The Review Panel

Annual Report 2021

Medicines and Healthcare products Regulatory Agency

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FOREWORD BY GRAHAM COOKE, CHAIR OF THE MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY

I am pleased to present the Annual Report of the Review Panel for 2021.

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.

Professor Graham Cooke
Interim Co-Chair
MHRA

THE REVIEW PANEL ANNUAL REPORT 2021

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"), which were undertaken before that date by:
    - the Independent Review Panel on the Advertising of Medicines
    - the Independent Review Panel on the Classification of Borderline Products
    - the Regulation of Medicines Review Panel.

2. The Review Panel performs statutory reviews of proposals, decisions and provisional decisions taken by the Medicines and Healthcare products Regulatory Agency (MHRA) on behalf of the Licensing Authority or Ministers where legislation provides an applicant or Marketing Authorisation Holder with the opportunity to request a review of the proposal or decision, and make representations to support their position.

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 by the Regulations 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 161 and 162 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; and

    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;

- impose, revoke or refuse to grant a waiver of the obligation under regulation 50A(3) of the Regulations to provide the Licensing Authority the results of all studies performed;
- suspend, vary or remove a person's entry on the list of authorised sellers of medicinal products at a distance under regulation 256I of the Regulations;
- grant or renew a UK marketing authorisation, certificate of registration, or traditional herbal registration under paragraph 10 or 12 of Schedule 11 to the Regulations;
- grant or renew an authorisation, certificate or registration under paragraph 10 or 12 of Schedule 11 to the Regulations;
- revoke, vary or suspend an authorisation, certificate or registration under paragraph 10 or 12 of Schedule 11 of the Regulations;
- 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;
- refuse or grant in terms outside the terms of application a variation application under paragraph 18 of Schedule 11 to the Regulations;
- refuse to agree a paediatric investigation plan or refuse to agree otherwise than in accordance with the request for agreement under paragraph 13A of Schedule 11 of the Regulations;
- refuse to a modification to a paediatric investigation plan or refuse to agree otherwise than in accordance with the request for modification under paragraph 13A of Schedule 11 of the Regulations; or
- revoke a waiver which was agreed as part of an agreed paediatric investigation plan under paragraph 13A of Schedule 11 of the Regulations.

c) to consider representations about decisions made in relation to advertising.

CHAIR AND MEMBERS

6. A list of the Review Panel's membership is at **Appendix I**.

7. The Secretariat is based at the MHRA. Contact details are provided in **Appendix II**.

MEETINGS

8. The Review Panel met on three occasions in 2021.

9. On 16 June 2021 the Review Panel met and advised on one case:

- The Review Panel considered oral submissions from the MHRA on behalf of the Licensing Authority and the Applicant for a medicine indicated for the treatment of severe pain.

10. The Review Panel met twice, in June and August 2021, and advised on the following case:

The Review Panel considered oral submissions from the Licensing Authority and the Applicant for a medicine indicated for the treatment of moderate to severe pain in patients with cancer and postoperative pain.

COSTS

11. Members were entitled to claim an attendance fee of £200 per day (Chair's fee £325). Travel and subsistence were also payable within Department of Health and Social Care guidelines.

12. From August 2021, members were entitled to claim an attendance fee of £325 per day (Chair's fee £500). Travel and subsistence were payable within the Departmental 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

Mrs Elizabeth Bamford MRPhS
Former Director of Regulatory, Medical & Consumer Affairs, GlaxoSmithKline Healthcare UK

Mr Richard Crossley LLB
Non-Executive Director, Fundraising Standards Board

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

Reviewers appointed under Schedule 5 paragraph 2 of the Human Medicines Regulations 2012 (as amended) (participation at specific appeals only)*

Dr Alan Fayaz MD(Res) MRCP FRCA FFPMRCA
University College London Hospital NHS Foundation Trust

Dr Roger Knaggs BSc BMedSci PhD EDPM FFRPS FRPharmS FFPMRCA
University of Nottingham and Primary Integrated Community Solutions

Dr Matt Mulvey BSc (Hons) PhD
University of Leeds

Dr Paul Farquhar-Smith MA, MB BChir, MA, PhD, FRCA, FFPMRCA
The Royal Marsden NHS Foundation Trust

* Reviewers were asked to complete their declaration of interest forms before their appointment to the specific appeal in all relevant pharmaceutical industry.

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

MEMBER	INTEREST TYPE	COMPANY / ORGANISATION NAME	NATURE OF INTEREST	CURRENT	ADDITIONAL INFORMATION
Neil Mercer	Personal	NIL	N/A	N/A	
Neil Mercer	Non-Personal	NIL	N/A	N/A	
Elizabeth Bamford	Personal	GLAXOSMITHKLINE PLC	Pension Shareholding	YES	
Elizabeth Bamford	Personal	PFIZER PLC	Shareholding	NO	
Elizabeth Bamford	Non-Personal	NIL	N/A	N/A	
Richard Crossley	Personal	NIL	N/A	N/A	
Richard Crossley	Non-Personal	NIL	N/A	N/A	
Nicola Robinson	Personal	NIL	N/A	N/A	
Nicola Robinson	Non-Personal	NIL	N/A	N/A	

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