



Department  
of Health

# Triennial Review of the British Pharmacopoeia Commission

Call for Evidence

<b>Title:</b> Triennial Review of the British Pharmacopoeia Commission – Call for Evidence
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<b>Target audience:</b> Individuals, pharmaceutical industry, civil society groups, and other health institutions with an interest in the Commission.
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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 Public Bodies (ANDPBs), Executive Agencies and Special Health Authorities. The British Pharmacopoeia Commission (BPC), 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 BPC both in terms of the functions it performs, and the way in which these are delivered.
- If it is agreed that the BPC 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 BPC

The 1968 Medicines Act established the legal status of the British Pharmacopoeia Commission (BPC) and of the British Pharmacopoeia as the UK standard for medicinal products under section 4 of the Act. This Act has since been superseded by the Human Medicines Regulations 2012. Its functions include:

- preparing new editions of the British Pharmacopoeia and the British Pharmacopoeia (Veterinary) and for keeping them up to date;
- providing advice to the United Kingdom delegation to the European Pharmacopoeia Commission, of which the United Kingdom is a member by virtue of its obligations under the Convention on the Elaboration of a European Pharmacopoeia; and
- selecting and devising British Approved Names (BANs).

## Useful links

[BPC 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 BPC 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/bpc> ; or
- ii. Downloading the form and emailing to the review team at [TR-BPC@dh.gsi.gov.uk](mailto:TR-BPC@dh.gsi.gov.uk); or
- iii. Printing the form and posting to: BPC 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 BPC, if applicable:

## Questions

There is no need to answer all eight 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-BPC@dh.gsi.gov.uk](mailto:TR-BPC@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 British Pharmacopoeia Commission (BPC) performs a number of functions:

- preparing new editions of the British Pharmacopoeia (BP) and the British Pharmacopoeia (Veterinary) and for keeping them up to date;
- providing advice to the United Kingdom delegation to the European Pharmacopoeia Commission, of which the United Kingdom is a member by virtue of its obligations under the Convention on the Elaboration of a European Pharmacopoeia; and
- selecting and devising British Approved Names (BANs).

1. Is each of the functions necessary?
  - a. What would the implications be of stopping the functions?
  - b. Is providing the functions a justifiable use of public money?
2. How well is the BPC currently delivering its functions? Are there any changes you think the BPC could make to improve its outputs or efficiency?
3. The BPC is required to cover its costs from the income it generates through royalties on the sale of the books and from sales of BP Chemical References Substances. What do you think is the optimal way to provide this service and to recover costs?
4. The BPC 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 more efficiently delivered if the BPC moved into the Department of Health?
  - b. **Delivery by another body:** could a function be better delivered by the Medicines and Healthcare Products Regulatory Agency or another body, as opposed to the BPC as an advisory NDPB?
  - c. **Commercial model:** could a function be better delivered by the private sector, or delivered under contract by the voluntary or private sector? Would a not-for-profit model be appropriate?
  - 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 BPC need to act independently of Ministers to establish facts and/or figures with integrity?
  - e. **Other:** [please explain.....]?
5. Do you think the BPC's expertise is utilised effectively? Are there other groups in the health and care system which would benefit from their advice?

6. Do you think the BPC operates in an open, transparent, accountable and responsive way?
7. Does the current membership composition of the Commission and the Expert Advisory Groups best support the functions you believe are necessary?
8. If you have any other comments on the BPC'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.