



Department  
of Health

# Triennial Review of the Medicines and Healthcare Products Regulatory Agency

## Call for Evidence

<b>Title:</b> Triennial Review of the Medicines and Healthcare Products Regulatory Agency – Call for Evidence
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# 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 Bodies (ANDPBs), Executive Agencies and Special Health Authorities. The Medicines and Healthcare Products Regulatory Agency (MHRA, or the Agency), an Executive Agency, is subject to review in 2014-15.

The programme of reviews builds on 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 Agency, both in terms of the functions it performs, and the way in which these are delivered.
- If it is agreed that the Agency 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.

# Innovative Medicines and Medical Technology Review

On 20th November 2014, George Freeman (Minister for Life Sciences) announced the Innovative Medicines and Medical Technology Review, which will consider how our healthcare and regulatory systems can best respond and adapt to the new landscape of innovation. This review is expected to start in 2015 and will report recommendations to the new Government. It will consider the pathways for the development, assessment and adoption of innovative medicines and medical technologies, including how the MHRA regulates the approval of medicines and medical devices.

We aim to avoid overlap and duplication of effort between these reviews. The MHRA Triennial Review will not be considering the detail of how the Agency approves new medicines and medical devices. Any material obtained as part of the Triennial Review that is relevant to the later review will be forwarded for consideration.

## About the MHRA

The Medicines and Healthcare Products Agency comprises:

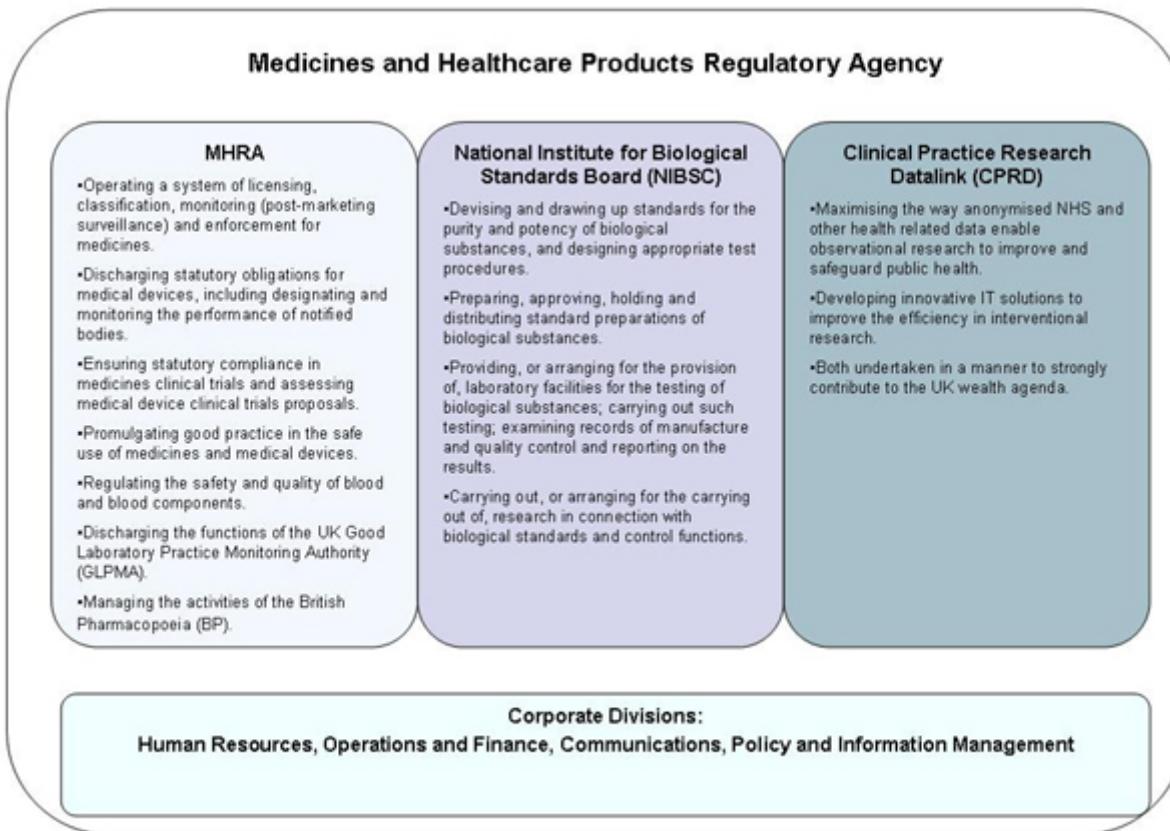
**MHRA Regulatory:** who protect health and improve lives by ensuring that medicines and medical devices work, and are acceptably safe; focusing on the core activities of product licensing, inspection and enforcement, and pharmacovigilance.

**The Clinical Practice Research Datalink (CPRD,**  
<http://www.cprd.com/intro.asp>): which gives access to an unparalleled resource for conducting observational research and improving the efficiency of interventional research, across all areas of health, medicines and devices. CPRD joined the Agency in 2012.

**The National Institute for Biological Standards and Control (NIBSC,**  
<http://nibsc.org>): world leaders in assuring the quality of biological medicines through product testing, developing standards and reference materials and carrying out applied research.

It exists as an Executive Agency and a Trading Fund of the Department of Health (DH) under the Medicines and Healthcare Products Regulatory Agency Trading Fund Order 2003. It employs approximately 1,200 staff and generated a net surplus of £16m in 2013-14 against income of £138m (largely from regulatory fees).

## The role and remit of each of the three elements



### MHRA

The MHRA is responsible for regulating all medicines and medical devices in the UK by ensuring they work and are acceptably safe. It must make robust and fact-based judgments to ensure that the benefits justify any risks. This is achieved through:

- i. authorising medicines before they can be marketed, taking both their safety and effectiveness into account
- ii. ensuring clinical trials meet robust standards and safeguard patient's interests
- iii. inspecting the quality of medicines as manufactured and distributed
- iv. overseeing UK Notified Bodies that audit medical device manufacturers
- v. encouraging everyone to report suspected problems with both medicines and devices and then investigating these reports
- vi. investigating, and prosecuting where necessary, cases of non-compliance including advertising claims.

### The Clinical Practice Research Datalink (CPRD)

- i. The Clinical Practice Research Datalink (CPRD) is the English NHS observational data and interventional research service, jointly funded by the NHS National Institute for Health Research (NIHR) and the MHRA. CPRD services are designed to maximise the way anonymised NHS clinical data can be linked to enable many

- types of observational research and deliver research outputs that are beneficial to improving and safeguarding public health.
- ii. CPRD provides value-added services to the General Practitioners who contribute to the database and to the researchers who want to make use of this unique public health research tool.

### **The National Institute for Biological Standards and Control (NIBSC)**

- i. The key function of NIBSC is the standardisation and control of biological medicines. It offers:
  - a. Biological reference materials and customized reference materials
  - b. OCABR testing and contract testing
  - c. Research collaborations
  - d. Advice and training.
- ii. NIBSC is a global leader in the field of biological standardisation, responsible for developing and producing over 90% of the International Standards in use around the world to assure the quality of biological medicines. NIBSC scientists have an international reputation for excellence in research and are widely consulted on issues of biological medicine safety and efficacy.
- iii. The Institute is the UK's Official Medicines Control Laboratory (OMCL), responsible for testing of biological medicines within the framework of the European Union. It has a particularly close relationship with the World Health Organisation (WHO) and is the leading WHO International Laboratory for Standards.
- iv. Its statutory duties are:
  - a. To devise and draw up standards for the purity and potency of biological substances, to design appropriate test procedures and to advise on these matters;
  - b. To provide or to arrange for the provision of laboratory facilities for the testing of biological substances, to carry out such testing, to examine records of manufacture and quality control of biological substances and to report on the results of such testing or examination;
  - c. To prepare, approve, hold and distribute standard preparations of biological substances;
  - d. To collaborate with the World Health Organisation, the European Pharmacopoeia Commission and other international organisations or bodies in relation to the establishment of standards for, the provision of standard preparations of, and the testing of biological substances;
  - e. To carry out or arrange for the carrying out of research in connection with the functions referred to in a) to d) above; and
  - f. To do all other things incidental or conducive to the discharge of the above functions.
- v. The delivery of these is of the utmost importance, since biological medicines include many of today's most widely used medicines (vaccines, blood products and biotherapeutics), together with some of the most exciting prospects for the future.

## Recent history

The formal regulation of medicines and medical devices is a relatively recent occurrence. The impact of the negative and unpredicted side-effects of Thalidomide led to the creation of the Committee on Safety of Drugs in 1963, which subsequently became the Committee on Safety of Medicines (CSM) under the terms of the Medicines Act 1968. In 2005 this committee became the Commission on Human Medicines (CHM). The Medicines Control Agency was created in 1989, and merged with the Medical Devices Agency to become the MHRA in 2003.

The CPRD merged with the MHRA in April 2012. In April 2013, the MHRA further merged with NIBSC and was rebranded, with the MHRA identity being used for the parent organisation and one of the centres within the group.

## Useful links

[Cabinet Office Triennial Review guidance](#)

[MHRA Website](#)

[MHRA Annual Report and Accounts](#)

[The National Institute for Biological Standards and Control](#)

## 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 Agency or have a wider interest in its operations. The key areas of enquiry, which incorporate some standard areas of focus that apply to all Triennial Reviews, are set out below. In particular, the review team will focus on considerations of alternative organisational forms, the potential to increase revenues and find efficiencies, and the Agency's capacity and capability to meet current and future challenges.

**The call for evidence is running from 1 December 2014 to 9 January 2015.**  
Responses can be provided by:

- i. Completing the online questionnaire at <http://consultations.dh.gov.uk/triennial-reviews/mhra>; or
- ii. Downloading the form and emailing to the review team at [TR-MHRA@dh.gsi.gov.uk](mailto:TR-MHRA@dh.gsi.gov.uk); or
- iii. Printing the form and posting to: MHRA Triennial Review Team, Room 220, Department of Health, Richmond House, 79 Whitehall, London SW1A 2N; and/or
- iv. Attending a round table workshop (see below) where stakeholders can share views directly with the review team.

**Workshops:** interested stakeholders are also invited to attend a round table workshop discussion to share their views on this Call for Evidence: To book a place please click on the relevant link

Date	Time	Location
11 December 2014	10:00-12:00 hours	Room LG21, Wellington House, London SE1 8UG <a href="#">View Google map</a>
<a href="https://www.eventbrite.co.uk/e/triennial-review-medicines-and-healthcare-products-regulatory-advisory-mhra-tickets-14476693179">https://www.eventbrite.co.uk/e/triennial-review-medicines-and-healthcare-products-regulatory-advisory-mhra-tickets-14476693179</a>		
5 January 2015	10:00-12:00 hours	Room LG21, Wellington House, London SE1 8UG <a href="#">View Google map</a>
<a href="https://www.eventbrite.co.uk/e/triennial-review-of-medicines-and-healthcare-products-regulatory-advisory-mhra-tickets-14601839495">https://www.eventbrite.co.uk/e/triennial-review-of-medicines-and-healthcare-products-regulatory-advisory-mhra-tickets-14601839495</a>		
7 January 2015	10:00-12:00 hours	Room 133B, Skipton House, London SE1 6LH <a href="#">View Google map</a>
<a href="https://www.eventbrite.co.uk/e/triennial-review-of-medicines-and-healthcare-products-regulatory-advisory-mhra-tickets-14602200575">https://www.eventbrite.co.uk/e/triennial-review-of-medicines-and-healthcare-products-regulatory-advisory-mhra-tickets-14602200575</a>		
<b>Please note places are limited and will be allocated on a first come, first served basis.</b>		

## Call for Evidence Questions

Triennial Reviews are asked to apply a two stage approach to their considerations. The key lines of enquiry for the Agency review across these two stages are:

- i. **Stage one** of the review will verify the functions of the Agency, assess how the functions contribute to the core business of the health and care system, and consider whether they are still needed. Within this context, the review will consider:
  - a. Whether delivery of the functions continues to contribute to wider government policy and constitutes a justifiable use of public money;
  - b. Whether there is a demand for the function or activity from users;
  - c. The cost and effects of not delivering the function;
  - d. How the EU legal requirements for health (drug and product licensing) link to the core legal requirements for a licensing function; and whether/where the Agency goes beyond that core legal requirement.

- ii. Where it is concluded that a function is still needed, stage one will go on to examine how this function might best be delivered. The review will first examine whether the function could be better delivered through an alternative delivery model. For example, this might mean delivery by the private or voluntary sector, or merger with another body (either another area of central government or another public body).
- iii. If the outcome of stage one is that the MRHA should retain its current status, **stage two** will go on to review its control, governance and efficiency. The review will adopt a ‘comply or explain’ approach to examine whether the Agency is operating within the recognised principles of good corporate governance in relation to its accountability arrangements, roles and responsibilities, financial management, communications, and behavioural conduct. The review will also consider whether there is adequate capability within the organisation. Within this context, the review will consider the following key lines of enquiry:
  - a. Whether the Agency makes the best use of public money and assets;
  - b. Whether internal processes are sufficiently lean;
  - c. Whether there is any scope for efficiencies through shared services, digitisation of processes, etc;
  - d. How well the MHRA has assimilated the various elements with which it has merged over recent years (e.g., The National Institute for Biological Standards and Control);
  - e. The Agency’s capacity and capability to respond effectively to changing demands or a changing regulatory environment;
  - f. The balance between risk and benefit in the decision-making process.

The review team is particularly interested in evidence in support of responses to the questions set out below but does not seek to restrict responses provided they are relevant to the key lines of enquiry.

The review will aim to obtain evidence from different sources. As well as this call for evidence the review will analyse published material and will undertake interviews and workshops with key stakeholders.

## **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 (if applicable):**
- **Telephone:**
- **Email:**
  
- **Would you categorise your response as from:**
  - Individual
  - Public sector
  - Charitable/voluntary sector healthcare organisation
  - Private sector – pharmaceutical or medical devices
  - 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 interactions/relationship you have with the Agency:**

## 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-MHRA@dh.gsi.gov.uk](mailto:TR-MHRA@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. Any such issues should be directed to the MHRA. Individually identifiable information should be avoided.

### Performance, capacity and capability

- 1. How would you rate the performance of the Agency?**
  - Very good
  - Good
  - Average
  - Poor
  - Very poor
  - Please briefly explain your answer:
- 2. Where do you think the Agency performs particularly well or needs to improve?**
- 3. How well does the Agency respond to relevant public health issues, e.g. safety issues with products, product defects, or new priority concerns?**
- 4. How effectively does the Agency balance risk/benefit decisions?**
- 5. How well does the Agency negotiate and influence nationally and internationally? How might it exploit further opportunities?**
- 6. How well does the Agency support innovation and what more could be done?**
- 7. How well does the Agency communicate and engage with its stakeholders?**
  - Very good
  - Good
  - Average
  - Poor
  - Very poor
  - Please briefly explain your answer:
- 8. How would you measure the performance of the Agency?**
- 9. How effectively do the various elements of the Agency work together? Are there more synergies that could be achieved? Further information is provided in Annex I of the response form.**

## Functions

**10. Is there a continuing need for the functions undertaken by the Agency?**

- Yes
- No
- Don't know
- Please briefly explain your answer:

**11. Are there any functions that should be added, dropped, undertaken by another organisation, or which overlap with another organisation?**

**12. How effectively does the Agency contribute to wider government policy? Are the Agency's activities effectively aligned with the rest of the health and social care system?**

## Form

**13. The section 'About the MHRA' explains some of the recent changes and mergers. Annex II (in the response form) below provides brief background on potential options for different forms and structures. Do you think the Agency should:**

- Remain in its current form (Executive Agency and Trading Fund)?
- Merge with another public sector organisation?
- Move into the private or voluntary sector?
- Don't know
- None of the above? Please briefly explain your answer:

**14. If the Agency continues in its current form, are there opportunities for greater cooperation and joint working with other organisations?**

- Yes
- No
- Don't know
- Please briefly explain your answer:

## Efficiency

**15. How could the Agency reduce costs or improve performance through efficiencies?**

**16. Are there any opportunities for the Agency to make more effective use of its assets and/or to increase commercial revenues?**

**17. The Agency applies a licence fee to fund its medicines' regulatory activities. Do you think devices' regulation should operate under a similar funding model?**

- Yes
- No
- Don't know
- Please briefly explain your answer:

### Governance

**18. Does the Agency follow best practice governance arrangements?**

**19. How effective are the Agency board and senior management team?**

**20. How well are risks and opportunities identified and managed?**

### Other Comments

**21. Are there any other issues or evidence you think the review team should take into account?**

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