



Department
of Health

Triennial Review of the British Pharmacopoeia Commission

Review Report

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Author: Jamie Grant, Lead Reviewer – BPC, Assurance Division, Group Operations (17152)
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Contact details: Triennial Review Programme Team Department of Health 220 Richmond House London SW1A 2NS TR-BPC@dh.gsi.gov.uk

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Triennial Review of the British Pharmacopoeia Commission

Review Report

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Executive summary

The Department of Health's (DH) Triennial Review of the British Pharmacopoeia Commission (BPC) was conducted to provide assurance to the Department and the public that the BPC's functions are required and that it is operating effectively. This review forms one of a series of reviews being conducted by the DH between 2014-15 and 2016-17 of all of its arm's length bodies and Special Health Authorities. The review of the BPC was announced by Written Ministerial Statement on 30 October 2014.

Stage One of the review examined the functions and form of the BPC. The BPC has three main functions which together perform a role protecting public health of UK and European citizens by establishing public standards for pharmaceuticals. The evidence suggested these are still required, and that the optimal form for the BPC is in a position close to the Medicines and Healthcare Products Regulatory Agency whilst being independent of it. The Advisory Non-Departmental (Advisory NDPB) model facilitates this, as well as enabling the BPC to harness potential information, communication, laboratory and expertise synergies.

Stage Two of the review examined the efficiency, governance and performance of the BPC. The evidence suggested that the BPC operates efficiently, is mostly compliant with the principles of good corporate governance and is considered to be a leading global pharmacopoeia. In particular, stakeholders highlighted the BPC's innovative work, the dedication and expertise of members and the Secretariat, industry engagement and transparency.

The key concern emerging from the review relates to the number of appointment terms due to finish at the end of the year, which will result in a significant loss of experience and expertise. The report also makes a number of minor recommendations summarised on the next page.

Stage One: Function and Form

Recommendation 1: the BPC should continue to deliver its existing functions as an Advisory NDPB.

Stage Two: Efficiency, Governance and Performance

Contract management

Recommendation 2: in order to deliver best value, the BPC Secretariat and the Agency should ensure they generate as much competitive interest in tendering as possible during the next exercise, and that the appropriate support or advice is sought from the Crown Commercial Service.

Recommendation 3: in addition to managing a competitive tendering process as referred to in Recommendation 2, within the lifetime of the next contract the Secretariat should explore the feasibility of bringing the digital element of the BP in-house (consulting the Government Digital Service as appropriate).

Commission/Secretariat relationship

Recommendation 4: the BPC Chair should be formally consulted as part of individual Secretariat staff appraisals, with the views of other members of the BPC to be sought as appropriate.

Recommendation 5: The BPC Secretariat should consult the BPC Chair/Vice-Chair regarding strategic and financial considerations impacting the BPC, and together determine the degree of detail relevant for consideration by Commission members to inform their input.

Commission member appointments

Recommendation 6: BPC Secretariat and the DH Appointments Team should meet post-election to agree an appropriate model for future appointments. Ahead of this the BPC should gather data on the pool of qualified people being targeted. **[Key Recommendation]**

Recommendation 7: appointment term end dates should be clustered into small groups across a spread of years to ensure continuity of service.

Recommendation 8: the BPC and Secretariat should consider draft monograph publication to a specific predictable timetable, including a deadline for comments.

Recommendation 9: the Secretariat should ensure the redeveloped website explains the work and procedures of the BPC more effectively, for example by making the terms of reference, expenses policy, appointments procedures and a list of members of the Commission and its supporting groups publically available.

Recommendation 10: the Secretariat should ensure the redeveloped website is used to help build a list of interested people to be approached during Commission recruitment campaigns or to fill Expert Advisory Group vacancies.

Recommendation 11: the BPC Secretariat should work with the department to establish a process whereby the Chief Medical Officer writes to Commissioners' employers on appointment or reappointment, highlighting the importance of their work and the value such experience provides.

Acknowledgements

The review team would like to thank members of the BPC and the Secretariat for their constructive engagement throughout the review process, as well as the stakeholders who were interviewed or submitted responses to the online Call for Evidence.

1. Introduction

Aims of the Review

- 1.1 It is Government policy that a Non-Departmental Public Body (NDPB) should only be set up, or remain in existence, where the model can be clearly evidenced as the most appropriate and cost-effective way of delivering the functions in question.
- 1.2 In April 2011, the Cabinet Office announced that all NDPBs still in existence following the Government's review of public bodies in 2010 would have to undergo a substantive review once in a three year cycle. Triennial Reviews have two principal aims, represented by two stages:
 1. To provide a robust challenge of the continuing need for individual NDPBs – both their functions and their form; and
 2. Where it is agreed that a body remain as an NDPB, to review:
 - a. its capacity for delivering more effectively and efficiently, including identifying potential for efficiency savings and its ability to contribute to economic growth; and
 - b. the control and governance arrangements in place to ensure that the public body and the sponsoring department are complying with recognised principles of good corporate governance. This should also include an assessment of the body's performance.
- 1.3 Following the health and social care system reforms, set out in the Health and Social Care Act 2012 and the Care Act 2014, functions and powers were devolved away from the Department of Health (DH) to arm's length bodies and local health and care organisations. As steward of this evolving system, the DH has extended the Triennial Reviews programme to all of its arm's length bodies and Special Health Authorities to provide assurance that the system, and the new and reformed bodies within it, are fit for purpose and operating effectively. The review of the British Pharmacopoeia Commission (BPC), an Advisory NDPB of the Department, was scheduled for 2014/15.

Review Principles

- 1.4 All Triennial Reviews are carried out in line with Cabinet Office guidance "Guidance on Reviews of Non-Departmental Public Bodies", revised in 2014. This guidance states that all reviews should be conducted in line with the following principles:

Challenge: Reviews should take a first principles approach to whether the function of a body is still needed and, if so, what then is the best form for delivery of that function. Reviews should consider efficiency and performance.

Proportionality: Reviews must not be overly bureaucratic and should be appropriate for the size and nature of the NDPB. Where appropriate, reviews of similar bodies should be

combined or clustered to ensure the maximum benefit in terms of streamlining the review process, identifying synergies across departments and NDPBs, and considering efficiency.

Contextual: Reviews should not be undertaken in silos, but should wherever possible be integrated with other departmental policy initiatives.

Pace: Reviews must be completed quickly to minimise disruption to the business and reduce uncertainty about the NDPB's future.

Inclusivity: Reviews must be open and inclusive. The NDPB being reviewed must be engaged in reviews. Users and stakeholders should have the opportunity to contribute to reviews. Parliament should be informed about the commencement and conclusions of reviews. Departmental Select Committees must be given the opportunity to input.

Transparency: All reviews must be announced formally, both to Parliament and to the public. All review reports must be published once clearance has been given by the Minister for the Cabinet Office. The results of reviews must be announced to Parliament.

Process

- 1.5 The review was conducted by the DH Triennial Review Team. The start of the review was announced by Written Ministerial Statement to both Houses of Parliament on 30 October 2014 in tandem with the reviews of the Medicines and Healthcare Products Regulatory Agency ('the Agency'), the National Institute for Health and Care Excellence (NICE), the Commission on Human Medicines (CHM), the Administration of Radioactive Substances Advisory Committee (ARSAC) and the Independent Reconfiguration Panel (IRP).
- 1.6 In accordance with Cabinet Office guidance that Triennial Reviews should be proportionate to the size of the body, the BPC review followed a 'light touch' approach with evidence gathered simultaneously for both stages of the review. It was agreed with the Cabinet Office to 'cluster' the governance arrangements with the parallel reviews of the CHM, another Advisory NDPB of the DH, and the Agency, an Executive Agency of the DH, which oversees and supports both the BPC and the CHM.
- 1.7 The three reviews were overseen by a DH director-level Senior Review Sponsor (SRS). A Project Board made up of the Agency's Chief Operating Officer, the Agency's Director of Policy, a DH Sponsor Team representative and a member of the Triennial Review Team was chaired by the SRS, and was responsible for holding the review team to account and ensuring the final report is balanced and evidence-based.
- 1.8 In line with Cabinet Office guidance, for the larger reviews of the Agency and NICE a Challenge Group was formed to test and challenge the assumptions and conclusions of the review. As the reviews were clustered, the BPC Scoping Document (including Key Lines of Enquiry) and emerging findings were put to the group for comment and approval.

- 1.9 Additionally, a Triennial Review Steering Group chaired by the Director of the DH Assurance Division oversaw the wider review programme of work.
- 1.10 The Terms of Reference, membership of the Challenge Group and the Written Ministerial Statement announcing the review can be found in Annex E.

Evidence and Stakeholder Engagement

- 1.11 A joint Stakeholder Engagement Strategy was produced for the reviews of the BPC, the CHM and the Agency. Extensive input was provided from the bodies under review, and the document was approved by the Project Board and Challenge Group.
- 1.12 Evidence was gathered through a variety of means including desk-based research, submitted evidence, interviews with key stakeholders and a public Call for Evidence. Stakeholder engagement is summarised in Annex D.
- 1.13 The review was announced by Written Ministerial Statement and ministers wrote to the Health Select Committee to inform them of the review.

Background on the BPC

- 1.14 The BPC, appointed under Part 2 of the Human Medicines Regulations 2012, is an Advisory NDPB of the DH. The BPC has three formal functions:
- i. preparing new editions of the British Pharmacopoeia (BP) and the British Pharmacopoeia (Veterinary) and for keeping them up to date under regulation 317 of the 2012 Regulations. The BP is a publication (both print and electronic) of publicly available standards for active pharmaceutical ingredients and finished dosage forms of pharmaceutical products. Where a monograph¹ exists, it is a legal standard for manufacturers to follow when requesting marketing authorisation for their products;
 - ii. providing advice to the United Kingdom delegation to the European Pharmacopoeia Commission (Ph. Eur. 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

¹ A monograph includes the name of the ingredient or preparation, the Definition, a series of tests, procedures for the tests, acceptance criteria and storage and labelling requirements where necessary. These tests and procedures often require the use of official Chemical Reference Substances such as the BP Chemical Reference Substance.

- iii. selecting or devising names to be used at the head of monographs, which are subsequently published as British Approved Names (BANs), under regulation 318(2) of the 2012 Regulations.

Historical Context

- 1.15 The BP was formed from the merger of the London, Edinburgh and Dublin Pharmacopoeias in 1864. Between 1864 and 1971 the BP was produced by the General Medical Council. With the implementation of the 1968 Medicines Act, the publication became the responsibility of the BPC, a Section 4 Committee under the Act, which published the BP on behalf of Health Ministers. With the implementation of the Act the BP staff became a part of the DH.
- 1.16 The 1987 Cunliffe report, which led to the formation of the Medicines Control Agency (MCA) as the UK Licensing Authority, recommended that the BP should be transferred to the Royal Pharmaceutical Society but this was rejected. With the formation of the MCA in 1989, the Secretary and Scientific Director and the BP Laboratory Director became employees of the MCA but all other costs were met by the DH.
- 1.17 In 1999, DH commissioned Roy Cunningham to review the role and operation of the BPC. It was agreed that the BP publication should continue but that the DH would no longer fund it. In 2003, with the merger of the MCA and Medical Devices Agency (MDA) to form the Medicines and Healthcare Products Regulatory Agency, the BP became a part of the trading fund and thus a business unit of the Agency. A business case showing that the BP would operate as a self-sufficient unit was agreed with HM Treasury. The BP was required to cover the costs and expenses of the BPC and its committees, the BP Secretariat at the Agency, the BP Laboratory and the expenses and fees of UK members of Ph. Eur. Groups of Experts from the income it generated from the royalties on the sale of the publication, and from the sales of BP chemical reference substances (BPCRS).
- 1.18 The Government undertook a review of public bodies and functions in 2010, encompassing more than 900 public bodies across 17 departments. It was decided that the BPC should continue as an Advisory NDPB.
- 1.19 In 2011, the then BP Secretary & Scientific Director reviewed the BP's national and international role, concluding that that it was a valuable international asset and there was strong evidence to support a ten-year publication programme for the BP.

Structure

- 1.20 The BPC has 17 members appointed by Ministers and meets 3 times a year. The work of the BPC is supported by 9 Expert Advisory Groups² (EAGs), 6 Panels of Experts³ and 2 Working Parties⁴ collectively comprising approximately 100 experts and meeting sixteen times in 2014.
- 1.21 The Commission undertakes the key work of the organisation, it does not simply provide oversight, as is the case for other types of public bodies. Scientific advisory bodies often need larger boards in order to cover the range of expertise necessary to perform the work effectively.
- 1.22 The annual spend of the Commission, comprising attendance fees, travel & expenses and hospitality, is approximately £60,000.
- 1.23 The BPC Secretariat ('the Secretariat') is part of the Inspection, Enforcement and Standards Division of the Agency.

² Under regulation 14 of Part 2 of the 2012 Regulations, an advisory body may, with the approval of the Licensing Authority (the Agency), appoint one or more sub-committees, or the Licensing Authority may direct an advisory body to appoint an EAG to advise on specific matters. They are chaired by a member of the BPC.

³ The remit of the Panels mainly covers European Pharmacopoeia specifications and advice is normally sought by correspondence.

⁴ There are currently two Working Parties advising the BPC on excipients and Analytical Quality by Design. Working Parties are normally formed on an ad hoc basis to cover particular areas of interest and provide specialist advice.

2. The Review: Stage One

- 2.1 Stage One of the review addresses two fundamental questions: do the functions provided by the BPC still need to be performed; and if they do, what is the appropriate delivery model for those functions?

Functions

- 2.2 The BPC provides three main functions: producing and updating the BP, providing advice to the UK Delegation to the Ph. Eur. Commission and selecting or devising BANs.

The BP

- 2.3 The BP is published annually in August, with an effective date of 1 January the following year. It is available as a package containing the six volumes currently comprising the BP 2015, the one volume of the British Pharmacopoeia (Veterinary) 2015 and access to the electronic versions of both publications (online and single-user USB format). It contains almost 3500 monographs for substances and articles used in the practice of medicine⁵ and over 400 infrared reference spectra⁶, together with appendices and supporting material.
- 2.4 Article 63(1) of the 1973 European Patent Convention specifies the term of a European patent to be 20 years from the date of filing of the application and article 63(2b) allows for an extension under national law to compensate for pre-marketing regulatory approval. Once the patent term of a drug expires, the drug loses its legal protection and can be synthesised as a generic medicine. Any manufacturer is then free to apply for a marketing authorisation. Generic drugs comprised 22% of the UK medicines in 2011, and this is expected to increase to 27% by 2020.⁷
- 2.5 The work of the BPC is to create monographs for medicinal substances either off, or coming-off patent, or to revise existing monographs reflecting new methodologies, processes or in response to problems. Inclusion of monographs in the BP creates a legally binding, up-to-date set of minimum standards, which ensure the safety and quality of medicines available in the UK.

⁵ Monographs exist for active substances, excipients (pharmacologically inert ingredients used in medicines) and finished products.

⁶ Used to identify medicinal substances.

⁷ PwC (2012) 'From vision to decision Pharma 2020' (available online).

Advice to the European Delegation

- 2.6 The European Pharmacopoeia Convention was established in 1964 to create harmonised European standards for medicinal substances. The Ph. Eur. Commission, which develops the European Pharmacopoeia (Ph. Eur.), is formed of delegations from the 37 signatory Member States.
- 2.7 Further to the UK delegation on the Ph. Eur. Commission, a number of BPC and EAG members participate in the Groups of Experts and Working Parties.
- 2.8 The BP Laboratory provides technical support for the work of the Ph. Eur. Commission, participating in the voluntary scheme to validate draft European monographs and providing technical data in support of the elaboration of new monographs and revision of existing monographs.

BANs

- 2.9 The third responsibility of the BPC is to select or devise names to be used at the head of monographs, which are subsequently published as BANs.
- 2.10 A BAN is the official non-proprietary name (also known as a generic name) given to a pharmaceutical substance for use in the UK (e.g. 'paracetamol' or 'ibuprofen'). BANs are short, distinctive names for substances where the systematic chemical or other scientific names are too complex for convenient use⁸. BANs are adopted where required for those substances that are subject of a BP monograph and for products with a UK marketing authorisation.
- 2.11 The BANs are published every 5 years, with supplements issued annually at the same time as the BP in August.

International Collaboration and Harmonisation

- 2.12 In addition to these three responsibilities, the BPC is involved in a range of international collaboration and harmonisation activities. Harmonisation is the process of developing common methods, standards, monographs and good working practices across different international jurisdictions. This activity includes formal collaboration through establishing Memoranda of Understanding with equivalent international bodies, informal collaboration and information sharing, supporting monograph development for the WHO International Pharmacopoeia and nomenclature work.

⁸ For example, the chemical name of paracetamol is 'N-(4-Hydroxyphenyl)acetamide'.

Assessment: are the functions still required?

2.13 The BAN function fulfils a statutory requirement of the 2012 Human Medicines Regulations. The evidence suggested that the function needs to be delivered to ensure a consistent approach to the naming of pharmaceuticals in the UK. This implicitly supports public and professional confidence in medicines regulation.

2.14 **Assessment: BAN function is required.**

2.15 The function of providing advice to the UK Delegation to the Ph. Eur. Commission is an international legal requirement under the Convention on the Elaboration of a European Pharmacopoeia.

2.16 The Medicines Directive EU 2001/83 requires pharmaceutical products to comply with the monographs of the Ph. Eur. or, where no such monograph exists, that of a national pharmacopoeia. In other words when the European Pharmacopoeia publishes a monograph for a particular ingredient or finished product it replaces any pre-existing version in the national pharmacopoeias of member states. Therefore the UK has a vested interest in ensuring that the output of the Ph. Eur. Commission is of a high standard by contributing a delegation of experts.

2.17 Having a voice in those proceedings ensures decisions that are taken are in the interests of UK industry and the public.

2.18 **Assessment: advice to the UK delegation of the Ph. Eur. Commission function is required.**

2.19 The processes of harmonisation at the European and global level have implications for the BP as a national pharmacopoeia. In particular, given the legal precedence of the Ph. Eur. monographs over the BP monographs described above, by supporting the elaboration of the Ph. Eur. the unique content in the BP diminishes. Taken to the extreme, the BP would eventually become obsolete if the Ph. Eur. expanded to include the same finished product monographs.

2.20 One of the key lines of enquiry of the 1999 Cunningham Review was to assess whether there was still a role for the BP given the continuing development of the Ph. Eur, concluding that finished product monographs were unlikely to form part of the Ph. Eur. in the foreseeable future. By the time of the next review of the BP in 2011, the Ph. Eur. still had no mandate or programme to elaborate monographs for finished products.

2.21 The European Medicines Agency (EMA) was established on the 26 January 1995, introducing the Centralised Product⁹ authorisation procedure for human and veterinary

⁹ This procedure results in a single marketing authorisation that is valid in all EU countries, as well as in the European Economic Area (EEA) countries Iceland, Liechtenstein and Norway.

medicines. As described, patent terms are typically twenty years which means those products marketed through the European procedure are reaching the stage when generic versions can be developed.

- 2.22 Recently the Ph. Eur. made the decision to extend its remit of publishing drug substance monographs to drug product monographs and has instigated a Working Party to elaborate monographs on finished dosage forms. The current proposal is to publish a limited number of finished product monographs.
- 2.23 Since one of the BP's strengths lies in its set of finished product monographs, this raises the question that if the Ph. Eur. remit extends to tackling all finished products it could potentially obviate the need for the BP. The issue can be separated out into implications for medicinal products newly coming off patent, and those for which the patent term has already expired.
- 2.24 For products coming off patent, a number of stakeholders questioned the Ph. Eur.'s capacity to take on preparation of finished product monographs. Following its decision to expand into finished products, it had initially looked at developing monographs for established (off-patent) drugs, for which there are multiple manufacturers of finished products. However, it has since decided to focus on drugs coming off patent, for which there is a single finished product manufacturer.
- 2.25 Beyond this there is the subset of drugs which are off-patent but have no monograph yet. There are currently ~600 monographs in the BP work programme (excluding revisions). Using the current average rate of 40 new monographs a year (see Annex C), this is 15 years work even if the Ph. Eur. takes all products newly coming off patent.
- 2.26 Even if the Ph. Eur. did have the capacity to develop finished product monographs for all drugs coming off patent, and had begun to tackle preparations for existing off-patent drugs, that still leaves the 1421 existing finished product monographs in the BP. Interviews suggested that it was even more difficult to harmonise existing monographs than agreeing one for a new generic product. Harmonisation is difficult to achieve due to differences in legislation, minimum standards, pharmacopoeial operations and resources. Large pharmaceutical companies and regulators would prefer harmonisation, but not at the cost of relaxing standards to the lowest common denominator. There is a trade-off between speed of harmonisation and getting the right approach. Additionally there are questions around the value of doing the work again.
- 2.27 If the BP ceased to be published, the Ph. Eur. would provide standards for the majority of pharmaceutical ingredients employed in medicines used in the UK. However, there would be no published finished product monographs providing enforceable standards for the large majority of formulated medicines. This would impact on the UK and the other (mainly Commonwealth) countries which have the BP as a legal standard. There was a range of views on how long it would take for harmonisation of finished product monographs with the Ph. Eur. to significantly impact the work of the BPC, but most agreed it was likely to take a decade or more.

2.28 Interviews also highlighted additional benefits of having a national pharmacopoeia. The European process is slower since it involves the 37 signatory states. Comments also reflected that there is national variation in what drugs are used: Germany and France for example have a greater focus on herbal and homoeopathic products than the UK. A national pharmacopoeia enables prioritisation of standards which are more relevant to that nation's actual usage.

2.29 Assessment: whilst there is uncertainty over the long-term future, the BP function is required in the medium term. Stopping the functions now would result in no recognised standards for the majority of finished pharmaceutical products.

2.30 Finally, with regard to international collaboration and harmonisation a number of stakeholders doubted whether there would ever be a global, harmonised, pharmacopoeia. However, in the context of globalisation and an expansion in international trade, quality standards are a vital instrument for registration, market surveillance, and free movement and trade of medicines. While some stakeholders expressed doubts that harmonisation will ever be achieved, it is an ambition that many would like to see happen and would help to reduce costs in producing medicines, and therefore costs to purchasers.. The BPC is well placed to influence moves to further harmonisation through international collaboration.

2.31 Assessment: the international collaboration and harmonisation function is required.

Form

2.32 It is Government policy that NDPBs should only be set up, or remain in existence, where the NDPB model can be clearly evidenced as the most appropriate and cost-effective model for delivering the function in question. Cabinet Office guidance has a checklist of delivery options reproduced in Table 1. Some of the options were rejected early as being inappropriate. For those which remained, further evidence was gathered from stakeholder interviews and the Call for Evidence.

Delivery option	Initial Assessment
Abolish	Consider – are the functions required?
Move out of central government	Rejected – works closely with other central government bodies, moving to a local level would be ill-suited with its international role.
Commercial model	Consider – in particular a not-for-profit model, as used by the United States Pharmacopeia Convention.
Bring-in house	Consider – the BPC was funded by the Department until 2003.
Merger with another body	Consider – in particular becoming an Expert Committee of the Agency.
Less formal structure	Rejected – the Cabinet Office Categories of Public Bodies list a number of options for less formal advisory bodies: Temporary Advisory Bodies, Task Forces and Reviews, Stakeholder Groups/Forums, Public Sector Working Groups and Internal Advisory Committees. All were rejected as the functions require long-term, specialist and impartial advice.
Delivery by a new Executive Agency	Rejected – the BPC does not deliver services. It is very small, costs very little and does not employ any staff.
Continued delivery by an NDPB.	Consider – does it meet one or more of the three tests.

Table 2.1: Checklist of Delivery Options

2.33 As detailed in the Introduction, over the course of the past 150 years the BP has been delivered through a number of different forms. This review considered abolishment (through the ‘functions’ component of Stage One), a commercial model, bringing in-house, merging with another body or continued delivery as an Advisory NDPB. An international comparison is included for reference in Annex B.

Commercial Model/ Not-for-profit

2.34 The majority of responses received opposed commercialisation, with none in favour. Of potential commercial models, the review primarily considered a not-for-profit model¹⁰. The

¹⁰ Chapter 6 of HM Treasury’s Managing Public Money guidance makes clear that in order to charge more than full cost recovery for a public service, ministers must choose to do so, parliament has to consent and there must be full disclosure.

United States Pharmacopeia (USP) is the only pharmacopoeia to operate as a 'scientific non-profit.' Again, the majority of responses opposed a not-for-profit model. The reasons are cited below.

- 2.35 In order to develop monographs and establish the associated BP chemical reference standards, the BPC relies on data and reference material from industry. There is no legal obligation to provide information: the BPC relies on voluntary cooperation from industry. For innovative companies in particular, getting this cooperation is already proving challenging because companies don't necessarily want to reveal this information, but equally don't wish to see an incompatible standard being set.
- 2.36 A number of comments that were received expressed concern that a commercial approach would risk driving inappropriate behaviour for a body concerned with promoting public health. In particular, a commercial model would incentivise (international) expansion and initiatives that are designed to increase the requirements and sales of reference standards over what is considered its primary goal of quality standards.
- 2.37 Another concern was that a complete separation from the Licensing Authority (i.e. moving out of government) would reduce the effectiveness of the BPC in producing appropriate standards. In the USA, though the USP works closely with the FDA, it has a more limited relationship and is not privy to internal discussions and information.
- 2.38 **Assessment: a commercial model is not appropriate.**

Bring in-house

- 2.39 As noted in the Introduction, the 1987 Cunliffe report recommended the BP become the responsibility of the Royal Pharmaceutical Society, but this was rejected and it was moved into DH.
- 2.40 All stakeholders who expressed a view on this option felt that moving the functions back into DH would have a negative impact on the standard-setting work. Most importantly, the alignment between the BPC and the Agency avoids the establishment of inappropriate specifications in monographs in relation to those approved by the Licensing Authority. However, an additional risk of moving into the DH is the BPC losing the ability to deliver its functions without compromise and make the most appropriate decisions.
- 2.41 Locating alongside the Agency provides efficiencies through optimising experts and laboratory activity. Additionally, the Agency can call on expertise to advise in the event of incidents. An example cited was during the BSE crisis, when there was a concern of a possible risk of transmission of the BSE agent in gelatin products. Gelatin can be used as an excipient (a pharmacologically inactive substance) in capsules, and the Agency was able to draw on the expertise of BPC and CHM members.

2.42 Finally, many stakeholders emphasised the requirement for the functions to be delivered independently of ministers and political considerations, see the 'Three Tests' section below.

2.43 Of the comments received, none advocated a move into the DH.

2.44 Assessment: moving in-house is not appropriate.

Merger with another body

2.45 This option was considered as part of the 2010 review of public bodies by the Cabinet Office. As a result of this review, the Advisory Board on the Registration of Homeopathic Products and the Herbal Medicines Advisory Committee were both merged into the Agency as Expert Committees. The BPC and CHM both retained their Advisory NDPB status.

2.46 Merging the BPC into the Agency would make little difference in terms of working practices. The BPC Secretariat is part of the Inspection, Enforcement and Standards Division of the Agency and Commission meetings are held at the Agency's Headquarters in London.

2.47 That said, the vast majority of comments stated a merger would still be inappropriate. In the previous section it was noted that it was important for close working with the Agency to ensure standards were set that were acceptable to the Agency in its capacity as the Licensing Authority. There are also a number of informational and financial synergies (e.g. the laboratory contract, shared IT and meeting arrangements) between the BPC and the Agency.

2.48 However, standards also need to be developed in partnership with industry to ensure suitable quality. Companies will have developed and produced a medicinal product over the twenty-year patent term and setting standards without consideration to the existing production and quality control methods risks excluding existing products or introducing additional hurdles to industry. Companies would also be reluctant to provide data and reference materials which the BPC relies on to ensure quality standards if they felt that it would result in an incompatible standard being developed. In order to ensure compatible standards, approximately half of BPC members are drawn from industry.

2.49 This need for expert industry involvement and Licensing Authority input requires careful handling to ensure public confidence in the licensing process is not undermined by perceived conflicts of interest (since the regulator needs an appropriate degree of separation from industry).

2.50 Similarly, a merger with the other Human Medicines Regulations 2012 Advisory Body, the Commission on Human Medicines (also an advisory NDPB) would also be inappropriate

both because of the risk of a perception of conflicts of interest and because there would be no additional synergies to be gained.

2.51 Having previously ruled out a commercial model or bringing in-house, the need for proper separation between industry and the regulator leaves two options. The first is removing industry experts from the BPC. Beyond risking setting inappropriate standards for industry as discussed above, a merger would also change industry's perception of the process. In order to obtain the required data and reference materials from industry, the BPC needs to be seen to be supporting them as well as the regulator.

2.52 Assessment: merging with another public body is not appropriate.

Continued delivery as an NDPB

2.53 The second option is continued delivery as an Advisory NDPB. This model enables the BPC to exploit potential efficiency savings (e.g. sharing laboratory facilities with the Agency) and facilitates close working with both the industry and the Agency in its Licensing Authority capacity. The formal separation of standard setting from the Agency in its industry regulator capacity maintains public and industry confidence.

2.54 The value the BPC's independence offers is that it thinks flexibly and can deliver its functions without compromise to other aims. The BPC works closely with the Agency but its independence is also important in ensuring that its priorities are not lost within the larger organisation.

2.55 No comments on form were received calling for anything other than continued delivery as an Advisory NDPB.

2.56 So, in order for the BPC to set quality standards which are acceptable to both the Licensing Authority and industry, the optimal form for the BPC is in a position close to the Agency whilst being independent of it. The Advisory NDPB model facilitates this, as well as harnessing potential information, communication, laboratory and expertise synergies.

2.57 Assessment: continued delivery as an Advisory NDPB is the most appropriate model.

The Three Tests

2.58 Government policy states that if a public function is needed, it should be undertaken by a body that is democratically accountable at either the national or local level. A body should only exist at arm's length from government as an NDPB if it meets one or more of three tests:

- i. it performs a technical function which needs external expertise to be delivered – for example a function that could not be delivered in a department by civil servants, and where it would not be appropriate to recruit staff with the necessary skills to the department to undertake the function;
- ii. its activities need to be, and be seen to be, delivered with absolute political impartiality – for example where political involvement, or perceived involvement, could adversely affect commercial considerations, growth, or the financial markets, or could lead to criticism of partiality; or
- iii. it needs to act independently of Ministers to establish facts and/or figures with integrity – for example in the compilation of National Statistics.

2.59 The BPC meets the first test. Members are appointed on the basis of their expertise in relevant specialist fields. This expertise could not be found within the civil service, and the infrequent meetings and high market rate for their skills would mean employment is neither possible nor appropriate.

2.60 The BPC meets the second test. As established, the BPC relies on buy-in from industry to provide the data and reference materials substances and needs assurance that the process is independent of political considerations. Public confidence in medicine standards is ensured through political impartiality.

2.61 The BPC meets the third test. The Commission considers and produces scientific data relating to the ingredients of medicines (monographs). These must be followed by any companies producing medicines for sale in the UK. In order to fulfil its implicit public health function, it is necessary that the scientific work of the BPC is independent of ministerial influence. A recent example of a politically sensitive topic considered was e-cigarettes. Trust in public standards derives from recognition of independent advice and expertise.

2.62 All stakeholders who expressed a view suggested the BPC met all three tests.

2.63 Assessment: the BPC meets all three tests.

3. Conclusions of Stage One

- 3.1 Stage One of the review examined the functions and form of the BPC. The BPC has 3 main functions which together perform an implicit role protecting public health of UK and European citizens by establishing public standards for pharmaceuticals.
- 3.2 The BAN function is statutory and ensures a consistent approach to the naming of pharmaceuticals in the UK and is required.
- 3.3 The advice to the UK Delegation to the European Pharmacopoeia Commission is an international commitment. Since European monographs take precedence over national ones, contributing ensures the quality of the standards and that decisions which are taken are in the UK interest.
- 3.4 Delivery of the BP is a statutory function. The Ph. Eur. has recently extended its remit into finished product monographs, a traditional strength of the BP. If this continued, there are questions as to whether the BP would eventually become obsolete. However, stakeholders doubted the capacity of the Ph. Eur. to take on finished product monographs for all drugs newly coming off patent, and this would still leave monographs for drugs off-patent, requiring either harmonisation or development of monographs. The expectation is that the BP will not be significantly affected for a decade or more. Whilst the longer-term is unclear, in the medium-term stopping functions would result in no published standards for a large number of generic pharmaceuticals in the UK, and so it is required.
- 3.5 The BPC also engages in wider international collaboration and harmonisation activity. This helps improve the global standard of pharmaceutical products, and is required.
- 3.6 Given that the functions are still required, the review went on to consider the most appropriate delivery model. After ruling out inappropriate models, the review considered in detail: commercial models, moving in-house, merger with another body and continued delivery as an NDPB. In order for the BPC to set quality standards which are acceptable to both the Licensing Authority and industry, the optimal form for the BPC is in a position close to the Agency whilst being independent of it. The Advisory NDPB model facilitates this, as well as harnessing potential information, communication, laboratory and expertise synergies.
- 3.7 **Stage One finding: the functions provided by the body are still required and the most appropriate form is an Advisory NDPB. The BPC meets the three tests to remain an NDPB.**
- 3.8 **Recommendation 1: the BPC should continue to deliver its existing functions as an Advisory NDPB.**

4. The Review: Stage Two

- 4.1 If the outcome of Stage One is that the functions should still be performed by the existing NDPB, Stage Two examines the NDPB's capacity for delivering more effectively and efficiently, as well as the control and governance arrangements in place to ensure that the public body and the sponsoring department are complying with recognised principles of good corporate governance. It includes an assessment of the body's performance.

Efficiency

- 4.2 As an Advisory NDPB, the BPC employs no staff and has no physical assets so the scope for efficiency savings is limited.
- 4.3 As discussed in Stage One, the BP was incorporated into the Agency trading fund in 2003. The costs and expenses of the BP Commission and its committees, the BP Secretariat at the Agency and the BP laboratory are recovered from the income it generates from the royalties on the sale of the BP and from the sales of BP chemical reference substances (BPCRS). This means that financial matters are handled by the BPC secretariat, supported by the Agency. The BPC Secretariat is assigned an annual budget as a subset of the Inspection, Enforcement and Standards Division and can bid for additional funds for particular projects.
- 4.4 There are three ways to increase efficiency: increasing income, decreasing costs or increasing the quality or level of output from the same resources.
- 4.5 The BPC provides a public service in setting standards through preparation of the BP. Chapter 6 of HM Treasury's Managing Public Money guidance makes clear that the scope for charging more or less than full cost recovery requires ministers choosing to do so, Parliament consenting and full disclosure. The Office of National Statistics normally classifies charges higher than the cost of provision, or not clearly related to a service to the charge payer, as taxes. Therefore there is no practical ability to increase income above costs.
- 4.6 If sales of the BP or reference substances were to increase, the price of the BP and reference substances would have to be adjusted accordingly to ensure that income generally equated to full cost recovery, but this should still be considered an efficiency saving (as lower costs are passed on to users of the BP).
- 4.7 The following sections examine the publishing and laboratory contracts, Commission costs and other efficiencies.

Publishing Contract

- 4.8 Prior to 2002 the BP was published by HM Stationery Office which became The Stationery Office (TSO) on privatisation. TSO published the BP under a licensing agreement between 2002 and 2007. In 2006, following an OJEU tender exercise, TSO was again awarded the publication contract, and were re-awarded the contract following a further tender exercise in June 2011. The current contract with TSO runs from 2011-2016 and is completed with the publication cycle of the BP 2017.
- 4.9 The contract provides an annual Guaranteed Royalty Payment with an additional Royalty if sales exceed the agreed threshold.
- 4.10 The BPC Secretariat is actively managing the contract and work jointly with TSO to continuously improve performance.
- 4.11 The current contract with TSO comes to end with the BP 2017 (which will be published in August 2016). During the last tendering exercise a number of publishers were approached and four eventually bid (TSO, Continental Data Graphics, Pharmaceutical Press and the Royal Society of Chemistry). As the incumbent, TSO were well placed to retain the contract due to their knowledge and experience of the BP publication process. Ensuring a competitive tendering process is clearly a key element of obtaining the best value for money and it isn't clear that maximum market interest was generated from appropriate potential bidders.
- 4.12 Recommendation 2: in order to deliver best value, the BPC Secretariat and the Agency should ensure they generate as much competitive interest in tendering as possible during the next exercise, and that the appropriate support or advice is sought from the Crown Commercial Service.**
- 4.13 At the time of the last tendering exercise, the Agency did not have the resources or expertise to bring publication in-house. A feasibility study was carried out and it was not considered cost-efficient for the BP to carry out all the functions of a publisher. The ready availability of publishing software, particularly for online publications, may well have changed this balance, and there could be scope to bring the digital element of the BP in-house. This would require an in-depth feasibility study to examine impact on the business model, the Quality Management System and sales administration. Given the next tendering process is already underway, the review team recommend that consideration should be given to bringing at least the digital element in-house over the course of the next contract.
- 4.14 Recommendation 3: in addition to managing a competitive tendering process as referred to in Recommendation 2, within the lifetime of the next contract the Secretariat should explore the feasibility of bringing the digital element of the BP in-house (consulting the Government Digital Service as appropriate).**

4.15 The review team received a suggestion that the BP increases the compliance period (the time between a pharmacopoeia's publication and its effective date) to 6 months in line with other major pharmacopoeias. The BP is published in August ahead of the effective date of 1st January, a compliance period of 4 months. The Ph. Eur. and USP have compliance periods of 6 months, though the Japanese pharmacopoeia's is 0-1 months (see the international comparison in Annex B). The timings of publication and the effective date are written into the publishing contract and therefore can't be changed until its expiry after BP 2017. The review team considered that the Secretariat were already stretched to deliver to the existing timetable and so this report doesn't make any recommendation one way or the other.

Laboratory Contract

4.16 The BP Laboratory provides technical and laboratory validation of new and revised monographs, and establishes and supplies BP chemical reference substances (BPCRS) as primary standards used in the application of the BP monograph methods and tests. Sales of BPCRS are the other source of income for the BP.

4.17 The BP Laboratory was formerly sited at Canons Park, north London. In 2005 the site was closed and the laboratory was co-located with the Agency's Official Medicines Control Laboratory (OMCL) at the Laboratory of the Government Chemist (LGC) in Teddington. When both the OMCL and BPC contracts expired at in 2011, a joint contract with LGC was signed ending in 2021.

4.18 The contract stipulates a minimum of 30 new monographs a year, 140 re-tests of existing BPCRS stocks, 60 analyses of new and replacement BPCRS stocks, 10 technical queries and revisions and a target stock availability of above 96%.

4.19 The contract is under strain on a number of fronts. The targets were based on a much smaller catalogue, but each year approximately 30 new samples are added. The strong sales of BPCRSs have put pressure on stock levels and squeezed resources available for monograph development.

4.20 Monograph development often relies upon data provided by the manufacturer of a product, which then has to be tested in the laboratory. There is an iterative cycle between the laboratory, EAGs and the Commission. Ultimately, the review team considered that the structure of the laboratory contract limits the amount of work which can be done by the BPC overall. The Agency is working with LGC to update and revise the contract terms.

4.21 The National Institute for Biological Standards and Control (NIBSC), which merged with the Agency in 2013, has laboratory facilities of a similar size to the LGC's Teddington site. There is increasing collaboration between the BPC, NIBSC and OMCL laboratories which has enabled synergies to be harnessed. For example, gas chromatography (a chemical technique) has been moved to the LGC laboratory as NIBSC's focus on biological techniques means it is not used regularly.

Commission Expenses

- 4.22 Under Schedule 2 of the 2012 Human Medicines Regulations, ministers may pay to the members of each advisory body and expert advisory group such remuneration (if any) and such allowances as may be determined by the Ministers with the consent of the Treasury.
- 4.23 According to the Cabinet Office Public Bodies 2014 publication, the Chair's attendance fee (£500 a day) is at the higher end of the spectrum for Advisory NDPBs; there is no benchmarking data available to compare the member attendance fee (£325). These fees have been unchanged for more than three years. The total annual cost for BP and Ph. Eur. meetings (including expenses) is approximately £60,000.
- 4.24 The fees are a small fraction of the consulting rate members could expect for their expertise (£300-400 an hour). In addition, there is a large amount of reading and preparation work for meetings for which no additional remuneration is provided. There is no sense in which Commission members might be considered to be enticed by the attendance fees. Members are providing their time and expertise due to a combination of public service ethics and the prestige that serving on such a Commission brings. These are the key recruitment tools for future members.
- 4.25 Overall, the fees represent exceptional value for money for the calibre of expertise in the BPC. Members are very dedicated and have a strong sense of public service.

Other Efficiencies

- 4.26 The Secretariat are proactive in identifying potential efficiencies, including savings through streamlining of laboratory and publishing processes, electronic integration with the Ph. Eur. (which is reproduced in the BP), promoting the BP in conjunction with TSO at international events and reviewing the need for EAGs.
- 4.27 The annual number of Commission meetings was reduced from four to three in 2008, which was considered an appropriate number of meetings by stakeholders. Whilst there are potentially small efficiencies to be made around timetabling of meetings, this is complicated by Ph. Eur. meeting dates only being announced one year in advance, and knock-on implications for EAG meetings. The Secretariat is exploring what can be done.
- 4.28 Meetings are scheduled to begin in the late morning, which reduces the need for overnight expenses. Paperless working is being trialled.
- 4.29 Teleconferencing is used where appropriate, for example for the UK Delegation briefing meetings. Stakeholders agreed that teleconferencing for Commission and EAG meetings would negatively affect the contributions of Commissioners and would be detrimental to EAGs due to the technical nature of proceedings.

Contribution to Economic Growth

- 4.30 The 1999 Cunningham Review highlighted the role of the BP in facilitating a competitive market for generic drugs as well as overseas development in view of its importance to Commonwealth, emerging, and Eastern European countries.
- 4.31 Whilst a detailed analysis of the economic contribution of the BP was beyond the scope of this review, stakeholders did highlight a streamlining role of the BP. As discussed in Stage One of the Report, through setting minimum standards for generic medicines the burden on both industry and the Agency is reduced. Manufacturers need to do less work to demonstrate the quality, safety and efficacy of their product, and the assessment, by the Agency of Marketing Authorisation applications is facilitated through standardisation of tests assays and limits.
- 4.32 Additionally, through facilitating a competitive market of safe generic products, costs are reduced for the NHS and the public.

Governance

- 4.33 Cabinet Office guidance states that departments must assess the controls, processes and safeguards in place in the NDPB against the principles and supporting provisions set out in the code of good corporate governance.
- 4.34 The full assessment for each principle is detailed in tabular form in Annex A. Overall the BPC is fully compliant with two, mostly compliant with three and partially compliant with one principle. Non-compliance is acceptable where this is justified by the particular circumstances and the appropriate alternative arrangements are in place. This section highlights themes emerging from stakeholder evidence.

Accountability

- 4.35 **Assessment: the BPC is mostly compliant.**
- 4.36 There are clear lines of accountability for members of the BPC: Commissioners are annually appraised by the Chair, the Chair is annually appraised by the Chair of the Agency and the Chair of the Agency is accountable to ministers.
- 4.37 As established in Stage One, the independence, and perceived independence, of the BPC is necessary for industry and public confidence in the standard setting process. Given the close working relationship between the BPC and the Agency, and the BP's incorporation in the trading fund, it is important that lines between the BPC and the Agency do not become too blurred.
- 4.38 Secretariat staff are currently appraised as part of the Inspections, Enforcement and Standards Division of the Agency. This is appropriate since the Secretariat are employees of the Agency. However, there is no formal mechanism for seeking BPC members' views on Secretariat performance. Since delivery of the functions of the BPC is heavily dependent upon the work of the Secretariat, it is appropriate that Commission members should have an opportunity to contribute to the appraisal of staff.
- 4.39 **Recommendation 4: the BPC Chair should be formally consulted as part of individual Secretariat staff appraisals, with the views of other members of the BPC to be sought as appropriate.**
- 4.40 Under regulation 317(1) of the Human Medicines Regulations 2012, the BPC's remit is to prepare or cause to be prepared editions of the British Pharmacopoeia. Under regulation 317(4) it is the responsibility of ministers to arrange for the publication of the BP. This responsibility is delegated to the Secretariat through the Agency.
- 4.41 Unusually for Advisory NDPBs, the scientific advice is published and available for purchase by industry and other groups. This means there are greater financial and strategic considerations than is usual for Advisory NDPBs.

- 4.42 Given that members are not full-time employees of the body, and are appointed due to their expertise in areas relevant to monograph development, it is appropriate that financial and strategic considerations are handled by the BPC Secretariat with support from the Agency. However, as an independent organisation, Commission members should have the opportunity to input into these matters, especially given their diverse experience across different fields.
- 4.43 As an example, the BPC Secretariat produced a comprehensive five-year strategy document that was presented to members with some of the financial detail removed. The review team considered that this information would have been relevant for consideration by Commission members. Given that members have a vested interest in the delivery of the BP function, as well as its future role and form (which it is their responsibility to prepare), it is appropriate that they be given the opportunity to shape its strategic direction.
- 4.44 **Recommendation 5: The BPC Secretariat should consult the BPC Chair/Vice-Chair regarding strategic and financial considerations impacting the BPC, and together determine the degree of detail relevant for consideration by Commission members to inform their input.**

Role of the Sponsoring Department

4.45 **Assessment: the BPC is partially compliant.**

4.46 The DH delegates scrutiny and oversight to the Agency, an Executive Agency of the DH..

Role of the Chair

4.47 **Assessment: the BPC is fully compliant.**

4.48 In particular, the current Chair has encouraged discussion at Commission meetings ensuring expertise is utilised to its full potential and proceedings are not perceived as a rubber-stamping exercise.

Role of Other Members

4.49 **Assessment: the BPC is fully compliant.**

4.50 Ultimately the credibility of the BPC derives from its members. All stakeholders who expressed a view on this issue thought that there was a good balance of backgrounds and expertise. The BPC and Secretariat work hard to ensure optimal coverage. There are two lay members on the Commission, which reportedly works well.

- 4.51 However, recruitment of Commissioners is challenging as the pool of qualified people for their specialist work is very limited, and becoming smaller over time.
- 4.52 One major concern is the number of appointment terms coming to an end at the end of 2015. Initial appointment terms are usually for 4 years (12 meetings). Under the Code of Practice issued by the Commissioner for Public Appointments the maximum period any member can serve is 10 years (although there is an exemption in place to allow those members who are also members of the UK Delegation to the European Pharmacopoeia Commission to serve for 16 years).
- 4.53 At the end of 2015, 7 members will have served for 10 years; of these the Vice-Chair is eligible for a further reappointment (as he is a member of the UK Delegation to the European Pharmacopoeia Commission), but 6 members will not be eligible for reappointment. This will mean a substantial loss of experience and expertise and leaves a minimum of 6 vacancies that will need to be filled from a limited pool of candidates. At the same time 8 members will reach the end of their current term of office; these members will have served varying terms (between 4 and 8 years) and are thus eligible for reappointment.
- 4.54 If only a limited number of reappointments will be allowed, this means that there is the potential for additional vacancies to arise. Given the small pool of suitably qualified and experienced people, the requirement for continuity of service and the fact that new Commissioners gain regulatory experience over time (i.e. there is a period of learning before they can contribute effectively), losing a significant proportion of highly experienced, committed members at once is detrimental to delivering the BPC's outputs. The issue is being discussed with a view to adding it to the Agency's risk register.
- 4.55 The BPC and Secretariat have taken actions to address these issues. The Secretariat are developing a plan of action on increasing applications. 60 new members have joined EAGs this year which will assist succession planning. Additionally Commissioners approach contacts and refer them to the application process and mention the BPC's work in lectures they give. However, this is not the first time this problem has occurred and will need to be addressed.
- 4.56 **Recommendation 6: BPC Secretariat and the DH Appointments Team to meet post-election to agree an appropriate model for future appointments. Ahead of this the BPC should gather data on the pool of qualified people being targeted.**
- 4.57 **Recommendation 7: appointment term end dates should be clustered into small groups across a spread of years to ensure continuity of service.**

Communications

4.58 **Assessment: the BPC is partially compliant.**

4.59 All stakeholders who expressed a view on transparency thought the BPC operated transparently.

4.60 Two sets of minutes are produced. Web minutes have commercially sensitive data removed.

4.61 The potential for open meetings was considered as part of the review. There is a wider move towards greater openness, for example NICE's advisory committee meetings, technology appraisal appeal hearings, public board meetings and a range of other meetings are open to the public to observe. However BPC meetings are highly technical and consider commercially sensitive information as well as discussion of BPC policy. If reconfiguration of agendas was required to accommodate public attendance this could prove disruptive given there are only three meetings a year.

4.62 The BPC extensively engages industry stakeholders. Each EAG Secretariat team gives relevant industry contacts the opportunity to comment on draft BP and Ph. Eur. monographs. Members drawn from industry also inform their contacts about anything relevant, and request additional data as required. Stakeholders appreciated the opportunity for informal contact during monograph development. Additionally, the BPC Secretariat attend Agency industry and stakeholder meetings, for example with the European Federation of Pharmaceutical Industries and Associations (EFPIA).

4.63 Draft monographs are posted online for comments. Whilst this does facilitate feedback from the BP's international stakeholders there is a general information gap around who these stakeholders are. TSO and the LGC are able to provide some information on the geographical distribution of buyers of the BP and delivery of the reference substances, and the Secretariat have commissioned research to obtain more information.

4.64 The review team received a suggestion that a more consistent process for the publication of draft monographs and other compendial changes for public comment should be considered, as is reportedly the case for other pharmacopoeias.

4.65 **Recommendation 8: the BPC and Secretariat should consider draft monograph publication to a specific predictable timetable, including a deadline for comments.**

4.66 A project is underway to redevelop both the British Pharmacopoeia website (www.pharmacopoeia.com) and the website providing the online BP (www.pharmacopoeia.co.uk). The project will result in one new consolidated website, which will replace the two existing websites whilst maintaining the functionality of both. The redeveloped website is designed to offer an improved user experience and to incorporate feedback from current users of both sites. The design follows the Government Digital Service's Digital by Default Service Standard.

- 4.67 Stakeholders welcomed the anticipated changes to improve the websites used for the BP and the BP Commission, highlighting that provision of a single website would facilitate industry monitoring for changes and developments in the BP and communication of other notices, vacancies in the EAGs or Commission etc. It was suggested that an alerting service would be appropriate, and this is planned.
- 4.68 The redevelopment of the websites also gives the opportunity to build on the BPC's strength of transparency. Following the move to gov.uk, the Advisory Board on the Registration of Homeopathic Products¹¹ and the Herbal Medicines Advisory Committee¹² (both Expert Committees of the Agency) maintain a page of their membership. Similarly, the Japanese Pharmacopoeia website¹³ has a good range of information, clearly presented. A number of stakeholders felt more could be done on the website to explain the work of the BPC.
- 4.69 **Recommendation 9: the Secretariat should ensure the redeveloped website explains the work and procedures of the BPC more effectively for example by making the terms of reference, expenses policy, appointments procedures and a list of members of the Commission and its supporting groups publically available.**
- 4.70 By using the new website to publicise the different roles available within the Commission, and the required qualifications and experience for those roles, the website could be used to increase applications for vacancies.
- 4.71 **Recommendation 10: the Secretariat should ensure the redeveloped website is used to help build a list of interested people to be approached during Commission recruitment campaigns or to fill EAG vacancies.**

Conduct and Behaviour

4.72 **Assessment: the BPC is mostly compliant.**

4.73 The Chair is not permitted to hold any personal interests; members can hold such interests provided these are declared. There are no rules on acceptance of appointments or employment after resignation or retirement. This is required since the BPC relies on industry input, and members can be employed by industry (or others). The Code of Practice on interests sets out the declaration policy and the importance of impartiality and the Rules Governing Proceedings have a confidentiality clause. Interests are published in the Annual Report.

¹¹ <https://www.gov.uk/government/groups/advisory-board-on-the-registration-of-homeopathic-products>

¹² <https://www.gov.uk/government/groups/herbal-medicines-advisory-committee>

¹³ <http://www.pmda.go.jp/english/pharmacopoeia/about.html>

Performance

- 4.74 As part of the review, the performance of the BPC was considered. Metrics from the last three annual reports are summarised as Annex C.
- 4.75 On average, the BPC develops 40 new monographs per year. Whilst new monographs and changes can take a long time to become incorporated in the BP, it was acknowledged that this is because of the robust processes that ensure the output is accurate and reliable.
- 4.76 Sales of reference materials increased 11% between 2012 and 2013 and by 24% between 2013 and 2014. Approximately 75% of these are shipped overseas.
- 4.77 The BP is regarded as one of the more established pharmacopoeias, alongside the Ph. Eur., USP, Chinese, Indian and Japanese Pharmacopoeias. This is supported by its adoption as a legal standard in a number of countries (including Australia, Canada, Ireland, New Zealand and Brazil), and its wider use in nearly 100 countries. It is reportedly the most extensively used pharmacopoeia across Europe, in cases where the Ph. Eur. has not published a monograph.
- 4.78 The BPC makes a significant European contribution, providing Chairs to three Groups of Experts and seven Working Parties, and experts to all of the principal Expert Groups and Working Parties.
- 4.79 Commissioners have a clear sense of public service and are very dedicated, devoting large amounts of their time to reading and preparing for meetings. Their expertise is respected internationally, and the monographs developed are recognised as being of high quality.
- 4.80 The Expert Advisory Groups make a significant contribution to the BPC's work.
- 4.81 The Secretariat is proactive, professional and capable. There is a strong working relationship between the BPC and the Secretariat.
- 4.82 Stakeholders highlighted the innovative work of the BPC. Since the 2003 incorporation of the BP into the Agency trading fund, the BPC has expanded its standardisation work, introducing monographs for traditional herbal medicines¹⁴, unlicensed medicines, as well as homeopathic stocks and mother tinctures.¹⁵
- 4.83 The inclusion of unlicensed medicines is particularly significant. Before a medicine can be sold in the UK, it must first be granted a licence or 'marketing authorisation' by the European Medicines Agency (EMA) or the Agency. 'Off-label' or 'off-licence' usage refers

¹⁴ A new regulatory framework, the EU Directive on Traditional Herbal Medicinal Products 2004/24/EC, came into force in 2011.

¹⁵ A new regulatory framework, the Medicines for Human Use (National Rules for Homeopathic Products) Regulations 2006, came into force in September 2006.

to when a medicine is used to treat a different condition or patient group than specified in the licence. Where a licensed preparation is not appropriate for specific patients, e.g. for patients who are unable to swallow tablets or capsules, 'unlicensed' liquid medicines can be prepared in pharmacies to meet their needs. By inclusion of monographs for unlicensed medicines, the BP provides legally enforceable standards for widely used preparations, which benefits the high numbers of patients who receive extemporaneously prepared medicines in hospitals.

4.84 More recently, the BPC has taken forward projects on herbal products with the National Institute for Biological Standards and Control¹⁶ (NIBSC) and the application of the principles of Quality by Design to the analytical methods in monographs, which were valued by stakeholders. Looking forward, biological medicines are becoming increasingly important, and continued collaboration with NIBSC will be essential.

Concerns

4.85 One issue highlighted by stakeholders was the difficulty for members in securing time off work from employers. The drive for efficiency in the pharmaceutical industry makes it more difficult for companies to offer up experts. A strength of the BPC is the mix of academic and industry experts.

4.86 Higher Education Institutions face comparable financial pressures, with staff encouraged to focus on core activities, particularly research and research income generation. This has been compounded by changes to how academic research quality is assessed¹⁷. Consequently, external commitments, such as serving on the BPC may not be supported by institutions, and can be perceived by individuals as unhelpful and potentially damaging to their academic careers.

4.87 Recommendation 11: that the BPC Secretariat works with the department to establish a process whereby the Chief Medical Officer writes to Commissioners' employers on a appointment or reappointment, highlighting the importance of their work and the value such experience provides.

¹⁶ NIBSC merged with the Agency in 2013.

¹⁷ Before 2014, research of HEIs was evaluated every five years through the Research Assessment Exercise (RAE). Research quality was graded between one and four stars, with each level attracting different Higher Education Funding Council for England (HEFCE) 'Quality-Related Income.' This was achieved by examining research outputs (65%), research environment (20%) and esteem (15%). In 2014, RAE was succeeded by the Research Excellence Framework (REF), which entirely replaced esteem and 5% of the research environment component with the 'impact' of research outside academia. Whereas, under RAE, time spent on BPC (and similar) activity contributed to the esteem component, under REF, there is little or no recognition of activities which are not directly related to specific research activity.

5. Conclusions of Stage Two

- 5.1 Stage Two of the review examined the efficiency, governance and performance of the BPC.
- 5.2 Overall the BPC operates efficiently, is mostly compliant with the principles of good corporate governance and is considered to be a leading global pharmacopoeia. Particular strengths highlighted by stakeholders were the BPC's innovative work, the dedication and expertise of members and the Secretariat, industry engagement and transparency.
- 5.3 The BPC Secretariat has developed a comprehensive five-year strategy document with a robust plan of actions and activity. This report has sought to avoid making recommendations where work is already anticipated.
- 5.4 The key concern emerging from the review relates to the number of appointment terms due to finish at the end of the year. The report also makes a number of minor recommendations.

Efficiency

- 5.5 **Recommendation 2: in order to deliver best value, the BPC Secretariat and the Agency should ensure they generate as much competitive interest in tendering as possible during the next exercise, and that the appropriate support or advice is sought from the Crown Commercial Service.**
- 5.6 **Recommendation 3: in addition to managing a competitive tendering process as referred to in Recommendation 2, within the lifetime of the next contract the Secretariat should explore the feasibility of bringing the digital element of the BP in-house (consulting the Government Digital Service as appropriate).**

Governance

- 5.7 **Recommendation 4: the BPC Chair should be formally consulted as part of individual Secretariat staff appraisals, with the views of other members of the BPC to be sought as appropriate.**
- 5.8 **Recommendation 5: The BPC Secretariat should consult the BPC Chair/Vice-Chair regarding strategic and financial considerations impacting the BPC, and together determine the degree of detail relevant for consideration by Commission members to inform their input.**
- 5.9 **Recommendation 6: BPC Secretariat and the DH Appointments Team to meet post-election to agree an appropriate model for future appointments. Ahead of this the BPC should gather data on the pool of qualified people being targeted.**

- 5.10 **Recommendation 7:** appointment term end dates should be clustered into small groups across a spread of years to ensure continuity of service.
- 5.11 **Recommendation 8:** the BPC and Secretariat should consider draft monograph publication to a specific predictable timetable, including a deadline for comments.
- 5.12 **Recommendation 9:** the Secretariat should ensure the redeveloped website explains the work and procedures of the BPC more effectively, for example by making the terms of reference, expenses policy, appointments procedures and a list of members of the Commission and its supporting groups publically available.
- 5.13 **Recommendation 10:** the Secretariat should ensure the redeveloped website is used to help build a list of interested people to be approached during Commission recruitment campaigns or to fill EAG vacancies.

Performance

- 5.14 **Recommendation 11:** that the BPC Secretariat works with the department to establish a process whereby the Chief Medical Officer writes to Commissioners' employers on a appointment or reappointment, highlighting the importance of their work and the value such experience provides.

Annex A: Compliance with the Principles of Good Corporate Governance

Principles of Good Corporate Governance		Findings of Review
Accountability	<p>Principle:</p> <p>The minister is ultimately accountable to Parliament and the public for the overall performance, and continued existence, of the advisory NDPB.</p>	The BPC is mostly compliant overall.
	<p>Provision 1</p> <p>The minister and sponsoring department should exercise appropriate scrutiny and oversight of the advisory NDPB. This includes oversight of any public monies spent by, or on behalf of, the body.</p>	<p>The BPC is fully compliant:</p> <p>The BP is managed by the Agency, an Executive Agency of the DH. As part of the trading fund, financial oversight is their responsibility.</p>
	<p>Provision 2</p> <p>Appointments to the advisory NDPB should be made in line with any statutory requirements and, where appropriate, with the Code of Practice issued by the Commissioner for Public Appointments.</p>	<p>The BPC is fully compliant.</p> <p>All DH public appointments follow the Code.</p>
	<p>Provision 3</p> <p>The minister will normally appoint the Chair and all board members of the advisory NDPB and be able to remove individuals whose performance or conduct is unsatisfactory.</p>	The BPC is fully compliant.
	<p>Provision 4</p> <p>The minister should meet the Chair on a regular basis.</p>	<p>The BPC is not compliant:</p> <p>The Chair of the BPC is annually appraised by the Chair of the Agency, who is accountable to ministers.</p>
	<p>Provision 5</p> <p>There should be a requirement to inform Parliament and the public of the work of the advisory NDPB in an annual report (or equivalent publication) proportionate to its role.</p>	<p>The BPC is fully compliant:</p> <p>An annual report is published and laid before Parliament.</p>
	<p>Provision 6</p> <p>The advisory NDPB must be compliant with Data Protection legislation.</p>	<p>The BPC is fully compliant.</p> <p>The Secretariat is responsible for compliance.</p>
	<p>Provision 7</p> <p>The advisory NDPB should be subject to the Public Records Acts 1958 and 1967.</p>	<p>The BPC is fully compliant.</p> <p>The Secretariat is responsible for ensuring compliance.</p>

Role of the Sponsoring Department	<p>Principle:</p> <p>The departmental board ensures that there are appropriate governance arrangements in place with the advisory NDPB.</p> <p>There is a sponsor team within the department that provides appropriate oversight and scrutiny of, and support and assistance to, the advisory NDPB.</p>	<p>The BPC is partially compliant overall.</p>
	<p>Provision 1</p> <p>The departmental board's agenda should include scrutiny of the performance of the advisory NDPB proportionate to its size and role.</p>	<p>The BPC is partially compliant:</p> <p>The BP is managed by the Agency as part of the Inspection, Enforcement and Standards Division, whose Director sits on the executive board of the Agency. Additionally, papers on specific projects are presented to the Corporate Executive Team.</p> <p>This is appropriate to its size and role.</p>
	<p>Provision 2</p> <p>There should be a document in place which sets out clearly the terms of reference of the advisory NDPB. It should be accessible and understood by the sponsoring department and by the Chair and members of the advisory NDPB. It should be regularly reviewed and updated.</p>	<p>The BPC is fully compliant:</p> <p>Terms of reference are derived from the Human Medicines Regulations 2012 and set out in the Annual Report and in editions of the BP.</p>
	<p>Provision 3</p> <p>There should be a dedicated sponsor team within the sponsor department. The role of the sponsor team should be clearly defined.</p>	<p>The BPC is not compliant:</p> <p>There is no dedicated sponsor team for the BPC. Since the BPC and the Agency are so closely linked, it would be inappropriate to have a separate sponsor team.</p>
	<p>Provision 4</p> <p>There should be regular and ongoing dialogue between the sponsoring department and the advisory NDPB.</p>	<p>The BPC is not compliant:</p> <p>However, there is regular and ongoing dialogue between DH and the Agency, which hosts and manages the BPC.</p>
	<p>Provision 5</p> <p>There should be an annual evaluation of the performance of the advisory NDPB and any supporting committees – and of the Chair and individual members.</p>	<p>The BPC is fully compliant:</p> <p>The BPC produces an annual report detailing its activity, and that of its EAGs which is signed off by the Agency and ministers. Members are appraised annually by the Chair.</p> <p>The Chair is appraised annually by the Chair of the Agency.</p>

Role of the Chair	<p>Principle: The Chair is responsible for leadership of the advisory NDPB and for ensuring its overall effectiveness.</p>	The BPC is fully compliant overall.
	<p>Provision 1</p> <p>The advisory NDPB should be led by a non-executive Chair.</p>	The BPC is fully compliant.
	<p>Provision 2</p> <p>There should be a formal, rigorous and transparent process for the appointment of the Chair. This should be compliant with the Code of Practice issued by the Commissioner for Public Appointments . The Chair should have a clearly defined role in the appointment of non-executive board members.</p>	<p>The BPC is fully compliant.</p> <p>All DH public appointments follow the Code.</p> <p>The role of the Chair in the appointments process was made clear on appointment.</p>
	<p>Provision 3</p> <p>The duties, role and responsibilities, terms of office and remuneration (if only expenses) of the Chair should be set out clearly and formally defined in writing. Terms and conditions must be in line with Cabinet Office guidance and with any statutory requirements. The responsibilities of the Chair will normally include:</p> <ul style="list-style-type: none"> • representing the advisory NDPB in any discussions with ministers; • advising the sponsoring department and ministers about member appointments and the performance of members ; • ensuring that the members have a proper knowledge and understanding of their role and responsibilities. The Chair should ensure that new members undergo a proper induction process and is normally responsible for undertaking an annual assessment of non-executive board members’ performance; • ensuring that the advisory NDPB, in reaching decisions, takes proper account of guidance provided by the sponsoring department or ministers; • ensuring that the advisory NDPB carries out its business efficiently and effectively; and • representing the views of the advisory NDPB to the general public, when required. 	<p>The BPC is fully compliant:</p> <p>All public appointees have terms and conditions of appointment attached to their offer letter. These are cleared by lawyers and any statutory requirements would be set out. The responsibility to abide with the Cabinet Office’s Code of Conduct is made clear.</p>

Role of other members	<p>Principle: The members should provide independent, expert advice.</p>	<p>The BPC is fully compliant overall.</p>
	<p>Provision 1</p> <p>There should be a formal, rigorous and transparent process for the appointment of members to the advisory NDPB. This should be compliant with the Code of Practice issued by the Commissioner for Public Appointments.</p>	<p>The BPC is fully compliant.</p> <p>All DH public appointments follow the Code.</p>
	<p>Provision 2</p> <p>Members should be properly independent of the department and of any vested interest (unless serving in an ex-officio or representative capacity).</p>	<p>The BPC is fully compliant:</p> <p>With the exception of the Chair, BP Commission members are permitted to hold interests. Members declare interests at meetings and complete an Annual Declaration of Interests which is published in the Annual Report.</p> <p>If an interest is declared at a meeting, the Chair will decide whether or not that member participates in the discussion. The interest declared at the meeting is recorded in the minutes and whether the member participated in the discussions is recorded.</p>
	<p>Provision 3</p> <p>Members should be drawn from a wide range of diverse backgrounds, but should have knowledge and expertise in the field within which the body has been set up to advise ministers. The advisory NDPBs as a whole should have an appropriate balance of skills, experience, independence and knowledge.</p>	<p>The BPC is fully compliant:</p> <p>Members are drawn from a range of relevant stakeholders including the pharmaceutical industry, academia, contract laboratories, retired regulators, veterinary manufacturers, the herbal industry, legal firms and the NHS.</p> <p>There are also 2 lay Members of the BPC.</p>
<p>Provision 4</p> <p>The duties, role and responsibilities, terms of office and remuneration of members should be set out clearly and formally defined in writing. Terms and conditions must be in line with Cabinet Office guidance and with any statutory requirements.</p>	<p>The BPC is fully compliant:</p> <p>Duties, roles and responsibilities are published in the BP annually; fees are published in the Annual Report.</p> <p>All public appointees have terms and conditions of appointment attached to their offer letter. These are cleared by lawyers and any statutory requirements are set out. The responsibility to abide with the Cabinet Office's Code of Conduct is made clear.</p>	

<p>Provision 5</p> <p>All members must allocate sufficient time to the advisory NDPBs to discharge their responsibilities effectively.</p>	<p>The BPC is fully compliant:</p> <p>Members respond in a timely manner to requests, circulars and reviews of draft texts.</p> <p>Members attend meetings as required and chair Expert Advisory Groups. These activities are assessed as part of the appraisal process.</p>
<p>Provision 6</p> <p>There should be a proper induction process for new members. This should be led by the Chair. There should be regular reviews by the Chair of individual members' training and development needs.</p>	<p>The BPC is fully compliant:</p> <p>Induction is tailored to Commissioners' specific needs during meetings with the Secretariat.</p> <p>The Chair ensures that they are welcomed and fully briefed as to the workings of the BPC and responsibilities of Commissioners, as outlined in the Roles and Responsibilities of the Chair document, received on appointment.</p> <p>Training and development needs are discussed at their annual appraisal.</p>
<p>Provision 7</p> <p>All members should ensure that high standards of corporate governance are observed at all times. This should include ensuring that the advisory NDPB operates in an open, accountable and responsive way.</p>	<p>The BPC is fully compliant.</p>

Communications	<p>Principle: The advisory NDPB should be open, transparent, accountable and responsive.</p>	<p>The BPC is mostly compliant overall.</p>
	<p>Provision 1</p> <p>The advisory NDPB should operate in line with the statutory requirements and spirit of the Freedom of Information Act 2000.</p>	<p>The BPC is fully compliant:</p> <p>The Secretariat is responsible for ensuring compliance.</p>
	<p>Provision 2</p> <p>The advisory NDPB should make an explicit commitment to openness in all its activities. Where appropriate, it should establish clear and effective channels of communication with key stakeholders. It should engage and consult with the public on issues of real public interest or concern. This might include holding open meetings or annual public meetings. The results of reviews or inquiries should be published.</p>	<p>The BPC is fully compliant:</p> <p>Stakeholders are regularly consulted on changes in technical policies. Consultation documents are published on the BP website. Policies are also published as Supplementary Chapters in the BP.</p> <p>The Expert Advisory Group process provides a robust means for engaging with stakeholders.</p> <p>There is also means of receiving and responding to queries and feedback through the BP Secretariat's dedicated mailboxes.</p>
	<p>Provision 3</p> <p>The advisory NDPB should proactively publish agendas and minutes of its meetings.</p>	<p>The BPC is partially compliant:</p> <p>Agendas are not proactively published because of the technical nature of the work.</p> <p>Relatively extensive summary minutes of the BP Commission and the Expert Advisory Group meetings are published on the BP website once approved at the next meeting. Full minutes are not published due to commercial sensitivities.</p>
	<p>Provision 4</p> <p>There should be robust and effective systems in place to ensure that the advisory NDPB is not, and is not perceived to be, engaging in political lobbying. There should also be restrictions on members attending Party Conferences in a professional capacity.</p>	<p>The BPC is partially compliant:</p> <p>There are no systems in place to ensure the BPC is not, or is not perceived to be engaging in political lobbying. Given the size of the BPC this is appropriate.</p> <p>Guidance regarding political activity is provided to the BP Commission in the papers for the meetings ahead of elections.</p>

Conduct and Behaviour	<p>Principle: Members should work to the highest personal and professional standards. They should promote the values of the advisory NDPB and of good governance through their conduct and behaviour.</p>	<p>The BPC is mostly compliant overall.</p>
	<p>Provision 1</p> <p>A Code of Conduct must be in place setting out the standards of personal and professional behaviour expected of all members. This should follow the Cabinet Office Code. All members should be aware of the Code. The Code should form part of the terms and conditions of appointment.</p>	<p>The BPC is fully compliant</p> <p>All public appointees have terms and conditions of appointment attached to their offer letter. The responsibility to abide with the Cabinet Office's Code of Conduct is set out.</p>
	<p>Provision 2</p> <p>There are clear rules and procedures in place for managing conflicts of interest. There is a publicly available Register of Interests for members. This is regularly updated.</p>	<p>The BPC is fully compliant:</p> <p>Rules and procedures are explained in the publically available Code of Practice on Interests.</p> <p>A publically available Register of Interests is included in the Annual Report.</p>
	<p>Provision 3</p> <p>There must be clear rules in place governing the claiming of expenses. These should be published. Effective systems should be in place to ensure compliance with these rules.</p>	<p>The BPC is fully compliant:</p> <p>There is a formal expenses policy in place.</p> <p>Claims are checked by the Secretariat and the Agency's Finance staff.</p>
	<p>Provision 4</p> <p>There are clear rules and guidelines in place on political activity for members and that there are effective systems in place to ensure compliance with any restrictions.</p>	<p>The BPC is partially compliant:</p> <p>Guidance regarding political activity is provided to the BP Commission in the papers for meetings ahead of national and European elections.</p> <p>There is no formal system in place to ensure compliance. This is appropriate given the size of the BPC.</p>
	<p>Provision 5</p> <p>There are rules in place for members on the acceptance of appointments or employment after resignation or retirement. These are enforced effectively.</p>	<p>The BPC is not compliant:</p> <p>Members may be employed by industry (or other employers) and hold other appointments while serving their terms. The Code of Practice on interests sets out the importance of impartiality and the Rules Governing Proceedings have a confidentiality clause, which is reiterated at each meeting.</p> <p>This is appropriate given the need for industry expertise.</p>

Annex B: International Comparison

	British (BP)	European (Ph. Eur.) ¹⁸	Japanese (JP)	US (USP)
First Published	1864	1964	1886	1820
Form	Advisory NDPB	Published by the Council of Europe	Published by the Minister of Health, Labor and Welfare	Scientific nonprofit
Statutory?	Yes	Legally binding in EU Member States	Yes	Standards enforceable in the US by the FDA
Structure	Commission supported by 9 Expert Advisory Groups, 6 Panels of Experts, 2 Working Parties	Commission supported by 20 Groups of Experts and 52 Working Parties	15 Expert Committees, 2 sub-Committees and 4 Working Groups	Council of Experts, 24 Expert Committees and Expert Panels as required
Membership	Commission appointed by Ministers. EAGs recruited from, academia, industry and others	Commission made up of up to 3 delegates from each State. Delegations may propose Experts to the Groups of Experts and Working Parties	Experts from National Institutes, Universities etc. Representatives from industry groups	Council elected by the USP Convention membership. Committee members are elected by the Council of Experts
Conflict of interests	Chair none, members declare	All experts declare interests	unknown	Council of Experts and Expert Committees declare. Expert Panel members may represent interests such as their employer
Meetings	3 Commission, ~15 EAGs annually	3 Commission, 47 Groups of Experts annually	Each Expert Committee meets every two months	4 Council of Experts (2 physical, 2 teleconf.), Expert Committees meet physically 1-2 times a year and teleconf. up to once a month
Number of monographs	~3500	2224	1896	4900+
Publication	Annual	Triennial Edition with 8 supplements.	5 year edition, two supplements and a number of partial revisions in between	Annual
Implementation Period	4 months	6 months	0-1 months	6 months
Cost	£875 for print and either online or USB versions only, £1000 for package	~£300 (€405) for print or USB or online; ~£735 (€990 for package)	Free online, ~£650 (¥118,000) for published JP and supplements	~£560 (\$850), including the National Formulary
Number of Ref. Substances	~740	~2650	~300	3200+
Cost of Ref. Substances	£111 or £97	Generally ~£60 (€79)	Variable, average ~£135 (¥24,250)	Average ~£280 (\$429)

Source: online research, submitted evidence

¹⁸ Note: The Ph. Eur. cannot be considered a direct comparator to the BP as the BPC contributes to the Ph. Eur. under the European Pharmacopoeia Convention. The EU Medicines Directive 2001/83 requires pharmaceutical products to comply with the monographs of the Ph. Eur. or, where no such monograph exists, that of a National Pharmacopoeia (i.e. the BP). The BP therefore contains monographs which do not have a Ph. Eur. equivalent, as well as all Ph. Eur. monographs (8th Edition as amended by Supplements 8.1 and 8.2).

Annex C: Performance

		2012 Report/ BP 2013	2013 Report/ BP 2014	2014 Report ¹⁹ / BP 2015	
Overview	Number of Commissioners	19	18	17	
	Meetings	...of the Commission	3	3	3
		...of EAGs/ Panels of Experts/ Working Parties	16	14	14
British Pharmacopoeia	New monographs ²⁰	Total	41	40	39
		...of which Traditional Herbal Medicines	2	2	1
		...of which homeopathic ²¹	0	1	0
		...of which unlicensed	9	3	8
		...of which biotechnology ²²	0	1	0
	Revised/amended monographs	619	272	144	
	New infrared reference spectra	6	8	8	
	BP (Vet.) new monographs	2	4	0	
	BPCRS ²³	New p.a.	22	40	20
		Replaced p.a.	25	37	37
		Re-tested ²⁴ p.a.	260	129	138
Vials sold		15,161	16,853	20,920	
Europe	Number of Groups of Experts contributed to	19	19	18	
	Chairs of Groups of Experts	3	3	3	
	Number of Working Parties contributed to	40	40	33	
	Chairs of Working Parties	9	9	7	
Nomenclature	BAN: new names published		23	25	34
	Proposed invented names assessed ²⁵	On behalf of the Agency	582	824	1086
		On behalf of the EMA	1024	674	610

Source: annual reports, BP Website (<http://www.pharmacopoeia.co.uk/>)

¹⁹ In draft at time of writing.

²⁰ Of national origin.

²¹ A material used in the manufacture of Homoeopathic Preparations.

²² A product prepared by biotechnology.

²³ British Pharmacopoeia Chemical Reference Substances for use in connection with national monographs.

²⁴ Re-tested to ascertain their continued stability.

²⁵ The BP Secretariat is responsible for assessing proposed invented names for medicines in the UK and providing the UK input to the EMA Naming Review Group.

Annex D: List of Stakeholders Consulted

At part of the review process stakeholders were interviewed or otherwise submitted comments on the BPC:

Professor Kevin Taylor (Chair, BPC)
Professor Alistair Davidson (Vice-Chair, BPC)
Dr Graham Cook (Commissioner, BPC)
Mr Christopher Goddard (Commissioner, BPC)
Mr Barry Capon (Commissioner, BPC)
Dr Samantha Atkinson (BP Secretary & Scientific Director)
Matilda Vallender (Editor-in-Chief, BPC Secretariat)
Stephen Young (Head of Analytical Science, BPC Secretariat)
Dr Linda Anderson (the Agency)
Sandor Beukers (the Agency)
Dr Sarah Branch (the Agency)
Ged Nowlan (Public Appointments Team, DH)
Charlotte Firth (Public Appointments Team, DH)
Anya Tahir (The Agency & NICE Sponsor Team, DH)
Dr Sunjai Gupta (PHE)
Angela Long (U.S. Pharmacopeial Convention)
Dr Sabine Kopp (WHO)

A public Call for Evidence ran between 1 December 2014 and 13 January 2015. The following responses were received:

A joint response from the Association of the British Pharmaceutical Industry (ABPI) and the European Federation of Pharmaceutical Industries and Associations (EFPIA)

G R Lanes Health Products

NHS Pharmaceutical Quality Assurance Committee.

Three workshops were held as part of the Agency review. Comments relating to the BPC were received at the 5 January 2015 workshop, attended by the Proprietary Association of Great Britain, Roche, Eisai and the ABPI.

The Senior Review Sponsor and two members of the Review Team attended the December 2014 meeting of the BPC

Ministers wrote to the Health Select Committee to inform them of the review.

Annex E: Review Governance

BPC Review Terms of Reference

In line with Cabinet Office guidelines, this review has two principal aims, represented by two stages:

- i. To examine whether there is a continuing need for the functions performed by the BPC and, if there is, whether these functions should be delivered by an alternative delivery model;
- ii. If it is agreed that the functions of the BPC should continue to be delivered as an Advisory Non-Departmental Public Body, to review the control and governance arrangements in place to ensure that the BPC is complying with the recognised principles of good corporate governance. This stage will also include an assessment of the BPC's performance.

The structure, efficiency and effectiveness of the BPC will be considered as part of both stages.

Stage One

Stage one of the review will identify and examine the functions of the BPC, 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:

- i. Whether delivery of the functions continues to contribute to wider government policy and constitutes a justifiable use of public money;
- ii. Whether there is a demand for the function or activity from users;
- iii. The cost and effects of not delivering the function.

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 would be better delivered by an alternative delivery model.

Stage Two

If the outcome of stage one is that the BPC 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 BPC is operating within the recognised principles of good corporate governance in relation to its accountability arrangements, roles and responsibilities, communications, and behavioural conduct.

This stage will also consider the structure, efficiency and effectiveness of the organisation.

Key Lines of Enquiry

- Are the functions of the BPC required?
- What is the best model to deliver these functions?
 - Commercial/ not-for-profit

- Merge with the Agency or another body
- Continued delivery as an advisory NDPB
- Where does BPC sit within the health and care system? Is this the best structure?
- Could the BPC operate more efficiently? What is the scope to reduce costs or generate revenues?
 - Value for money of the publication and laboratory contracts?
- How is the BPC performing against its objectives?
- Does the BPC operate transparently?
- What control and governance arrangements are in place to ensure that the public body and the sponsoring department are complying with recognised principles of good corporate governance?
 - How well do the appointment processes for the Chair and members of the BPC and its Expert Advisory Groups function?

Challenge Group Membership

Attendees:	
Catherine Bell (Chair)	DH Non-Executive Board Member
Flora Goldhill (the Agency/BPC/CHM)	Senior Review Sponsors, DH
Andrew Sanderson (NICE)	
Jon Rouse	DG of Social Care, Local Government and Care Partnerships, DH
Oli Blackaby	Cabinet Office
Nisha De Silva	
Dr Anita Donley	Key stakeholder representatives
John Jeans	
Kathy Scott (NICE)	Lead Reviewers (and Secretariat)
David Dipple (the Agency/BPC/CHM)	

Written Ministerial Statement

Written Ministerial Statement

DEPARTMENT OF HEALTH

Triennial reviews of non- Departmental public bodies

Thursday 30 October 2014

The Parliamentary Under Secretary of State, Department of Health (George Freeman): I am today announcing the start of the triennial reviews of the National Institute for Health and Care Excellence (NICE), the Medicines and Healthcare Products Regulatory Agency (MHRA), the British Pharmacopoeia Commission (BPC), the Commission on Human Medicines (CHM), the Administration of Radioactive Substances Advisory Committee (ARSAC) and the Independent Reconfiguration Panel (IRP).

All Government Departments are required to review their non-Departmental public bodies (NDPBs) at least once every three years. Due to the wide ranging reforms made by the Health and Social Care Act 2012, the Department was exempt from the first round of reviews in 2011-14. In order to ensure that the Department is an effective system steward and can be assured of all the bodies it is responsible for, we have extended the programme of reviews over the next three years to all of its arm's length bodies and executive agencies.

The reviews of the aforementioned bodies have been selected to commence during the first year of the programme (2014-15). The reviews will be conducted in two stages. The first stage will examine the continuing need for the function and whether the organisation's form, including operating at arm's length from government, remains appropriate. If the outcome of this stage is that delivery should continue, the second stage of the review will assess whether the bodies are operating efficiently and in line with the recognised principles of good corporate governance.