Department of Health

Triennial Review of the Commission on Human Medicines

Call for Evidence

Title: Triennial Review of the Commission on Human Medicines – Call for Evidence
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www.gov.uk/dh

Introduction

In recent years, the health and social care system in England has undergone substantial change. The Health and Social Care Act 2012 and the Care Act 2014 have devolved functions and powers away from the Department of Health to local and Arm's Length Bodies.

In this new system, the Department has the key stewardship and assurance function designed to ensure that the new system, and so the multiple new and reformed bodies within it, have the appropriate functions and are performing to a high standard.

To perform this stewardship function, the Department is putting in place Triennial Reviews of all of its Arm's Length Bodies. This includes all Executive Non-Departmental Public Bodies (ENDPBs), Advisory Non-Departmental Public Bodies (ANDPBs), Executive Agencies and Special Health Authorities. The Commission on Human Medicines (CHM), an ANDPB, is subject to review in 2014-15.

The programme of reviews uses the approach developed by the Cabinet Office as part of their work on public bodies reform.

Purpose of the review

As noted above, this review is part of a wider programme the Department of Health has developed as part of its stewardship and assurance function. The review will have two main stages:

- The first is to provide a robust challenge of the continuing need for the CHM both in terms of the functions it performs, and the way in which these are delivered.
- If it is agreed that the CHM should retain its current function and utilise the same delivery model, the second stage of the review will then consider its performance, capability and governance, as well as considering opportunities for efficiencies.

This Call for Evidence seeks views from respondents to assist its consideration of both of the above stages. The evidence is being gathered simultaneously for stage one and stage two in the interests of timeliness and value for money only, and is not an expression of pre-judgement as to the outcome of stage one on the part of the review.

About the CHM

The Commission on Human Medicines (CHM) was established on 30 October 2005 under Section 2 of the Medicines Act 1968 (SI 2005 No. 1094), amalgamating the responsibilities of the Medicines Commission and the Committee on Safety of Medicines. It exists as an Advisory Non-Departmental Public Body of the Department of Health (DH).

Its functions are set out in regulation 10 of the Human Medicines Regulations 2012 (SI 2012/1916), and include:

- advising ministers on matters relating to human medicinal products (except those that fall under the remit of the Advisory Board on the Registration of Homoeopathic Products (ABRH) and the Herbal Medicines Advisory Committee (HMAC));
- advising the licensing authority (LA (in practice this is the MHRA)) where the LA has a duty to consult the Commission or where the LA chooses to consult the Commission including giving advice in relation to the safety, quality and efficacy of human medicinal products;
- considering representations made in relation to the Commission's advice (either in writing or at a hearing) by an applicant or by a licence or marketing authorisation holder; and
- promoting the collection and investigation of information relating to adverse reactions for human medicines (except for those products that fall within the remit of ABRH or HMAC) for the purposes of enabling such advice to be given.

Useful links

CHM Website

Cabinet Office Triennial Review guidance

Responding to the Call for Evidence

In order to conduct the review in an open and transparent manner and ensure that the findings are rigorous and evidence-based, the review team is seeking the views of a wide range of stakeholders. We are interested in the views of individuals and organisations that engage with the CHM or have a wider interest in its operations.

The call for evidence is running from 01 December 2014 to 11 January 2015. Responses can be provided by:

i. Completing the online questionnaire at http://consultations.dh.gov.uk/triennial-reviews/chm ; or
ii. Downloading the form and emailing to the review team at TR-CHM@dh.gsi.gov.uk; or
iii. Printing the form and posting to: CHM Triennial Review Team, Room 220, Department of Health, Richmond House, 79 Whitehall, London SW1A 2NS.

Call for Evidence Questions

Confidentiality

Information provided in response to this consultation, including personal information, may be published or disclosed in accordance with the access to information regimes (these are primarily the Freedom of Information Act 2000 (FoIA) and the Data Protection Act 1998 (DPA).

If you want the information that you provide to be treated as confidential, please be aware that under the FoIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this, it would be helpful if you could explain why you regard the information you are providing as confidential. If we receive a request for disclosure of the information, we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

The Department will process your personal data in accordance with the DPA and in the majority of circumstances this will mean that your personal data will not be disclosed to third parties.

About you

Name:

Organisation:

Email:

Would you categorise your response as from:

- Individual
- Public sector organisation
- Charitable/voluntary sector healthcare organisation
- Private sector – pharmaceutical industry
- Private sector – other
- None of the above. Please state:……..

If your response is from an umbrella organisation representing a wider membership, please indicate the number of members consulted and the number of responses received:

Please indicate what relationship you have with the CHM, if applicable:

Questions

There is no need to answer all seven questions unless you wish to do so. For those which you do answer, please provide evidence to support your answers wherever possible. If you wish to send us supporting documentation please email as an attachment to TR-CHM@dh.gsi.gov.uk. Information where relevance is not demonstrable will not be accepted as evidence. The review team is unable to respond to individual cases or consider complaints.

The Commission on Human Medicines (CHM) performs a number of functions:

- to advise the Health Ministers and the Licensing Authority (the Medicines and Healthcare Products Regulatory Agency) on matters relating to human medicinal products including giving advice in relation to the safety, quality and efficacy of human medicinal products where either the Commission thinks it appropriate or where it is asked to do so;
- to consider those applications that lead to Licensing Authority action as appropriate (i.e. where the LA has a statutory duty to refer or chooses to do so);
- to consider representations made (either in writing or at a hearing) by an applicant or by a licence or marketing authorisation holder in certain circumstances; and
- to promote the collection and investigation of information relating to adverse reactions to human medicines for the purposes of enabling such advice to be given.

The Commission is similarly involved in respect of medicinal products to which relevant EC legislation applies.

1. Is each of the functions necessary?
    a. What would the implications be of stopping these functions?
    b. Is providing the functions a justifiable use of Licensing Authority funds?
    c. Does the CHM duplicate work done elsewhere?

2. How well is the CHM currently delivering its functions? Are there any changes you think the CHM could make to improve its outputs or efficiency?

3. The CHM is currently an advisory Non-Departmental Public Body of the Department of Health. Do you think an alternative organisational structure would improve delivery of those functions you feel are necessary? Potential options include:
    a. **Bring in-house**: could a function be better delivered if the CHM became an advisory group of the Department of Health?
    b. **Merger with another body**: could a function be better delivered by becoming an Expert Committee of the Medicines and Healthcare Products Regulatory Agency or another body?
    c. **Commercial model**: could a function be better delivered under contract by the voluntary or private sector?
    d. **Continued delivery as an advisory NDPB**: Do its activities need to be, and be seen to be, delivered with absolute political impartiality? Does the CHM need to act independently of Ministers to establish facts and/or figures with integrity?
    e. **Other:** [please explain……]?

4. Do you think the CHM's expertise and advice (generally to Ministers and the Medicines and Healthcare Products Regulatory Agency) is utilised effectively? Are there other groups in the heath and care system which would benefit from their advice?

5. Do you think the CHM operates in an open, transparent, accountable and responsive way?

6. Does the current membership composition of the Commission and the Expert Advisory Groups best support the functions you believe are necessary?

7. If you have any other comments on the CHM's functions, organisational structure, performance, efficiency or governance that you would like to submit as part of this Call for Evidence, please do so here (stating what aspects it relates to).

Thank you for taking the time to respond to this Call for Evidence.