Medicines & Healthcare products
Regulatory Agency

Consultation

Strategy for pharmacopoeial public quality standards for biological medicines

Consultation period: 9 January to 10 April 2017

CPRD NIBSC MHRA

Strategy for pharmacopoeial public quality standards for biological medicines

Summary

Biological medicines are an increasingly important part of healthcare worldwide. Their quality is assured by a regulatory framework which includes compliance to public quality standards. Both documentary and physical standards work together to ensure that biological medicines are of acceptable quality for use by the patient.

In the UK, documentary standards exist as texts published in the British Pharmacopoeia. The Agency is developing a strategy for the creation of pharmacopoeial public quality standards for biological medicines. This public consultation seeks input from stakeholders regarding how they are used and can be improved as well as feedback on the Agency's draft strategy.

You can respond to this consultation by using the form at the end of this document, or by downloading a Microsoft Word version. Responses should be sent to BiolStandards@mhra.gsi.gov.uk by **10 April 2017**.

In this document there is:

- an introduction
- a draft pharmacopoeial biological standards strategy
- a response form

Confidentiality of information

Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

Please let us know if you would like any information you provide to be treated in confidence, and please indicate any commercial sensitivities. We will maintain that confidence and resist disclosure under the access to information regimes where possible and in compliance with our legal obligations. We will also consult you and seek your views before any information you provided is disclosed.

Introduction

The Agency is committed to ensuring the quality of biological medicines through its activities in the development of pharmacopoeial quality standards. Quality helps ensure medicines work and are acceptably safe.

One of the key priorities in the Agency corporate plan[1] is to promote international standardisation and harmonisation to assure the efficacy and safety of biological medicines. The success of the merger with the National Institute for Biological Standards and Control (NIBSC) in 2013 has ensured the Agency continues to play a world leading role in this field.

With the increasing importance of biological medicines to global healthcare strategies it is important that the Agency continues to ensure the quality of these medicines using authoritative pharmacopoeial quality standards as well as consider how standards can act as enablers for innovation now and in the future. For example, the advanced therapies taskforce has identified standards as a key area to support the development and manufacture of new and innovative medicines[2].

Within the Agency, the British Pharmacopoeia[3] (BP) and NIBSC[4] are responsible for the delivery of documentary and physical pharmacopoeial standards for biological medicines. These comprise:

Documentary standards:

- General monographs – overarching standardised requirements often related to dosage forms
- Monographs – quality standards for specific medicinal substances and products.
- Appendices – cross-applicable standardised requirements often related to analytical technologies and methods. These can enable the implementation of specific monographs
- Supplementary Chapters – advice and guidance relating to interpretation of the pharmacopoeia and the manufacture and quality control of medicines.

Physical standards:

- Pharmacopoeial potency, content and purity standards referenced in documentary standards.

The value of pharmacopoeial standards

Documentary standards enable users to make an objective assessment in relation to the quality of a material. Where necessary these are supported by physical standards. Quality is critical to ensuring the safety and efficacy of medicines taken by patients every day. Pharmacopoeial quality standards are one of the foundations of ensuring acceptable quality.

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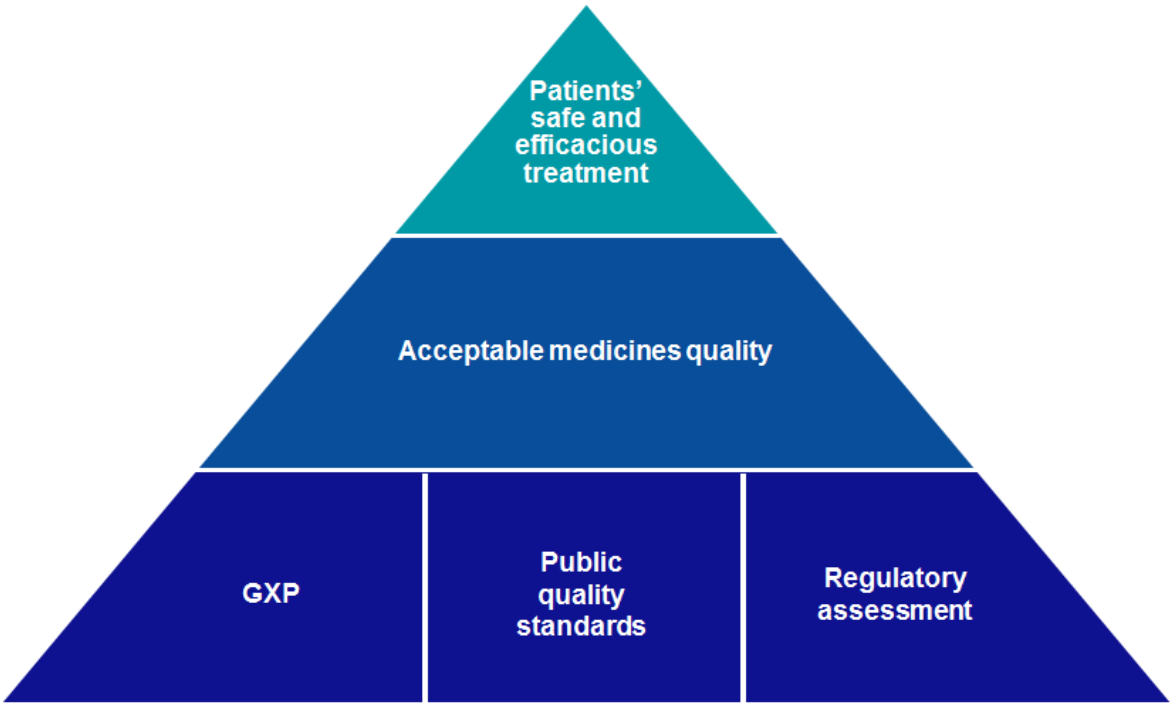
[1] https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/350879/con261796__1_.pdf

[2] http://www.abpi.org.uk/media-centre/newsreleases/2016/Pages/Action-Plan-for-UK-to-capture-the-next-generation-of-medicines-manufacturing-jobs.aspx

[3] www.pharmacopoeia.com

[4] www.nibsc.org



GXP – This refers to good practice quality guidelines and regulations. For medicines manufacture this refers to good manufacturing, distribution (GDP), clinical (GCP), laboratory (GLP) and pharmacovigilance (GPvP) practice.
Regulatory assessment – The independent review by a national competent authority of pharmaceutical, non-clinical and clinical data to demonstrate the quality, safety and efficacy of a medicinal product in order to evaluate its suitability for commercial supply.

The contribution that these three activities make to the assurance of product quality is interlinked. The successful implementation of each activity is reliant on the contribution of the others to ensure quality of medicines. The way these activities are interlinked can vary based on the products or materials that are being produced to ensure that the most appropriate control of product quality is implemented.

Within the above framework, pharmacopoeial standards can provide:

1. General monographs
    - Provides a description of the minimum quality attributes required for all medicines
    - Provide specific quality attributes required to ensure dosage-form product quality

2. Monographs
    - A description and statement of acceptable quality criteria for a medicine (for example identity, potency, purity)
    - A publicly-available description of the analytical methods used to demonstrate these criteria
    - A publicly-available description of the performance characteristics of those methods
    - The provision of reference materials for a specific use in a documentary quality standard including the performance of analytical methods
    - Support for independent drug analysis, including in the evaluation of adverse reactions or product defects

3. Appendices
    - Standardised descriptions of analytical technologies that support the specific monograph
    - Brings consistency to standards for analytical technologies to the wider environment
    - Standardised test methods that support the specific monograph

4. Supplementary Chapters
    - Publically establishes best practice guidance for new and emerging technologies, processes and products, often non-mandatory in nature

Agency pharmacopoeial biological standards strategy

Vision statement

To be the early adopter and driver of new and innovative approaches in standards setting for biological medicines for the protection of public health.

Strategy statement

Biological medicines are set to be of increasing importance in the healthcare landscape over the next five years with a greater number of products and Advanced Therapy Medicinal Products (ATMPs) available as well as representing an increasing proportion of healthcare expenditure. It is important that the Agency develops a strategy for pharmacopoeial standards to ensure it continues to contribute effectively to the assurance of quality.

This strategy contributes to key themes of our Corporate Plan:

- Enabling innovation
- Secure global supply chains
- Organisational excellence

Over the next five years, the Agency's strategy for biological pharmacopoeial standards will be to:

- Review the current approach taken for monograph development of biologicals, including new and alternative approaches, in order to ensure their future suitability as publicly available standards and the safeguarding of public health
- Develop close and co-operative relationships with our stakeholders, including the biopharmaceutical industry, in the establishment of biological pharmacopoeial standards
- Build on our existing knowledge of the process of manufacturing biological medicines, including innovative and novel medicines, to understand how manufacturers control product quality
- Review the current portfolio of BP biological documentary standards and explore current and future needs for new and revised standards.
- Support cross-Government and industry initiatives, for example the Strategy for UK Life Sciences and the Advanced Therapies Manufacturing Action Plan.
- Build close relationships with our international, regulatory and pharmacopoeial peers to share knowledge and understanding with the potential to facilitate adoption of best practice and joint working

To achieve this, the Agency will:

- Use our ability to be a fast and adaptable organisation to initiate discussions with industry and regulators on the exploration of innovative and alternative approaches to the pharmacopoeial control of biological quality

- Work with industry and other stakeholders to increase mutual understanding of challenges in the control of biological quality and the development of pilot projects to explore potential solutions

- Bring together the combined expertise of the regulatory, biological and standard setting functions of the Agency to ensure we continue to remain at the forefront of the development of biological quality standards both in the UK and Internationally

- Continue and grow the work of the BP and NIBSC for the development of physical biological pharmacopoeial standards

- Use our data and understanding of stakeholder needs to review our portfolio of biological quality standards

Response document for the Agency consultation on strategy for pharmacopoeial public quality standards for biological medicines

About You **Name:**
Position:
Organisation:
Email:
About your Organisation **Type:** Industry Innovator □ Biosimilar/Generic □ Trade Association □ Regulator National Competent Authority □ Pharmacopoeia □ Representative Body □ National testing laboratory □ Academic University □ Research organisation □ Other (Please state) □
Products (tick as many as apply): Recombinant proteins □ Monoclonal antibodies □ Vaccines □ Blood Products □ ATMPs (please state types) □ Biological extracts □ Other (please state) □
Location (country): Head office: Other Locations:
Organisation Size: 1-9 employees □ 10-49 employees □ 50-249 employees □ 250+ employees □
1. What do you see as the greatest opportunities and challenges affecting biological medicines in the next 5 years and why?

2. How can quality standards meet the needs of current and future products? For example, is there an unmet need for standards for new medicines?
3. How can quality standards enable innovation across the product lifecycle? For example, the development of standards for new analytical technologies.
4. How can we work with you to develop the best and most appropriate standards for biological medicines?
5. What would you like to see in the strategy which is not already there?
6. Do you have any other comments regarding the strategy?
7. Would you be happy for the Agency to contact you in order to discuss your responses in further detail? Yes ☐ No ☐
8. The Agency may publish consultation responses. Do you want your response to remain confidential? Yes ☐ Partially* ☐ No ☐ *If partially, please indicate which parts you wish to remain confidential. In line with the Freedom of Information Act 2000, if we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. Responses to consultation will not normally be released under FOI until the regulatory process is complete.

Responses can be continued onto a separate page if required. This form should be returned by email (BiolStandards@mhra.gsi.gov.uk) to arrive by **10 April 2017.** Contributions received after that date cannot be included in the exercise.