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INFECTED BLOOD INQUIRY

FIRST WRITTEN STATEMENT OF DR ANNA-MARIA BRADY

Contents

Contents 1
Section 1: Introduction 3
Section 2: Professional history 3
Qualifications 3
Employment history 3
Table 1 4
Memberships 4
Litigation history 5
Section 3: The role and remit of the BPC 5
The DHSC's Appointments Team 5
Section 4: The BP 9
The BP and its processes 9
The role of domestic producers in informing the standards contained in the BP .. 12
The DHSC's role in informing the standards contained in the BP 13
The BP's publication 13
Table 2 13
The BP and the UK 16

The BP and its influence outside the UK 17

The links between the BP and the leading world pharmacopoeias..... 18

Conforming standards 19

The BP and its communications with clinicians 20

The BP and emerging risk 20

Section 5: Chairs of the BP 20

Table 3..... 20

Section 6: The BP during the 1960s to the 1980s 21

The process of producing BP 22

Differences in the degree of authority the BP had in and outside the UK 22

Conforming standards 22

Differences between the international links between the BP and the leading world pharmacopoeias 22

Domestic producers in informing the standards contained in the BP..... 23

PFC, PFL and the BPL 24

Section 7: Other issues 24

Section 1: Introduction

I, Dr Anna-Maria Brady, will say as follows: -

1.1. My name is Dr Anna-Maria Brady and my date of birth is GRO-C. My office address is GRO-C London GRO-C

1.2. I am providing this written statement in response to the Inquiry's Rule 9 request dated 28 October 2022 and a supplementary request dated 14 December 2022.

Section 2: Professional history

Qualifications

2.1. My professional qualifications are as follows:

a. Ph.D., Applied Biochemistry, (1985);

b. B.Sc Honours Degree, Biochemistry, (1980)

Employment history

2.2. In the first part of my career, I was employed as a scientific researcher and team leader in the Research and Development Department of the Blood Products Laboratory/Bio-Products Laboratory ("BPL") from 1984 - 1998.

2.3. I worked within the analytical biochemistry and novel product unit and was not directly involved in research and development of BPL's conventional product portfolio.

2.4. I joined the Government's department responsible for veterinary medicines regulation (the Veterinary Medicines Directorate ("VMD")) in 1998 as an assessor specialising in immunological products (mainly vaccines).

2.5. Between 2008 until 2016, I led the biologicals assessments group and the VMD's administrative division as Head of Unit. During this period, I represented the UK at the European level and was an active member of the European

Committee on Veterinary Medicines ("CVMP"), leading on many novel veterinary biological product scientific assessments.

2.6. Since 2008, I have been a member of various pharmacopoeia expert groups on veterinary and human immunological products (as outlined below in Table 1).

Table 1

Expert Group	Scope
Veterinary Immunological Products Panel ("VIP")[1]	Immunosera, Vaccines and Diagnostic Preparations intended for use in animals
Biological and Biotechnological Products ("BIO")	Immunosera, Vaccines and Diagnostic Preparations
BIO-DPS Working Party:	Alternative Approaches for Documentary and Physical Standards for Biotechnological Products

2.7. Blood Products are covered by a dedicated expert panel, namely Blood Products, because of their specialist nature. I am not, and never have been, a member of that group.

2.8. In 2016, I joined the British Pharmacopoeia Commission ("BPC") as a member. In 2021, I became Vice-Chair and in 2022, I became Chair.

Memberships

2.9. I am not a member of any, past or present, committees, associations, parties, societies or groups relevant to the Inquiry's Terms of Reference.

[1] From 2008 to present day, I am also a member of the European Pharmacopoeia's expert group for Veterinary Vaccines.

Litigation history

2.10. I have not provided evidence or been involved in any other inquiry, investigation or litigation relevant to the Inquiry's Terms of Reference.

Section 3: The role and remit of the BPC

3.1. The BPC is an Advisory Non-Departmental Public Body, sponsored by the Department of Health and Social Care ("DHSC").

3.2. The legal status of the BPC was established under Part VII of the Medicines Act 1968 ("the Medicines Act"). The Human Medicines Regulations 2012 ("the HMR 2012") superseded the Medicines Act; regulation 11 and Part 15 (regulations 317-321) contain provisions relating to the BPC.

The DHSC's Appointments Team

3.3. The DHSC's Appointments Team, on behalf of the Secretary of State and the Minister of Health for Northern Ireland, appoints members of the BPC. The Appointment term end dates are clustered into small groups across a spread of years to ensure continuity of service.

3.4. Ahead of any scheduled recruitment exercises, the British Pharmacopoeia ("BP") Secretariat gathers data on suitably qualified people to create a pool of potential candidates. The BPC Secretariat and the DHSC's Appointments Team meet to agree an appropriate model for appointments and posts are advertised on the government website. The BP Secretariat and current members promote vacancies within their networks of experts. To be considered for the role, candidates must be able to demonstrate that they have the qualities, skills, and experience to meet all the essential criteria for appointment. These are listed below:

<u>General Competencies</u>:

a) to be able and prepared to contribute actively to the work of the BPC;
b) to be able to assimilate complex information at pace; and
c) to be a skilled communicator.

Specialist Competencies[2]:

a) to have a general understanding of the purpose and function of a pharmacopoeia and its place in the overall regulatory system (UK and Europe);

b) to have significant experience in the pharmaceutical industry, academia, or the hospital service, including in one or more of the following areas:

   i. the quality control of medicinal products (human and/or veterinary (three or four posts); and
   ii. the analysis of biological and biotechnology products, ideally with expertise in the areas of advanced therapy medicinal products and/or biotechnologically produced proteins (at least two posts).

c) to be recognised by peers as an eminent member of relevant profession, with wide and recent experience in at least one of the following areas:

   i. the practice of pharmacy;
   ii. analytical chemistry;
   iii. biology;
   iv. the standardisation and specifications for human medicines;
   v. the standardisation and specifications for veterinary medicines; and
   vi. the standardisation and specifications for biological medicines.

3.5. Applicants are sifted against person and essential/desirable criteria by the panel members and those passing are interviewed (in person or remotely).

3.6. The selection panel consists of the Chair of the BPC, the Secretary & Scientific Director of the BP, the Chair of the Medicines and Healthcare products Regulatory Agency ("MHRA") and an independent board member.

3.7. Members are appointed on the basis of their expertise in relevant specialist fields. The initial period of tenure is usually 4 years and members may be re-appointed, up to a maximum of 10 years.

3.8. Members undergo an annual appraisal according to the DHSC's procedures and these appraisals form part of the information considered by the Appointments team for potential re-appointments, which can range from 2 - 4 years.

[2] This is the most recent list which can be modified according to specialist needs on the commission. The actual number of people being recruited and/or specialisms for each competency may vary in each recruitment campaign, depending on the expertise of the current members and any gaps.

3.9. Under the HMR 2012, the BPC is responsible for:

a) preparing new editions of the BP and the preparation and publication of any compendium containing information relating to substances and articles which are, or may be, used in the practice of veterinary medicine or veterinary surgery (the British Pharmacopoeia (Veterinary) (regulations 11 and 317)); and

b) the selection and publication of British Approved Names ("BANs") (regulation 318). BANs are the official, generic name given to a pharmaceutical substance as defined by the BP (for example, 'ibuprofen' is the British Approved Name whereas Advil and Nurofen are ibuprofen trade names).

3.10. BANs are short, distinctive names for use with medicines in the UK instead of the more complex systematic chemical or other scientific names, which are not convenient for general use. They are devised in accordance with a set of guiding principles, the key ones being:

a) they should be distinctive in sound and spelling and should not be liable to confusion with existing names (BAN, international non-proprietary name ("INN") or trademarks); and

b) drug substances belonging to a particular therapeutic or pharmacological group are linked by the use of common stems, for example '-vir' at the end of the name for antivirals.

3.11. In the case of an active pharmaceutical ingredient ("API") for use in the UK, the non-proprietary name or generic name is used as the BAN. In most cases, BAN are harmonised with the English form of the recommended international non-proprietary name ("rINN").

3.12. The BPC is also responsible for:

a) providing clear policies and technical advice for the BP;

b) providing advice to the United Kingdom delegation to the European Pharmacopoeia Commission; and

c) appointing members to expert advisory groups, panels of experts and working parties.

3.13. The BPC appoints experts to the Expert Advisory Groups ("EAGs"), Panels of experts and Working Parties. Members are drawn from the pharmaceutical industry, the MHRA, the NHS and academia. They are appointed by the BPC after a review of their qualifications and documentary evidence of their expertise in the relevant areas. Members are usually appointed for a 4-year term.

3.14. A full membership review is carried out every 4 years to ensure a satisfactory balance of expertise and representation from different sectors.

3.15. Potential experts are sourced through the extensive professional networks available to the BP, as well as sourced from direct expressions of interest.

3.16. Interest in membership can be registered directly at any time to the BP Secretariat and appointments can be made before the 4-year review point, where required. All candidates are reviewed by the Chair and Vice Chair of relevant groups against a list of criteria, which includes detailed evidence of technical expertise, qualifications and potential conflicts of interest and they forward a gap analysis and recommendation on suitability to the BPC for a decision on whether to appoint the candidate. A letter of invitation is sent to the individuals concerned outlining responsibilities and expectations.

3.17. All members are required to comply with the MHRA Code of Practice on Identifying, Declaring and Managing Interests [**WITN7639002**].

3.18. A list of current EAGs, Panels of Experts and Working Parties is published in the current edition of the BP and on the BP website [**WITN7639003**].

3.19. Working Parties have similar compositions and practices as EAGs/Panels but are established for a specific period and focus on a specialised area.

3.20. The Blood Products Panel of experts are responsible for drafting and updating Blood Product monographs. Where appropriate, additional input can be requested from other expert groups or other sources. The BP also appoints an expert representing the UK to the European Pharmacopoeia's expert group on Blood and Blood products.

Section 4: The BP

The BP and its processes

4.1. The BP is a reference book of standards for medicines and some medical devices. It covers both human and veterinary medicines and provides both legally binding quality standards as well as general methods and guidance chapters.

4.2. The BP, currently published annually, is available to buy in hard copy and electronic formats.

4.3. The legal status of the BP was established under the Medicines Act (as superseded by the HMR 2012).

4.4. The BPC has overall responsibility for new editions of the BP.

4.5. The BP is compiled by the BP Secretariat (part of the Medicines and Healthcare products Regulatory Agency ("MHRA")), working in collaboration with the BPC and its Expert Advisory Groups ("EAGs") and panels of experts as well as the BPL (the process is further described in paragraph 4.6 below).

4.6. The process of how an edition of BP is produced involves the BP preparing new monographs[3] and making amendments to existing texts by working with:

a) companies or individuals (marketing authorisation holders ("MAHs")). who are licensed to distribute, market and sell a medicinal product;

b) other pharmacopoeias;

c) the BPC, its EAGs, panels of experts and working parties (meeting regularly to work on texts and review final texts before publication);

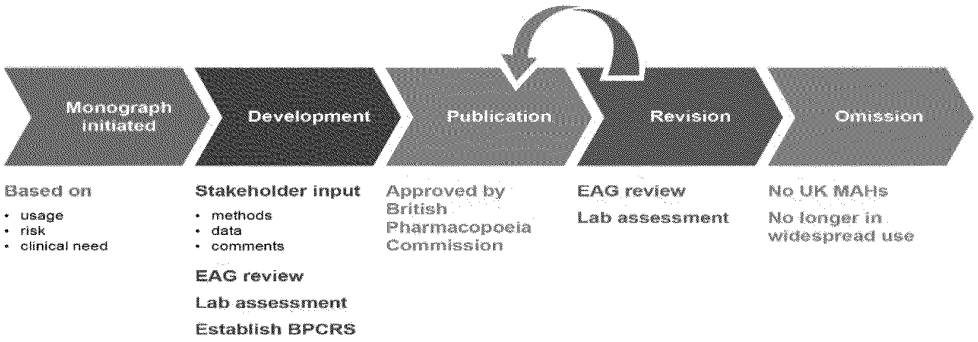
d) the BP Laboratory ("BPLab.") providing analytical and technical support to the development of new pharmacopoeia monographs by undertaking the development and validation of qualitative and quantitative test methods for new BP monograph specifications. It also refines and revalidates test methods for existing monographs. The BPLab. is also

[3] A monograph is a description of a product's preparation which describes the basic chemical information, description and function of a product; it contains details of tests for the purity and identification of the final product as well as other characteristics which allow verification of the product.

responsible for the procurement, establishment, maintenance and sale of BP Chemical Reference Substances ("BPCRS"). There are over 850 BPCRS, which are needed as standards for monograph tests in both the BP and the British Pharmacopoeia (Veterinary); and

e) interested parties e.g. National Institute for Biological Standards and Control ("NIBSC").

4.7. The high-level process of monograph production is illustrated below:



4.8. Monographs are initiated based on the degree of usage of a product and the clinical need for the product as well as the risk associated with a product.

4.9. Manufacturers and MAHs, as well as any other interested parties, can propose a new monograph or a revision to an existing monograph at any time through a portal on the BP website, as well as the opportunity to provide supporting data and physical material for testing at the BPLab. Such requests will be considered by the relevant expert groups and the BP secretariat against the criteria for initiation or the need for revision. It is important that any new monograph or revision can be applied to all existing authorised products and therefore all relevant manufacturers are consulted on draft texts at the earliest possible drafting stage and at further stages of monograph development.

4.10. The approval of the text is the responsibility of the BPC and the related MAHs direct approval is not necessary for publication. The BP Laboratory will also work with the MAH, when required, to understand in-house tests and specifications.

4.11. All members (within the conflict of interest rules) of the expert groups will contribute to the drafting of the monograph and once a complete draft is

achieved, it will be made publicly available on the BP website for comment. Where appropriate, industry liaison bodies will also be contacted to highlight the ongoing consultation. All comments received including those from MAH's will be considered by the expert drafting group and if they cannot be accepted as amendments to the monograph this will be justified in writing to the party concerned. Once the expert drafting group and the BP secretariat are satisfied with the draft monograph, it is forwarded to the BPC for review and final decision.

4.12. During the BPC's review, all members review the draft in detail and if there are divergent views, there will be a discussion led by the Chair of the relevant expert group, who highlights the issues.

4.13. The draft monograph will then go back to the expert group for consideration of the BPC comments. Once the BPC is content that the monograph is technically accurate and a workable standard for all authorised products, the monograph is published.

4.14. The various review cycles, including consultation, can occur more than once, if necessary, in order to produce a standard which is both robust but practical. Nevertheless, there are occasions where development of a monograph may need to be frozen for a period whilst further data are generated to ensure the standard is robust and equitable[4].

4.15. The revision history of all monographs and general chapters can be seen on the electronic copy of the BP on the BP's website. The revision history tool allows the user to see the number of revisions and the background to these revisions.

4.16. Monographs may be revised for various reasons, including, for example, the revision of methods or limits in line with the monographs in the European Pharmacopoeia ("Ph. Eur."), the inclusion of additional impurity methods as more information becomes available, the removal of reagents that are no longer recommended for use. Revisions may be due to requests from users of the BP,

[4] All members of the expert groups and the BPC including industry members are bound by the MHRA Code of Practice on Identifying, Declaring and Managing Interests [**WITN7639002**] and are required to act in accordance with the Code of Practice during discussions.

general policy changes that may affect several monographs or simple editorial changes or corrections.

4.17. There is a consultation period where the public can comment on new and revised monographs via the BP website. As a result of these comments, there may be changes or should further information become available, the draft texts may still be discussed at several meetings before they are considered ready for publication. The BP Commission are asked to approve the new and revised monographs for inclusion in each edition of the BP, which may result in further minor changes.

4.18. Comprehensive minutes of the EAG meetings are prepared. The minutes are approved by the Chair of the relevant group and endorsed by the BP Commission. They record the discussion and decisions taken and are retained. Publicly available summary minutes are also provided on the BP website.

The role of domestic producers in informing the standards contained in the BP

4.19. Information to support the development or revision of BP monographs is sought from companies producing the relevant medicinal products. Where the BPLab is asked to examine proposed monograph methods, companies are asked to provide a range of samples for testing. As noted in paragraph 4.17 above, the draft of new and revised monographs are made available for public comment, at which point any interested parties can submit comments for consideration before the text is finalised. Companies can raise issues and request revision of a published standard by submission of data to support changes.

4.20. Where companies request revision of a published monograph and provide supporting data to help justify the change(s), the information will be stored in the BP filing system whereby there is a separate file for every monograph.

4.21. For national BP monographs, information is kept throughout the monograph lifecycle that is from initial development, through to publication and any subsequent revision. This will include information provided by companies to

support monograph development, draft monographs, routine correspondence, and minutes from meetings at which the relevant monograph was discussed.

4.22. Records are kept from the date that a monograph is first agreed for development. Detailed records relating to the development and revision of Ph. Eur. monographs that have been reproduced in the BP are retained by the European Directorate for the Quality of Medicines and HealthCare.

The DHSC's role in informing the standards contained in the BP

4.23. The core of the Department of Health ("DH") does not have any formal role in the activities of the BP. However, the BP Secretariat regularly obtains prescribing data from the DHSC and this information is used to help identify widely used items for which a monograph has not yet been developed or is not on the current work programme. Exceptionally, DHSC may also request that a particular monograph to be added to the work programme. The BPC is supported by a Secretariat from the MHRA. Where appropriate, scientific experts from the assessment divisions of the MHRA, National Institute of Biological Standards and Control ("NIBSC") and other DHSC Agencies and partner organisations for example, the Human Tissue Authority, NHS Blood and Transplant may have roles in EAGs.

The BP's publication

4.24. The various editions of the BP (main editions and addenda) are listed in the Table 2 below:

Table 2

Edition	Main or addendum	Publication date	Official date
BP1958 Add 1960	Addendum	03/10/1960	01/03/1961
BP1963	Main	01-Jul-63	01/01/1964
BP1963 Add 1964	Addendum	01/12/1964	01/06/1965
BP1963 Add 1966	Addendum	15/03/1966	01/11/1966

BP1968	Main	04/09/1968	
BP1968 Add 1971	Addendum		
BP1973	Main	01/06/1973	01/12/1973
BP1973 Add 1975	Addendum	Apr-75	01/12/1975
BP1973 Add 1977	Addendum		01/12/1977
BP(Vet) 1977	Main		01/12/1977
BP1973 Add 1978	Addendum	01/05/1978	01/12/1978
BP1980	Main	Jun-80	01/12/1980
BP1980 Add 1981	Addendum		
BP1980 Add 1983	Addendum		01/06/1984
BP (Vet) 1977 Add 1985	Addendum		
BP1980 Add 1986	Addendum	Jun-86	01/12/1986
BP1988	Main	01/06/1988	01/12/1988
BP (Vet) 1988	Main		
BP (Vet) 1988 Add 1989	Addendum		
BP1988 Add 1990	Addendum		01/12/1990
BP1988 Add 1991	Addendum		01/12/1991
BP1988 Add1992	Addendum		01/12/1992
BP (Vet) 1988 Add 1992	Addendum		
BP1993 (see note)	Main	01/07/1993	01/12/1993
BP1993 Add 1994	Addendum	01/02/1994	01/12/1994
BP1993 Add 1995	Addendum	02/01/1995	01/12/1995
BP1993 Add 1996	Addendum	01/11/1995	01/12/1996
BP1993 Add 1997	Addendum	01/12/1996	01/12/1997

BP1998	Main	01/03/1998	01/12/1998
BP1999	Main	01/04/1999	01/12/1999
BP2000	Main		01/12/2000
BP2001	Main	23/05/2001	01/12/2001
BP2002	Main	29/08/2002	01/12/2002
BP2003	Main	04/09/2003	01/12/2003
BP2004	Main	30/08/2004	01/12/2004
BP2005	Main	26/08/2005	01/12/2005
BP2007	Main	26/08/2006	01/01/2007
BP2008	Main	Aug-07	01/01/2008
BP2009	Main	Aug-08	01/01/2009
BP2010	Main	Aug-09	01/01/2010
BP2011	Main	01/08/2010	01/01/2011
BP2012	Main	Aug-11	01/01/2012
BP2013	Main	Aug-12	01/01/2013
BP2014	Main	23/08/2013	01/01/2014
BP2015	Main	26/08/2014	01/01/2015
BP2016	Main	24/08/2015	01/01/2016
BP2017	Main	23/08/2016	01/01/2017
BP2018	Main	01/08/2017	01/01/2018
BP2019	Main	26/07/2018	01/01/2019
BP2020	Main	30/07/2019	01/01/2020
BP2021	Main	31/07/2020	01/01/2021
BP2022	Main	01/08/2021	01/01/2022
BP2023	Main	01/08/2022	01/01/2023

4.25. Notes on the table:

a) Blank entries show where dates could not be ascertained within the time available;

b) The first edition of the BP (Veterinary) was published in 1977;

c) From 1993 and all subsequent editions, the BP (Veterinary) was included as a volume of the main edition;

d) From BP 1998, the main edition was/is published annually; and

e) There was no edition published with the title "BP2006". The effective date was moved from 1st December to 1st January in 2007 so the title of the publication would coincide with the title. BP 2005 was in force for 13 months, from December 2005 to December 2006.

The BP and the UK

4.26. The BP provides legally binding authoritative quality standards for UK pharmaceutical substances and medicinal products. The legal status of the BPC and of the BP was established under the Medicines Act (as superseded by the HMR 2012) as described in paragraph 3.2 above.

4.27. Regulations 251 and 252 of HMR 2012 mandate that a person may not sell or supply a medicinal product, either on request, to fulfil a prescription, or that has been offered or exposed for sale, that does not comply with the relevant monograph in the BP. Regulation 255 stipulates that a person is guilty of an offence if they breach this regulation (regulation 251) and, if convicted, is subject to a fine and/or imprisonment of up to 2 years.

4.28. Any medicinal product licensed in the UK;

a) must be able to comply with the requirements of the BP at any time throughout its shelf life; and

b) must meet the standards of the BP regardless of whether compliance with the BP is claimed or it is not called by the name at the head of the monograph (regulation 251 of the HMR 2012).

4.29. For a medicinal product to be compliant with a BP monograph (regulation 320(3) and 321(3) of the HMR 2012):

a) the monograph that was in force at the date of product manufacture must be applied e.g. the BP 2019 was legally effective between 1 January 2019 and 31 December 2019. The effective date can be found in the Preliminaries section of the BP;

b) all ingredients (drug substances and excipients) that are used to make the product must comply with the published BP or Ph. Eur. monograph for those substances;

c) the product must comply with the relevant general monograph for the dosage form; and

d) the product must comply with the requirements of the specific monograph for the formulated preparation.

4.30. 'Supplementary Chapters' of the BP provide guidance on various aspects of current pharmacopoeia policy including an explanation of the basis of pharmacopoeia specifications, and information on the development of monographs including guidance to manufacturers.

4.31. Manufacturers are actively encouraged to contribute information to developing or amending monographs and also to provide experts to the expert advisory groups. As mentioned above, there is a public consultation process on all new monographs and changes to existing standards and the BP website provides up to date information on ongoing processes.

The BP and its influence outside the UK

4.32. The BP has the same authority over manufacturers, which are based outside of the UK (as stated in paragraph 4.26 above) if they manufacture medicinal products that are approved in or destined for the UK market (regulations 251 and 252 of the HMR 2012). If those manufacturers do not supply to the UK market then the BP may not have any legal authority.

4.33. The BP forms an inherent part of established medicines legislation in Commonwealth countries and continues to be a member of the Ph. Eur. Convention providing expert advice to the Ph. Eur. and playing a significant role in the standard-setting process in Europe.

4.34. Ph. Eur. texts are re-produced within the BP. In the absence of Ph. Eur. standards, European law allows the continued applicability of BP standards (as a third-party pharmacopoeia) for medicines and their components. Where the BP is appropriately referenced in the regulations of an EU member state, it may be considered a national pharmacopoeia of that EU member state.

4.35. Under the European Union medicines regulations (directive 2001/83/EC, as amended), the BP is a national pharmacopoeia of a member state if it is referenced in the regulations of that member state, for example the Republic of Ireland references it as the National Pharmacopoeia of Ireland.

4.36. If a medicinal product is licensed in a country where the BP is a legal standard:

a) it must be able to comply with the requirements of the BP at any time throughout its shelf life; and

b) it must meet the standards of the BP regardless of whether compliance with the BP is claimed or it is not called by the name at the head of the monograph.

The links between the BP and the leading world pharmacopoeias

4.37. The BP has a wide international reach with strong links to leading world pharmacopoeias, as well as providing expert advice to the World Health Organization (“WHO”) to inform the recommendations of the International Pharmacopoeia which is produced by the WHO.

4.38. There is no direct mutual recognition between national pharmacopoeias, but there is supranational adoption of compendia. For example, the Ph.Eur. is recognised across member states of the Council of Europe.

4.39. The UK was one of the initial signatories to the Convention on the Elaboration of a Ph. Eur. and continues to play a significant role in the Ph. Eur. standard-setting process.

4.40. The UK participates in the Good Pharmacopoeial Practices Initiative organised by WHO. This encourages interactions between different pharmacopeial organisations with the objective of harmonising approaches and policies towards establishing pharmacopoeial standards.

4.41. The BP works with a number of national pharmacopoeias such as the US, Indian and Chinese pharmacopoeias on a regular basis. There are ongoing work projects on informal harmonisation of product monographs with the US and Indian pharmacopoeias.

4.42. There are several memoranda of understanding in place with overseas organisations, which allow them to republish subsets of BP content in their respective pharmacopoeias, for example in Kazakhstan, Ukraine, and Croatia.

Conforming standards

4.43. The MHRA is responsible for ensuring that medicines and blood components for transfusion meet applicable standards of safety, quality and efficacy. It does this by firstly ensuring compliance with legal quality standards during the assessment of data submitted in support of an application to licence a medicine or to use a blood component and secondly by regular inspection of manufacturers and blood banks where compliance with legal quality standards such as the BP will be investigated.

4.44. The MHRA has a tiered approach to enforcement depending on the degree of non-compliance found at inspection, but serious non-compliances can lead to restriction notices for some processes or parts of a site or suspension of the authorisation for a product or site.

The BP and its communications with clinicians

4.45. The BP does not specifically communicate with clinicians outside the usual public consultation processes, at which point anyone is welcome to comment on our standards and policies.

The BP and emerging risk

4.46. The BP has a role in responding to emerging issues, within the wider regulatory framework. The MHRA as the competent authority takes the lead in decision-making and the pharmacopoeial standards may be introduced or updated where it is determined that such controls may be useful in responding to emerging issues.

Section 5: Chairs of the BP

5.1. Table 2 below contains a list of the names, compiled through research conducted by myself and colleagues, of those who have previously held the position of Chair of the BPC since 1968:

Table 3

Dates of appointment	Name
1 October 2013 (to 1 October 2022)	Professor Kevin Taylor
2012	Mr V'Iain Fenton-May (acting)[5]*
2006	Prof David Woolfson
1998	Prof Derek Calam
1990	Prof David Ganderton
1980	Prof John Bedford Stenlake

[5] Professor David Woolfson resigned for health reasons during 2012 and the Vice-Chair at the time (Mr V'Iain Fenton-May) acted as Chair until a replacement was appointed.

Dates of appointment	Name
1970	Dr. Frank Hartley
1963	Prof. Eric Frank Scowen

Section 6: The BP during the 1960s to the 1980s

6.1. The nature of the BP has not changed since the 1960s. It is, and has always been, a book of publicly available, legally enforceable, quality standards for medicines.

6.2. Prior to the Medicines Act, the General Medical Council ("GMC") was responsible for the publication of the BP. When the Medicines Act came into force, the Medicines Commission became responsible for the preparation of future editions of the BP and for their publication by Health Ministers. On the recommendation of the Medicines Commission, Health Ministers established the BPC in 1970 to continue the work of the previous Commission which had been appointed by the GMC. In 1982, the remit of the BP Commission was extended to include the preparation of a separate compendium relating to veterinary medicine.

6.3. When the Medicines Commission was superseded by the Commission on Human Medicines ("CHM") in 2005, the responsibilities of the Medicines Commission relating to the BP and the BPC were transferred to the CHM.

6.4. As I have already described, the HMR 2012 superseded the Medicines Act, consolidating the 1968 Act and over 200 statutory instruments relating to human medicines into a single set of requirements. This consolidation removed the role of the CHM regarding the publication of the BP and clarified the position of the BPC making it solely responsible for the publication of the BP, the BP (Veterinary) and BANs.

6.5. There was no change to the role of the BPC, in that the work was all previously carried out by the BPC, but the recommendation to publish was given by the Medicines Commission/CHM.

The process of producing BP

6.6. The high-level process was fundamentally the same as that described in Section 4: The BP and its processes. Some details, such as the names of EAGs or Committees, have changed and the technological processes to produce the publication have changed but the overall process is the same.

Differences in the degree of authority the BP had in and outside the UK

6.7. To the best of my knowledge, the BP has always had authority over medicines quality standards in the UK over this period. This will have been under different legislation and managed by different government departments at different times. Although I was not connected with the BP at this time, I understand that section 65 of the Medicines Act, which was in force from 1 June 1972 and then revised three times before August 2012, provides for compliance with standards specified in monographs in certain publications, including the BP. It was this, to the best of my understanding, which rendered BP's standards as set out in monographs legally binding.

Conforming standards

6.8. I cannot comment about monitoring and enforcement of conformity with the standards contained in the BP during the 1960s to the 1980s as I do not have specific knowledge of monitoring and enforcement of standards during this period. The BPC was established by the 1968 Medicines Act and it is my understanding that its role was essentially the same then as it is now.

Differences between the international links between the BP and the leading world pharmacopoeias

6.9. Prior to 1964, the BP was the sole legal standard in the UK.

6.10. The UK was a founding signatory to the Convention on the Elaboration of a Ph. Eur. which was signed on 22 July 1964. After this, convention required the signatories *"... to take the necessary measures to ensure that the monographs which will be adopted by… which will constitute the European Pharmacopoeia shall become the official standards applicable within their respective countries"* (Article 1) [**WITN7639004**].

6.11. The first volume of the Ph. Eur. was published in November 1969, to be made effective by 1 January 1972. The second volume was published in October 1971, to be made effective by 1 July 1973.

6.12. In 1975, European Community directive 75/318/EC established the legal requirements for starting materials (drugs and excipients) that were defined in the annex to the directive in terms of a pecking order of pharmacopoeias – if there was a Ph. Eur. monograph this should be used, if not, then a monograph from a national pharmacopoeia of a member state could be used. If there were neither a European nor a national monograph then a pharmacopoeia from a third country could be used.

6.13. At international level, efforts to harmonise standards and requirements between the Pharmacopoeias in Europe, Japan and the United States has been undertaken for many years. This is done through the Pharmacopoeial Discussion Group, to which the BP contributes via the Ph. Eur.

6.14. To date this work has mainly focussed on general chapters and monographs for excipients (inactive ingredients).

6.15. The first edition of the International Pharmacopoeia came out in 1951 but it is advisory only. The staff of the BP Secretariat on occasion provide input and comment on draft monographs during the consultation process.

Domestic producers in informing the standards contained in the BP

6.16. Historical records show that the process is fundamentally the same, as detailed in paragraph 4.19 above, and that is to seek information and data from interested parties and providing draft text for comment before it is published.

6.17. Regarding the role the DHSS and its divisions had in information the standards contained in the BP, our records indicate that the DHSS (and prior to that, the DH), had been asked to provide prescribing data for many years (as discussed in paragraph 4.23 above).

6.18. However, our historical records do not include reference to the DHSS. It is noted that DHSS became DH in 1988 and it is likely that requests for prescribing data took place prior to the change.

PFC, PFL and the BPL

6.19. To the best of my knowledge, if the Protein Fractionation Centre, the Plasma Fractionation Laboratory and the BPL were manufacturing medicinal products for the UK, they would have been bound by the standards in the BP, as would any other manufacturers as described in previous answers. I do not know the extent to which Crown Immunity affected this position.

Section 7: Other issues

7.1. I have no further information or views relevant the Inquiry's Terms of Reference, other than what I have expressed above.

Statement of Truth

I believe that the facts stated in this witness statement are true.

Signed: GRO-C

Dated: GRO-C 31/1/'23 GRO-C GRO-C