The Review Panel

Annual Report 2016

Medicines and Healthcare Products Regulatory Agency

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LIST OF CONTENTS

Appendices

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 2016

INTRODUCTION

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.

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). A list of the secretariat is at Appendix II.

MEETINGS

8. The Panel met on four occasions during 2016.

9. On 20 January 2016 the Panel considered oral submissions from the Licensing Authority and Laboratoires Ortis sprl in relation to the product "Ortisan Fruit and Fibre Cubes Regular". The disputed facts related to whether the properties of the product's active ingredient, senna leaf (Cassia angutfolia Vahl), had, and/or was presented as having, a metabolic effect. The Panel advised the Licensing Authority that it agreed with its provisional determination, that "Ortisan Fruit and Fibre Cubes Regular" was a medicinal product under Article 1 of directive 2001/83/EC as amended.

10. On 27 April 2016 the Panel met and advised on two cases:

    - The Panel considered written representations from the Licensing Authority and The Natural Health Practice in relation to the product "Agnus Castus Support". The disputed facts related to whether the product and its active ingredients, including black cohosh, vitex agnus-castus and milk thistle, fell within the definition of a medicinal product by satisfying both limbs of the medicines definition through its presentation and metabolic effect. The Panel advised the Licensing Authority that it agreed with its provisional determination, that "Agnus Castus Support" was a medicinal product under Article 1 of directive 2001/83/EC as amended.

    - The Panel considered written representations from the Licensing Authority and The Natural Health Practice in relation to the product "Black Cohosh Support". The disputed facts related to whether the product and its active ingredients, including dong quai, agnus-castus, black cohosh, milk thistle and sage, fell within the definition of a medicinal product by satisfying both limbs of the medicines definition through its presentation and metabolic effect. The Panel advised the Licensing Authority that it agreed with its provisional determination, that "Black Cohosh Support" was a medicinal product under Article 1 of directive 2001/83/EC as amended.

11. On 28 October 2016 the Panel considered written representations from the Licensing Authority and Solgar Vitamin and Herb UK in relation to the product "Solgar Echinacea Capsules". The disputed facts related to whether the

product and its active ingredient, echinacea, fell within the definition of a medicinal product either by presentation or by having a metabolic effect. The Panel advised the Licensing Authority that it agreed with its provisional determination, that “Solgar Echinacea Capsules” was a medicinal product under Article 1 of directive 2001/83/EC as amended.

12. On 4 November 2016 the Panel considered oral submissions from the Licensing Authority and a company in relation to a product, indicated for the treatment of type 2 diabetes mellitus, which had been refused a Marketing Authorisation by the Licensing Authority following consideration by the Commission on Human Medicines (CHM). The Panel agreed with the decision of the CHM and the Licensing Authority, and advised that the application could not be granted at this time, but should be resubmitted as a new application, addressing the concerns of the CHM.

COSTS

13. 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 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 Whittle BPharm MSc PhD
Consultant in Pharmaceutical Development

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 **(until 31st July 2016)**

Ms N Nolen
Secretary **(from 1st August 2016)**