraisal of new substances. Member of the working group on phosphates.			YES	
	European Food Safety Authority: NDA panel working group	Assessment of uncertainty factors to apply to assessed Upper Level for copper.			YES	
	European Food Safety Authority: Scientific Committee: working group.	Review of approaches to determination of Health Based Guidance Values For Nutrients			YES	
	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.			YES	

	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 PLC	Pension share holding	NIL	NIL	YES	NIL
	Pfizer PLC	Share holding			NO	NIL
Mr Michael Carroll	NIL	NIL	NIL	NIL	N/A	NIL
Mr Richard Crossley	NIL	NIL	NIL	NIL	N/A	NIL
Mrs Pamela Goldberg	NIL	NIL	NIL	NIL	N/A	NIL
Professor Nicola Robinson	NIL	NIL	NIL	NIL	N/A	NIL
Dr Jayne Spink	NIL	NIL	Novartis	Company sponsors of Rare Disease UK (a project of Genetic Alliance UK)	YES	NIL
Dr W. Stephen Waring	NIL	NIL	NIL	NIL	N/A	NIL
Dr David Webster	Smith & Nephew PLC	Shares, Pension Trustee, Medical Insurance	NIL	NIL	YES	Family member owns shares in Smith & Nephew and is a beneficiary of my medical insurance provided by the company.

Contact for information about these reports:

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London
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