局方当局に示される。

２．適正薬局方規範の目的

WHO適正薬局方規範：WHO Good Pharmacopoeial Practices（GPhP）は薬局方基準を確立する上でのアプローチや方針の調和を目的にしたものであり、その結果医薬品有効成分、医薬品製剤、およびその他の物質の品質を管理する上で規制当局の助けになるとともに、薬局方ユーザーあるいは関係者が品質を判定し、公衆衛生において安全確保手段を提供することとなる。

GPhPは、各国薬局方および地域薬局方当局が薬局方基準の適切なデザイン、作成、維持、発行、配布を促進する上でのガイダンスとなる、一連の原則を述べたものである。

３．適正薬局方規範の恩恵

GPhPは薬局方間の協力を助長するようにデザインされるので、薬局方間の作業の分担、プロスペクティブな基準の調和、発表された基準の認証、さらに高品質の医薬品へのアクセスや利用に結びつく。

加えて、GPhPの作成によって以下のことが期待される。

- 薬局方間の世界的な協力体制の強化
- 薬局方基準が透明性をもって作成、維持される方法についての利害関係者の理解
- 薬局方基準の世界的な調和の促進という視点のもとに、薬局方間および関係者間の協力関係の改善

GPhPに基づいて作成された薬局方基準は、適合性決定手順に支えられ、適切に検証された分析手順および適切な標準品を伴い、信頼性の高いものとなる。GPhPへの遵守は薬局方間の意見交換、作業の分担、各条の受入れの助長を可能にするものである。

最終的には、GPhPは薬局方基準の調和を可能にすることになるはずである。

４．施行

適正薬局方規範を各薬局方が施行するかどうかは任意であるが、多くの薬局方が施行すれば薬局方の利害関係者や最終的に患者にとって益するところは大きいので、施行することが推奨されるとともに奨励される。

C-6-3. 適正薬局方規範GPhP本体

GPhPドラフト作成は第一回会議の結果を受けて開始されたが、コンセプトペーパー作成を先行することとなり、本格的なドラフト作成は第二回会議前の電話会議をうけ始まっている。

構成は、コンセプトペーパーと同様の１．背景、２．目的、３．恩恵（波及効果）、４．施行の四つの導入部から始まり、GPhP本体部分である、５．各条の作成、６．標準品、７．分析法、８．薬局方間の協力と交流、９．利害関係者との協力からなる予定である。

この中で、５．各条の作成は、5.1 概論、5.2 技術ガイダンス（5.2.1 原薬および添加物を含む原材料の各条、5.2.2 製剤（最終製品）の各条、5.2.3 生物製剤の各条、5.2.4 生薬の各条、5.2.5 その他の各条）から構成される（参考資料３、図29、30参照）。電話会議で、5.1はUSPおよび日局を中心として、5.2.1はEPを中心として、5.2.2はBPが中心として、６はEPおよびUSPを中心として原案作成を行うこととなった。

その結果第二回会議前に提出された第一次ドラフトでは、5.1および5.2.2がハイレベルな原則を記したドラフトであった一方で、5.2.1はEPの原案作成要領に基づいた詳細な記述にわたるドラフトが提出された。また第二回会議での審議により、まずは5.2.1～5.2.2をもってGPhPを作成し、5.2.3生物製剤各条、5.2.4生薬各条についてはその後の経過をみて作成を行うこととした。その中で5.2.4についてはインド薬局方がドラフト作成を担当したいとの表明がなされた。

D．考　察

PDGは平成25年度は２回の対面会議および、その間進捗状況の確認のための月一回の電話会議がコン

スタントに開催され、添加物各条の調和においては順調に実績があがっている。そのためもあり、今現在はICH-Q4B終了が決定された平成22年11月福岡でのICH専門家会議直後のようにPDGの継続が危ぶまれる状況にはない。一方で、調和作業は継続しているものの、既に上げられていた調和予定課題について調和作業を進めているのみであり、新たな調和課題の提案はすべて不調に終わっている。このことはレトロスペクティブな国際調和は極めて困難という欧米でのPDGに対する評価が定着してしまっているためもある。一方でプロスペクティブな調和に傾注すべきという意見は、特にEP関係者に強く、今後のPDGの新たな課題を探る上での大きなヒントとなると思われる。即ち、新技術による一般試験法や、バイオ医薬品等の新しいタイプの医薬品の分析方法等が今後のPDGにおける一般試験法の調和候補になるものと思われる。

一方で、USPは今後のPDGでは、添加物各条の近代化Modernizationを行うべき、という考えを表明している。即ち、添加物各条の試験法を、質量分析等の選択性の高い分析法に置き換え、違法混入物等に対する検出力の高い各条に近代化させようとする主張である。この主張は極めてわかりやすいものの、我が国のように小規模な添加物企業の対応には困難が予想され、日局としてどのように対応するかは議論の余地がある。

ICH-Q4B活動は平成25年度のAnnex6製剤均一性試験法のStep4合意によって終息した。しかし、今後の試験法の改正時の規制当局の相互受け入れの議論を含め、PDGにおける調和内容の実効性を高めるために、薬局方の調和内容に対して、規制当局の受け入れを確認するシステムをどのように構築するかについては、今後の大きな課題といえる。

世界各国の薬局方の交流活動は活発化しているが、その中で最大の会議である世界薬局方国際会議でGPhPの作成が開始された。作成をめざすGPhPについては、当初は薬局方作成にあたってのハイレベルな一般原則の作成と思われた。しかしドラフト作成にあたってEPは原薬各条についてEPの原案作成要領をもとにした詳細な案を提出してきた。これはEPがEPにおける各条形式を世界標準にしようとする戦略が背後にあるものと思われる。日局の国際的立場を強化する意味から、日局としてもこの度のGPhP作成には積極的に関わるべきであることはもちろんであるが、このようなEPのドラフト案については、日局の記載とあわない部分も多く、日局としては是々非々を明らかにして対応する必要がある。

E. 結　論

従来日本薬局方の国際活動は、PDGを舞台とした日米欧三薬局方間の国際調和を意味していた。しかし医薬品の製造・流通の国際化に伴い、薬局方においても国際的な情報交換、意見交換、協力活動が活発化しており、薬局方の国際交流をテーマとして国際会議の開催も続いている。このような背景の中、日本薬局方としてはPDG活動についても、今後の活用の方向への提案が必要となっている。その際、世界の薬局方を先導する役割を果たすような方向性を提案することが重要と考える。一方薬局方間での国際活動として、世界薬局方国際会議においてGPhPの作成が開始されたが、日局の国際的な役割を果たす意味からも積極的な関与が必要と考える。

F. 研究発表

1. 論文発表

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disaccharides in frozen solutions, *Eur J Pharm Biopharm* 85, 177-183 (2013)

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(6) 川西　徹，清原　孝雄，檜山　行雄，津田　重城：今後の日本薬局方の新しい流れ，医薬品医療機器レギュラトリーサイエンス 44, 790-801 (2013)

G．添付資料

・参考資料１．Global Summit of the Pharmacopoeias (GSP) 2013, Meeting #3 Program

・参考資料２．GOOD PHARMACOPOEIAL PRACTICES CONCEPT PAPER ON PURPOSE AND BENEFITS

・参考資料３．班会議資料（スライド）

Global Summit of the Pharmacopoeias 2013

Global Summit of the Pharmacopoeias (GSP)
Friday, September 20, 2013

Meeting #3 Program
(Updated September 12, 2013)

Public Meeting: 8:00 a.m. – 12:00 Noon

8:00 a.m. 1. Welcome and Introductions

a. Welcome from the Chinese Pharmacopoeia Commission — Mr. Zhang Wei
b. Welcome from the United States Pharmacopeial Convention — Dr. Roger Williams
c. Introductions

8:15 a.m. 2. General Session I — *Moderator: Angela Long*

a. Good Pharmacopoeial Practices — Dr. Sabine Kopp, WHO (video)
b. ChP Updates (2015 Edition, Index) — Mr. Wang Ping, ChP
c. Pharmacopeial Discussion Group Update — Dr. Kevin Moore/USP
d. European Pharmacopoeia Update — Ms. Cathie Vielle, EDQM
e. Japanese Pharmacopoeia Update — Dr. Hiroshi Tokunaga, JP
Brief Q&A

10:00 a.m. Coffee/Tea Break

10:30 a.m. 3. General Session II — *Moderator: TBD*

a. API/Product Monographs – Industry Approaches — Mr. Mark Wiggins, Merck
b. Prospective Harmonization: EP, BP, USP — Ms. Vielle/Ms. Vallender/Dr. Cecil
c. The USP Reference Procedure — Dr. Srinivasan/USP
d. Can Pharmacopoeial Paradigms Change? — Dr. Williams/USP
e. ASEAN Harmonization of Pharmaceutical Reference Standards — Ms. Distor

11:45 – 12:15: 4. Panel Discussion/Audience Q & A

12:15 p.m. Group Photograph

12:15–1:30 p.m. Lunch

Pharmacopoeias Meeting: 1:30 - 3:00 p.m.

1:30 pm – 2:45 p.m. 5. General Session III — *Moderator: Roger Williams*

a. Review of Prior Meetings/Actions
b. Round the Table: Strategies for Collaboration
c. Next Global Summit of the Pharmacopoeias

3:00 p.m. Adjourn

Working document QAS/13.518/Rev.1
May 2013
RESTRICTED

World Health Organization

GOOD PHARMACOPOEIAL PRACTICES

CONCEPT PAPER ON PURPOSE AND BENEFITS

(MAY 2013)

DRAFT FOR COMMENT

Please address any comments on this proposal by 12 July 2013 to Dr S. Kopp, Medicines Quality Assurance Programme, World Health Organization, 1211 Geneva 27, Switzerland, fax: (+41 22) 791 4730 or e-mail: kopps@who.int with a copy to gaspardm@who.int.

We are sending out our working documents electronically only and they are also laced on the Medicines web site for comment. If you do not already receive our documents please let us have your e-mail address (to bonnyw@who.int) and we will add it to our electronic mailing list.

SCHEDULE FOR THE PROPOSED ADOPTION PROCESS OF DOCUMENT QAS/13.518: *GOOD PHARMACOPOEIAL PRACTICES CONCEPT PAPER ON PURPOSE AND BENEFITS*

Need for good pharmacopoeial practices (GPhP) stated during first international meeting of world pharmacopoeias, Geneva, and other related events with stakeholders	28 February-1 March 2012 7-8 October 2012 9-12 October 2012 21-22 October 2012
First draft of good pharmacopoeial practices (GPhP) sent out for comment (QAS/12.516)	17 October 2012
Compilation of feedback and comments received	November-December 2012
Circulation of GPhP to drafting group on good pharmacopoeial practices with comments, as well as Concept paper on scope and background (QAS/13.518)	18 January 2013
Formation of initial drafting group (IDG), including representatives from each pharmacopoeia, as per self-nomination, to review draft concept paper via teleconference call	February 2013
Preparation of new skeleton and first draft with more detailed structure	February 2013
Mailing to world pharmacopoeias for additional feedback, preparation of draft chapters by drafting group	February-March 2013
Compilation of feedback	April 2013
Discussion of draft working document on good pharmacopoeial practices at second international meeting of world pharmacopoeias, New Delhi, India	18-19 April 2013
Revised version of GPhP concept paper prepared and mailed out for comments	May 2013
Discussion of any feedback during informal consultation to discuss new medicines, quality control and laboratory standards	12-14 June 2013

Compilation of feedback	August-September 2013
Presentation to forty-eighth meeting of the WHO Expert Committee on Specifications for Pharmaceutical Preparations	October 2013
Sharing of feedback with world pharmacopoeias in next face-to-face meeting, i.e. Third international meeting of world pharmacopoeias	… (dates tbd)

GOOD PHARMACOPOEIAL PRACTICES

CONCEPT PAPER ON PURPOSE AND BENEFITS

1. BACKGROUND

Harmonization efforts in the area of pharmacopoeias started more than a century ago. WHO was mandated with its Secretariat in 1948. This led to the creation of *The International Pharmacopoeia*.

Pharmacopoeias are embedded in their respective national or regional regulatory environment. Retrospective harmonization has proven difficult to achieve. Prospective harmonization may be easier but presents certain challenges after the initial work has been done, as the maintenance process over time of the pharmacopoeial standards (pharmacopoeial texts and reference standards) needs to be viewed within a long-term perspective.

Complete pharmacopoeial harmonization is only possible once regulatory systems have also been harmonized. Developments in science and medical practice, globalization and the presence of adulterated products require pharmacopoeias to constantly revise. Convergence and reinforced collaboration among pharmacopoeial committees and regulators, supported by adequate interaction with industry, will assist in facing new challenges and resource constraints.

A first initiative to reopen the discussion on international harmonization of quality control specifications on a global scale was taken in a side meeting of the 10th International Conference of Drug Regulatory Authorities (ICDRA) entitled: "Pharmacopoeial Specifications – Need for a Worldwide Approach?" in Hong Kong on 24 June 2002. This further led to discussions among regulators during the 11th ICDRA meeting held in Madrid in 2004.

Other international events during the following years enabled discussions with and among pharmacopoeias on this topic.

In 2012 a series of meetings and events focused on and reopened this debate worldwide among the pharmacopoeias and their stakeholders. These events included:

- 28 February-2 March 2012: the first international meeting of world pharmacopoeias held at WHO, Geneva, Switzerland;

- 7-8 October 2012: joint FIP-WHO Conference during the FIP Centennial Congress, Amsterdam, Netherlands;

- 9-12 October 2012: 47th meeting of the WHO Expert Committee on Specifications for Pharmaceutical Preparations, Amsterdam, Netherlands;

- 21-22 October 2012: pre-ICDRA meeting on *Quality of medicines in a globalized world: focus on active pharmaceutical ingredients*, Tallinn, Estonia;

- 23-26 October 2012: 15th International Conference of Drug Regulatory Authorities (ICDRA), Tallinn, Estonia.

The main emerging suggestion from all these events was the development of good pharmacopoeial practices to favour prospective harmonization facilitated by WHO.
A number of pharmacopoeias agreed to participate in an initial drafting group.

It was agreed to develop the harmonized good pharmacopoeial practices under the auspices of the WHO Expert Committee on Specifications for Pharmaceutical Preparations, benefiting from its well-established international standard-setting processes and procedures. These processes include an international wide consultation process,

which enables participation of all stakeholders and users in the development process. The final guidance would then be presented, in line with the procedure, to WHO's 194 Member States and pharmacopoeial authorities.

2. PURPOSE OF GOOD PHARMACOPOEIAL PRACTICES

The primary objective of the *WHO Good Pharmacopoeial Practices* (GPhP) guidance is to harmonize approaches and policies in establishing pharmacopoeial standards, which will support regulatory authorities in controlling the quality of pharmaceutical ingredients and their finished products, and other materials provide a tool by which the user or procurer can make an independent judgement regarding quality, thus safeguarding the health of the public.

GPhP describes a set of principles that provides guidance for national (NPAs) and regional pharmacopoeial authorities (RPAs) which facilitates the appropriate design, development, maintenance, publishing and distribution of pharmacopoeial standards.

3. BENEFITS OF GOOD PHARMACOPOEIAL PRACTICES

GPhP is designed to facilitate collaboration among pharmacopoeias leading to possibilities for work sharing, prospective harmonization of standards and the recognition of published standards between NPAs and RPAs, increasing access to and availability of quality medicines.

In addition to the above, the establishment of GPhP may result in the following:

- strengthening of global pharmacopoeial cooperation;
- providing stakeholders with a better understanding of how pharmacopoeial standards are developed and maintained in a transparent manner;

- improving cooperation between NPAs/RPAs and stakeholders (e.g. regulators, industry) with a view to facilitating the global harmonization of pharmacopoeial standards, to reduce duplication of work.

Pharmacopoeial standards that are developed following GPhP can be relied upon for adequately validated analytical procedures and suitable reference standards in support of compliance determination. Adherence to GPhP can foster exchanges, work sharing and acceptance of monographs among pharmacopoeias.

GPhP should ultimately enable harmonization of pharmacopoeial standards.

4. IMPLEMENTATION

While the implementation of GPhP by NPAs and RPAs is voluntary, it is recommended and encouraged, as a high level of participation will result in greater benefit to the stakeholders and ultimately to patients.

[*Note from the Secretariat: Nomenclature may change with different pharmacopoeias and use of legal terms.*]

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Working document QAS/13.526/Rev.2 draft
January 2014
RESTRICTED

World Health Organization

GOOD PHARMACOPOEIAL PRACTICES

(DRAFT 24 JANUARY 2014)

DRAFT FOR COMMENT

Please address any comments on this proposal by 15 March 2014 to Dr S. Kopp, Group Lead, Medicines Quality Assurance, World Health Organization, 1211 Geneva 27, Switzerland, fax: (+41 22) 791 4730 or email: kopps@who.int with a copy to gaspardm@who.int The document will then be prepared for the 3rd international meeting of world pharmacopoeias, London, 10–11 April 2014.

38 SCHEDULE FOR THE PROPOSED ADOPTION PROCESS OF DOCUMENT QAS/13.526:
39 *GOOD PHARMACOPOEIAL PRACTICES*

40

Need for good pharmacopoeial practices (GPhP) stated during first international meeting of world pharmacopoeias, Geneva, and other related events with stakeholders	28 February–1 March 2012 7–8 October 2012 9–12 October 2012 21–22 October 2012
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Revised version of GPhP prepared and mailed out for comments to all pharmacopoeias, for feedback to be provided to lead pharmacopoeias for each chapter	28 May 2013
Discussion of feedback during informal consultation to discuss new medicines, quality control and laboratory standards	12–14 June 2013

Revision of each chapter by each GPhP lead pharmacopoeia	28 June 2013
Mailing of each chapter to WHO for compilation into a revised working document	July 2013–December 2013
Presentation to forty-eighth meeting of the WHO Expert Committee on Specifications for Pharmaceutical Preparations	October 2013
Compilation of all various chapters received from the Lead Pharmacopoeias and mailing out to all world pharmacopoeias	January 2014
Compilation of all comments received	March 2014
Discussion during the 3rd international meeting of world pharmacopoeias in London, United Kingdom	10–11 April 2014
Continuation of consultation process with world pharmacopoeias and worldwide	…

[Note from the Secretariat:

Terminology – please use the following terms:

– active ingredient, or

– excipient, or

– pharmaceutical substance;

– dosage form.

– Renumbering of chapters, as necessary, will be done in next version of guidelines.

– Paragraph numbering will be done in next version of guidelines.]

CONTENTS

page

1. INTRODUCTION .....

2. PURPOSE AND SCOPE OF GOOD PHARMACOPOEIAL PRACTICES .....

3. MONOGRAPH DEVELOPMENT .....
   3.1 General considerations ... .
   3.2 Technical guidance .....
      3.2.1 Monographs for starting materials, including active ..... pharmaceutical ingredients and excipients
      3.2.2 Monographs for finished products .....
      [3.2.3 Monographs on biologicals] *Action: on hold, to be discussed later*]
      3.2.4 Monographs on herbals .....
      [3.2.5 Monographs on other products] *Action: on hold, to be discussed later*]

4. REFERENCE SUBSTANCES .....

5. ANALYTICAL TEST PROCEDURES AND METHODOLOGIES ..... (ANALYTICAL METHOD)

[6. PRINCIPLES OF COLLABORATION AND EXCHANGES AMONG ..... PHARMACOPOEIAS
including discussion on coordinating versus leading pharmacopoeias, etc.
Action: on hold, to be discussed later]

[7. COLLABORATION WITH STAKEHOLDERS
Action: on hold, to be discussed later]

GOOD PHARMACOPOEIAL PRACTICES

1. BACKGROUND

[WHO Secretariat – *replaced as discussed and included in Concept Paper*]

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A number of pharmacopoeias agreed to participate in an initial drafting group.

It was agreed to develop the harmonized good pharmacopoeial practices under the auspices of the WHO Expert Committee on Specifications for Pharmaceutical Preparations, benefiting from its well-established international standard-setting processes and procedures. These processes include an international wide consultation process, which enables participation of all stakeholders and users in the development process. The

final guidance would then be presented, in line with the procedure, to WHO's 194 Member States and pharmacopoeial authorities.

Following meetings held in 2012, a draft table of content was composed by the WHO Secretariat to initiate the process. A number of pharmacopoeias agreed to participate in an initial drafting group. The feedback received upon circulation to all pharmacopoeias, resulted in a *Draft Concept paper on the Scope and Purpose of the Good Pharmacopoeial Practices (GPhP)* and a timeframe for the development of the GPhP. The drafting group of interested pharmacopoeias agreed to continue their active contribution in the drafting process as leads in coordinating with other pharmacopoeias. The members of the Drafting Group agreed to work on various chapters prior to the 2nd meeting of world pharmacopoeias in India.

WHO subsequently collated all inputs received into a working document for discussion among the world pharmacopoeias.

During the 2nd international meeting of world pharmacopoeias co-hosted by the Indian Pharmacopoeia Commission (IPC), the concept paper and the initial comprehensive draft GPhP in collated form, including the various inputs, were discussed. Based on the discussions and the feedback received, the lead pharmacopoeias committed to revise again each of the chapters. WHO again collated the feedback into a new draft which will be discussed during the 3rd international meeting of world pharmacopoeias.

2. PURPOSE OF GOOD PHARMACOPOEIAL PRACTICES

[*WHO Secretariat, changed in line with the concept paper, 2nd meeting*]

The primary objective of the *WHO Good Pharmacopoeial Practices* (GPhP) guidance is to harmonize approaches and policies in establishing pharmacopoeial standards, which will support regulatory authorities in controlling the quality of pharmaceutical ingredients and their finished products, and other materials provide a tool by which the user or

procurer can make an independent judgement regarding quality, thus safeguarding the health of the public.

GPhP describes a set of principles that provides guidance for NPAs and RPAs which facilitates the appropriate design, development, maintainance, publishing, and distribution of pharmacopoeial standards.

3. BENEFITS OF GOOD PHARMACOPOEIAL PRACTICES

[*WHO Secretariat, changed in line with the concept paper, 2nd meeting*]

GPhP is designed to facilitate collaboration among pharmacopoeias leading to possibilities for work sharing, prospective harmonization of standards, and the recognition of published standards between national (NPAs) and regional pharmacopoeial authorities (RPAs), increasing access to and availability of quality medicines.

In addition to the above, the establishment of GPhP may result in the following:

- strengthening of global pharmacopoeial cooperation;
- providing stakeholders with a better understanding of how pharmacopoeial standards are developed and maintained in a transparent manner;
- improving cooperation between NPAs/RPAs and stakeholders (e.g. regulators, industry) with a view to facilitating the global harmonization of pharmacopoeial standards, to reduce duplication of work.

Pharmacopoeial standards that are developed following GPhP can be relied upon for adequately validated analytical procedures and suitable reference standards in support of compliance determination. Adherence to GPhPs can foster exchanges, work sharing, and acceptance of monographs among pharmacopoeias.

GPhP should ultimately enable harmonization of pharmacopoeial standards.

4. IMPLEMENTATION

[*WHO Secretariat, changed in line with the concept paper, 2nd meeting*

While the implementation of the GPhP by NPAs and RPAs is voluntary, it is recommended and encouraged, as a high level of participation will result in greater benefit to the stakeholders and ultimately to patients.

5. MONOGRAPH DEVELOPMENT

[introduction paragraph revised as discussed, taking into consideration comments received from IPC]

(a) Development of a monograph requires consideration of information and candidate materials. This information may come from donors, literature, various publicly available material, from other pharmacopoeias, or may be generated within other available resources of a pharmacopoeia. Analytical data generated by a pharmacopoeial body should be available for scrutiny by its standards-setting expert body. The draft text should be displayed for public comments.

(b) Pharmacopoeial monographs conform where possible to regulatory decision-making reflected in the work of harmonizing bodies, such as those (e.g. WHO, International Conference on Harmonisation (ICH), and Pharmacopoeial Discussion Group (PDG).

(c) Pharmacopoeial monographs may incorporate by reference one or more general chapters as a means of conserving space or for other reasons as well.

3.1 General considerations [JP, *as received from* USP]

These *General considerations* provide principles for the standards-setting practices associated with the development of pharmacopoeial standards.