事　務　連　絡
平成 27 年 12 月 17 日

各 医 薬 品 製 造 業 者　様
各 医薬部外品製造業者　様

静岡県健康福祉部生活衛生局薬事課

医薬品ＧＭＰ査察情報の通報に係るＰＩＣ／Ｓ手順書の施行について

医薬品査察協定及び医薬品査察協同スキーム（以下「PIC/S」という。）加盟当局間の協力や効率的な情報交換の推進等を目的として、外国の PIC/S 加盟当局による医薬品 GMP 査察情報の通報に係る PIC/S 手順書（別添、以下「PIC/S 手順書」という。）が施行され、別添写しのとおり、厚生労働省医薬・生活衛生局監視指導・麻薬対策課（以下「厚生労働省」という。）から事務連絡がありましたので、御承知おきいただきますようお願いいたします。

なお、PIC/S 手順書に基づき、厚生労働省が PIC/S 加盟当局へ査察対象製造所の査察情報を提供するにあたり、厚生労働省から自治体に必要な情報提供の依頼があったときには、査察対象製造所において本県が実施した GMP 適合性調査に係る GMP 調査結果報告書の写しを PIC/S 加盟当局への提供することの可否及び査察対象製造所の英語表記について査察対象製造所に確認することとしましたので、御理解、御協力をお願いします。

担　　当　薬事課薬事審査班
電話番号　０５４－２２１－２４１４

写

事　務　連　絡
平成27年11月27日

各都道府県衛生主管部（局）長　殿

厚生労働省医薬・生活衛生局監視指導・麻薬対策課

医薬品ＧＭＰ査察情報の通報に係るＰＩＣ／Ｓ手順書の施行について

薬事監視指導行政の推進については、日頃より格別のご配慮を賜り厚く御礼申し上げます。

今般、医薬品査察協定及び医薬品査察協同スキーム（以下「ＰＩＣ／Ｓ」という。）加盟当局間の協力や効率的な情報交換の推進等を目的として、外国のＰＩＣ／Ｓ加盟当局による医薬品ＧＭＰ査察情報の通報に係るＰＩＣ／Ｓ手順書（別添）が施行されました。本手順書の運用にあたっては、下記のとおり取り扱うこととしますので、ご協力方お願い申し上げます。

記

１．ＰＩＣ／Ｓ加盟当局へ提供する査察情報について

本手順書では、外国のＰＩＣ／Ｓ加盟当局から我が国の医薬品製造所においてＧＭＰ査察を実施する旨の事前通報を受けた際に、当該ＰＩＣ／Ｓ加盟当局に対して以下の情報を提供することが求められています。

（１）査察対象製造所における、我が国査察機関による直近のＧＭＰ査察実施日
（２）当該製造所に係る査察報告書の提供の可否
（３）事前通報のあったＰＩＣ／Ｓ加盟当局による査察への、我が国査察機関からの同行希望の有無

２．我が国の医薬品製造所においてＧＭＰ査察を実施する旨の連絡を受けた後の手続きについて

ＰＩＣ／Ｓ加盟当局に対する上記１．（１）～（３）の情報は、当課から当該ＰＩＣ／Ｓ加盟当局へ提供します。査察対象製造所が自治体の許可に係る製造所であるときは、当該自治体の担当課に、当課から必要な情報提供を依頼することとなります。その際は、別紙を参考に、事前通報のあったＰＩＣ／Ｓ加盟当局による査察実施の１週間前を目処に、当課宛てにご連絡いただきますようお願いいたします。

別紙

査察事前通報に対する情報提供

都道府県名＿＿＿＿＿＿＿＿＿＿

１．　Site to be inspected：（査察対象製造所の名称）
２．　Date of the last inspection：（当該査察対象製造所における、自治体による直近の査察実施日）
３．　Possibility to share available inspection reports：（査察報告書の提供の可否）
注）査察報告書を提供する場合には日本語のままで差し支えありません。
４．　Request opportunities to participate in the inspection :（査察同行希望の有無）
５．　Name of inspector：（査察同行者の氏名）
６．　E-mail address：（連絡先）
７．　Office：（所属）
８．　Job Title：（職名）
９．　Date of participation：（同行日）
１０．　Participation preference：（同行目的。例えば joint, training, observing 等）
１１．　Other information：（その他特筆すべき事項。特になければ、none と記載することで差し支えありません。）

※　各項目は英語でご記入下さい。

PHARMACEUTICAL INSPECTION CONVENTION
PHARMACEUTICAL INSPECTION CO-OPERATION SCHEME

PI 039-1
1 November 2015

PROCEDURE TO INFORM FOREIGN REGULATORY AGENCIES OF FOREIGN INSPECTIONS TO BE CONDUCTED IN THEIR JURISDICTION

Editor: PIC/S Secretariat

e-mail: info@picscheme.org
web site: http://www.picscheme.org

TABLE OF CONTENTS

1. DOCUMENT HISTORY

Adoption by the PIC/S Committee	11-12 May 2015
Entry into force of PI 039-1	1 November 2015

2. INTRODUCTION

2.1 A PIC/S Participating Authority planning to conduct an inspection activity, which would be considered to be subject to the PIC Scheme, in the jurisdiction of another PIC/S Participating Authority should provide timely notification to the regulatory agency in that jurisdiction.

2.2 Judicial or administrative acts, such as an inspection or investigation activity performed by foreign officials may be subject to prohibitions related to the sovereignty of the country in which an inspection is planned. Open communications between regulatory agencies can help promote understanding of legal obligations, clarify necessary authorization processes, and potentially mitigate contravention to local law or to any agreement between both Participating Authorities (e.g. MRA).

2.3 The notification of the intent to conduct an inspection in the jurisdiction of another regulatory agency helps facilitate:

- promotion of cooperation and effective exchange of information between regulatory agencies,
- discussion on opportunities to observe inspections potentially enhancing domestic inspection programs through knowledge sharing gained in observing diversity in inspection approaches,
- discussion on opportunities for joint inspections where possible,

- monitoring of companies performing export only activities that may not have obtained domestic marketing authorization,
- promotion of PIC/S values relating to international cooperation, and
- where applicable, exchange of information on important legal prohibitions or authorizations applicable to foreign officials when acting in the sovereign territory of another state (see 2.2 above).

2.4 Where possible, a PIC/S Participating Authority planning to conduct an inspection in the jurisdiction of a non-PIC/S regulatory agency should provide timely notification to the regulatory agency in that jurisdiction.

3. PURPOSE AND SCOPE

3.1 The purpose of this Standard Operating Procedure (SOP) is to guide communications between regulatory agencies when one PIC/S Participating Authority's inspection is intended to be conducted in the jurisdiction of another regulatory agency.

3.2 Additional requirements beyond the scope of this SOP may apply where national legislation requires a foreign authority to officially give notification of inspections or to officially ask for permission to inspect. This is notably the case in the following countries:

3.2.1 Switzerland

4. NOTIFICATION OF AN INSPECTION IN THE JURISDICTION OF ANOTHER REGULATORY AGENCY

4.1 At earliest convenience, a PIC/S Participating Authority planning to conduct an inspection in the jurisdiction of another PIC/S Participating Authority should provide timely notification of the inspection to the PIC/S Participating Authority in that jurisdiction.

4.2 It is very important for notification to be provided well in advance of the inspection unless extraordinary circumstances warrant an inspection at short notice. "Well in advance" is intended to mean approximately two months prior to the scheduled inspection however flexibility in notification may be considered in recognition to challenges that may exist within a Participating Authority's process for the scheduling of international inspections.

4.3 Notification timelines in extraordinary circumstances (e.g. unannounced, for cause, or pre-market inspections) may be modified as necessary except where notification is required under national legislation in the jurisdiction where the inspection is being held (see paragraph 3.2). Out of courtesy to regulatory agencies such inspections should be notified as soon as possible.

4.4 Notification may be provided by:

4.4.1 electronic mail sent to contacts identified on the PIC/S document 02.3 *List of Committee Members, Partners, & (Pre-)Applicants* or through other contacts established with regulatory agencies that are not members, partners, or (pre-)applicants of PIC/S noting that marketing authorisation holders may be able to support identification of appropriate contacts when such contacts have not been well established (refer to paragraph 6 for the template of the notification).

or

4.4.2 an alternate means of communication where a regulatory agency has already been made aware of the inspection such as through the list of planned foreign inspections as distributed by the PIC/S Secretariat.

Note: When considering the list of planned foreign inspections as a form of notification; it should be noted which PIC/S Participating Authorities have been provided access to the list of planned foreign inspections. Depending on current practices, the list of planned foreign inspections may only have been shared among participating agencies that were willing to share information on foreign inspections. Additionally, in some case the list may not have adequately identified details relating to the inspection.

4.5 The subject line of electronic mail notification should consist of the following:

Subject Line: Notification of Inspection(s) by <Name of PIC/S Participating Authority Conducting the Inspection> in <Insert Country of Inspection(s)>

4.6 Electronic mail notification may be adjusted as necessary to reflect circumstances applicable to the inspection but should contain:

- name of the establishment to be inspected,
- location of the establishment,
- proposed dates of the inspection,
- names and contact information of inspectors,
- type of inspection,
- scope of the inspection (products, facilities, etc.), and
- the statement (or an equivalent statement) indicating

"Notification of this inspection is intended to support the collaborative vision of the Pharmaceutical Inspection Convention (PIC) and the Pharmaceutical Inspection Co-operation Scheme (PIC Scheme) which operate together as PIC/S. Further information on PIC/S is available at www.picscheme.org"

5. PIC/S PARTICIPATING AUTHORITIES RECEIVING NOTIFICATION OF AN INSPECTION IN THEIR JURISDICTION

5.1 A PIC/S Participating Authority receiving notification of inspection should:

- acknowledge the notification of the inspection,
- indicate the date of the last inspection and the possibility to share available inspection reports (in the language in which the inspection report was written),
- communicate any important legal prohibitions or authorizations applicable (including procedures for applying for such authorization) to foreign officials when acting in the territory, and
- where appropriate, request opportunities to participate as an observer in the inspection or explore options for that of a joint inspection.

5.2 The voluntary acceptance to involve another PIC/S Participating Authority in an inspection as an observer or for that of a joint inspection are at the discretion of the PIC/S Participating Authority who is planning the foreign inspection. This voluntary acceptance may not apply for countries listed under section 3.2.1.

6. Inspection Notification Template for Email Notification

NOTE: The template provided below is intended as an example. This template can be modified as deemed necessary to allow for flexibility in providing notification of an inspection.

Email Subject Line: Notification of Inspection(s) by <Name of PIC/S Participating Authority Conducting the Inspection> in <Insert Country of Inspection(s)>

Dear XXXXXXXXXXX,

I am contacting you in relation to a GMP inspection(s) planned to take place in <Insert Country>. Details of the inspection(s) can be found below. If your agency plans to observe the inspection(s) please advise the specified contact.

Inspection Date: <Insert Start Date> to <Insert End Date>
<Alternatively provide as much detail as possible for the inspection date such as month of inspection>
Site to be inspected: <Insert Name of Company>
Street Address: <Insert Street>
City: <Insert City>
Province/State: <Insert Province/State as Applicable>
Country: <Insert Country>
Inspection Type: <Insert Inspection Type (Routine GMP Inspection, Pre-market Inspection, For Cause Inspection, Unannounced)>
Scope of the Inspection: <Insert Scope of the Inspection>
Name of inspector(s): <Insert Names of Inspectors>

Contact Information: <Insert Contact Name> <Insert Email Address>
<Insert Additional Contact Details as Applicable>

<Insert Additional Sites as Applicable>

Notification of this inspection is intended to support the collaborative vision of the Pharmaceutical Inspection Convention (PIC) and the Pharmaceutical Inspection Co-operation Scheme (PIC Scheme) which operate together as PIC/S. Further information on PIC/S is available at www.picscheme.org

Yours Sincerely,

<Insert Signature Block>

7. REVISION HISTORY

Date	Version number	Reasons for revision