

## Annex 8

### **Interim guidelines for the assessment of a procurement agency (based on the draft model quality assurance system for procurement agencies)**

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#### **1. Introduction and background**

WHO has established a procedure describing the process of pre-qualifying procurement agencies (PAs). PAs interested in being pre-qualified for possible use by other organizations (including the United Nations) will have to submit information about their activities for assessment as part of a pre-qualification procedure. This information should be provided in a procurement agency information file (PAIF).

To further harmonize norms and standards in activities in PAs, WHO in collaboration with other United Nations procurement organizations, nongovernmental organizations and interested organizations, is in the process of preparing norms and standards for PAs. These will be reflected in a model quality assurance system (MQAS).

As the MQAS is not yet available in its final format, an “interim assessment Guideline” has been prepared that can be used until the MQAS document is available. The immediate objective of this interim assessment guideline is to provide an interim assessment tool for the pre-qualification of PAs. It recommends key (interim) requirements for quality assurance for PAs which could, in principle, be used, among others, by the Global Fund to Fight AIDS, TB and Malaria (GFATM) to pre-qualify such organizations. This document further reflects strategic objectives and operational principles for procurement and wholesale distribution that were developed and endorsed by the Interagency Pharmaceutical Coordination Group (IPC), which involved the pharmaceutical advisers of the United Nations Children’s Fund (UNICEF), the United Nations Population Fund (UNFPA), WHO and the World Bank.

Two of the objectives of these Guidelines are to ensure that reliable suppliers of high-quality products are pre-selected, and that active quality assurance programmes involving both surveillance and testing, are implemented.

It is recommended that:

- Procurement procedures (including pre-qualification of products and manufacturers as well as purchasing procedures) should be transparent.
- Efficient procedures should be in place to pre-select potential suppliers and manufacturers, to manage procurement and delivery, to ensure good quality of the product and to monitor the performance of suppliers and manufacturers and of the procurement system.
- Written procedures (describing the use of explicit criteria to award contracts) should be used throughout the process.
- Pre-qualified and selected products, manufacturers and suppliers should be monitored through a process which takes into account product quality, service reliability, delivery time and financial viability.

For the purpose of this interim assessment Guideline, the activities associated with the PA may include inter alia:

- pre-qualification (product dossier assessment and manufacturing site inspections);
- purchasing;
- storage; and
- distribution.

A PA could perform all four of the above-mentioned activities, but in some cases, one or more of the four may be contracted out to another organization. In such a case, the PA is still responsible for all the activities associated with the procurement or wholesale distribution of the products.

This interim assessment Guideline focuses on aspects of the active pharmaceutical ingredients and finished pharmaceutical products used in the treatment of HIV-related diseases, malaria and tuberculosis, as listed in the Invitations for Expression of Interest (EOIs) of the Pilot Procurement Quality and Sourcing Project (more information is available on the Internet at <http://www.who.int/medicines/>). However these principles are also applicable to other pharmaceutical products.

The checklist that follows can be used for guidance as well as an assessment tool during the interim pre-qualification period of PAs. Once the checklist is completed, it could serve as an assessment report.

An assessment report with the observations recorded should be communicated to the PA concerned.

The organization responsible for the interim assessment should decide whether an organization responsible for some of the activities (e.g. distribution by a distributor licensed by a national authority to perform this activity) should be inspected.

2. **Interim assessment tool for pre-qualification of a procurement agency site**

This report (based on the checklist) contains confidential information and shall not be divulged to any person other than those mentioned on this page, or without prior consent of the procurement agency. The report is the property of the organization responsible for performing the inspection.

**Part 1: General information about the agency**

Name of procurement agency:	
Physical address:	
Postal address:	
Telephone number:	
Fax number:	
E-mail address:	
24-hour contact number:	
Web page address:	
Summary of activities of the agency: (e.g. pre-qualification, purchasing, storage, distribution). List the names, addresses and contact details of organizations contracted to perform specific activities where relevant)	
Indicate type of products:	
Contact person:	
Person responsible for pre-qualification:	

Person responsible for purchasing:	
Person responsible for quality assurance:	
Person responsible for quality control:	
Person in charge of distribution/ shipping:	

Names of inspectors:	
Date of inspection:	
Project:	

### Summary and conclusion

**Summary:**

*(Provide a brief summary of the findings)*

**Conclusion:**

*(Select appropriate option)*

Based on the findings of the inspection, and the observations listed in the inspection report, the procurement agency was found to be operating/not operating (*select option*) at an acceptable level of compliance with the WHO recommendations for quality assurance systems for procurement agencies.

### Guideline and checklist: procurement agency

**Organizational structure**

<i>Guidelines</i>	<i>C</i>	<i>PC</i>	<i>NC</i>	<i>NA</i>
The agency should have an organizational chart indicating key persons in positions of responsibility.				
Persons in key positions should have written job descriptions.				
There should be a sufficient number of persons with suitable qualifications and experience responsible for pre-qualification.				
There should be a sufficient number of persons with suitable qualifications and experience responsible for purchasing.				

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**Organizational structure (continued)**

<i>Guidelines</i>	<i>C</i>	<i>PC</i>	<i>NC</i>	<i>NA</i>
There should be a sufficient number of persons with suitable qualifications and experience responsible for storage.				
There should be a sufficient number of persons with suitable qualifications and experience responsible for distribution.				
The agency should be licensed by the national authority to perform the activities listed above (licence number: _____) (Attach).				
There should be a responsible person who is authorized to perform the activities listed above.				
Clarification of observations made:				

C, compliant; NA, not applicable; NC, noncompliant; PC, partially compliant

**Quality assurance**

<i>Guidelines</i>	<i>C</i>	<i>PC</i>	<i>NC</i>	<i>NA</i>
The agency should have a documented quality policy and quality systems should be defined in writing.				
All activities should be defined in clear, unambiguous written procedures.				
Records should be maintained for defined periods of time that ensure traceable actions.				
Written contracts should exist with other organizations (as applicable), for performing activities on behalf of the agency.				
Provisions should be made for confidentiality undertakings regarding confidential information submitted to the agency by manufacturers and suppliers.				
The agency should have a written procedure for self-inspections (self-audits). These should be performed at regular intervals.				

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<i>Guidelines</i>	<i>C</i>	<i>PC</i>	<i>NC</i>	<i>NA</i>
The agency should have procedures for and records of the training provided to employees.				
Clarification of observations made:				

C, compliant; NA, not applicable; NC, noncompliant; PC, partially compliant

### ***Pre-qualification***

<i>Guidelines</i>	<i>C</i>	<i>PC</i>	<i>NC</i>	<i>NA</i>
The procurement agency should follow a written policy, standards and procedures describing the pre-qualification of products, suppliers and manufacturers.				
Product data and information should be requested from manufacturers and be assessed in accordance with the minimum data and information reflected in attachment A.				
Manufacturers should manufacture their products in compliance with WHO good manufacturing practices.				
Pre-qualification of manufacturers should include evaluation of evidence of compliance with WHO good manufacturing practices through assessment of: <ul style="list-style-type: none"> <li>• valid manufacturing licence issued by the competent authority; and</li> <li>• certificate of a pharmaceutical product (WHO type) issued by the competent authority; and /or</li> <li>• on-site inspection when necessary.</li> </ul>				
The pre-qualification of products should be linked to the manufacturing site for that particular product.				
Records of the assessment of products and manufacturers indicating the results and outcome of the assessment should be maintained.				
Clarification of observations made:				

C, compliant; NA, not applicable; NC, noncompliant; PC, partially compliant

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**Monitoring of product quality**

<i>Guidelines</i>	<i>C</i>	<i>PC</i>	<i>NC</i>	<i>NA</i>
A person should be responsible for the review of the certificate of analysis and/or related documents supplied by the manufacturer for the batches of products.				
The review should be carried out in accordance with a written procedure.				
Records for this should be maintained.				
The agency should have a written procedure to ensure that random samples of shipments are taken for analysis. The results of the analysis should be reviewed by a responsible person.				
The agency should have access to a laboratory, either their own or one contracted to perform analysis of the samples taken.				
A written procedure should be in place to review “out-of-specification” results, including the investigation of these results and appropriate action to be taken.				
The agency should have written procedures for the detection, identification and handling of counterfeit products.				
There should be a procedure for handling product complaints.				
Clarification of observations made:				

C, compliant; NA, not applicable; NC, noncompliant; PC, partially compliant

**Purchasing**

<i>Guidelines</i>	<i>C</i>	<i>PC</i>	<i>NC</i>	<i>NA</i>
The agency should have written, transparent procedures for purchasing of pre-qualified products from pre-qualified manufacturers and suppliers.				
The person responsible for purchasing should be free from any possible conflict of interest.				
Limited invitations for competitive bidding from pre-qualified suppliers should be the preferred option.				

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<i>Guidelines</i>	<i>C</i>	<i>PC</i>	<i>NC</i>	<i>NA</i>
Internationally accepted principles for purchasing should be followed. If tenders are used, these should be published with specifications for the products to be purchased.				
The adjudication should be transparent and fair. All decisions should be recorded and records kept.				
Procedures and agreements should be in place to ensure that the product purchased is the same as the product that had been pre-qualified.				
Clarification of observations made:				

C, compliant; NA, not applicable; NC, noncompliant; PC, partially compliant

### **Storage**

(The following key points are a summary of the guidelines on Good Storage Practices referred to in the text under “Introduction and background”.)

<i>Guidelines</i>	<i>C</i>	<i>PC</i>	<i>NC</i>	<i>NA</i>
<b>Personnel</b>				
There should be an adequate number of suitably qualified personnel to achieve pharmaceutical quality assurance objectives at each storage site. National regulations on qualifications should be followed.				
All personnel should receive proper training in relation to good storage practice, regulations, procedures and safety.				
All members of staff should be trained in, and observe high levels of, personal hygiene and sanitation.				
Personnel employed in storage areas should wear suitable protective or working garments appropriate for the activities they perform.				
<b>Premises and facilities</b>				
Precautions must be taken to prevent unauthorized persons from entering storage areas.				

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**Storage** (continued)

<i>Guidelines</i>	<i>C</i>	<i>PC</i>	<i>NC</i>	<i>NA</i>
Storage areas should be designed or adapted to ensure good storage conditions. In particular, they should be clean and dry and maintained within acceptable temperature limits. Where special storage conditions are specified on the label (e.g. for temperature and relative humidity), these should be provided, checked, monitored and recorded. Materials and pharmaceutical products should be stored off the floor and suitably spaced to permit cleaning and inspection. Pallets should be kept in a good state of cleanliness and repair.				
Storage areas should be clean and free from accumulated waste and from vermin. A written sanitation programme should be available indicating the frequency of cleaning, and the methods to be used to clean the premises and storage areas. There should also be a written programme for pest control. The pest-control agents should be safe, and there should be no risk of contamination of the materials and pharmaceutical products. There should be appropriate procedures for the cleaning up of any spillage to ensure complete removal of any risk of contamination.				
Physical or other equivalent validated (e.g. electronic) segregation should be provided for the storage of rejected, expired, recalled or returned materials or products. The materials or products, and storage areas concerned should be appropriately identified.				
Materials and pharmaceutical products should be stored in conditions which assure that their quality is maintained, and stock should be appropriately rotated. The “first expired/first out” principle should be followed.				
Narcotic drugs should be stored in compliance with international conventions, and national laws and regulations on narcotics.				

<i>Guidelines</i>	<i>C</i>	<i>PC</i>	<i>NC</i>	<i>NA</i>
<b>Storage requirements</b>				
Written instructions and records should be available which document all activities in the storage areas including the handling of expired stock. These should adequately describe the storage procedures and define the route of materials and pharmaceutical products and information through the organization in the event of a product recall being required.				
Comprehensive records should be maintained showing all receipts and issues of materials and pharmaceutical products according to a specified system, e.g. by batch number.				
All containers should be clearly labelled with at least the name of the material, the batch number, the expiry date or retest date, the specified storage conditions and reference to the pharmacopoeia, where applicable. Unauthorized abbreviations, names or codes should not be used.				
<b>Returned goods</b>				
Returned goods, including recalled goods, should be handled in accordance with approved procedures and records should be kept.				
<b>Product recall</b>				
There should be a procedure to recall from the market, promptly and effectively, pharmaceutical products and materials known or suspected to be defective.				
Clarification of observations made:				

C, compliant; NA, not applicable; NC, noncompliant; PC, partially compliant

**Distribution**

<i>Guidelines</i>	<i>C</i>	<i>PC</i>	<i>NC</i>	<i>NA</i>
<b>Dispatch and transport</b>				
Materials and pharmaceutical products should be transported in such a way that their integrity is not impaired and that suitable storage conditions are maintained.				
Records for dispatch should be retained, stating at least: <ul style="list-style-type: none"> <li>• the date of dispatch</li> <li>• the customer's name and address</li> <li>• the product description, e.g. name, dosage form and strength (if appropriate), batch number and quantity</li> </ul>				
The transport should be readily accessible and available on request.				
There should be a procedure to ensure that the products are supplied to authorized recipients only.				
Appropriate documentation should accompany the consignment to the recipient.				
Clarification of observations made:				

C, compliant; NA, not applicable; NC, noncompliant; PC, partially compliant

\_\_\_\_\_  
Inspector's signature:

\_\_\_\_\_  
Date:

Name: \_\_\_\_\_

Appendix

**Attachment A: interim assessment guideline for procurement agencies**

**Pharmaceutical product questionnaire**

**I. Product identification**

Active pharmaceutical ingredient(s) (use INN where possible):

\_\_\_\_\_  
Generic name of the product:

Dosage form:  Tablets  Capsules  Ampoules  
 Vial  Other

Strength per dosage unit:  
\_\_\_\_\_

Route of administration:  Oral  Intramuscular  Intravenous  
 Subcutaneous  Other

Pack size:  50  100  1000  1000ml  Other

Description of primary packaging materials: \_\_\_\_\_

Description of secondary packaging materials: \_\_\_\_\_

**II. Manufacturer of the product**

Name, address and activities of the manufacturer(s) (or contract manufacturer(s))

Name	Physical address	Telephone number, facsimile number and e-mail contact details	Activity (e.g. packaging)

Are all sites listed above licensed by the relevant authority to perform the activity?  Yes  No

Is the manufacturing site for THIS product pre-qualified by the Procurement Agency?  Yes  No

Has the manufacturing method for each standard batch size been validated?  Yes  No

List the standard batch size: \_\_\_\_\_

III. **Supplier identification** (to be filled in if information is not identical to that given in answer to question II)

Name: \_\_\_\_\_

Address: \_\_\_\_\_

Telephone number: \_\_\_\_\_

Facsimile number: \_\_\_\_\_

E-mail contact details: \_\_\_\_\_

Link with the product:  Marketing licence holder  Distributor  
 Manufacturer  Other: \_\_\_\_

IV. **Regulatory situation (licensing status) in the country of manufacture**

Product registered and currently marketed  
licence no. \_\_\_\_\_

Product registered for marketing in the country of manufacture but not currently marketed  
licence no. \_\_\_\_\_

Product registered for export only licence no. \_\_\_\_\_

Product not registered (please clarify) : \_\_\_\_\_

Please attach a Certificate of Pharmaceutical Product according to the WHO Certification Scheme (WHO Technical Report Series No. 863 (1996): an earlier version is not acceptable).

V. **Regulatory situation (licensing status) in other countries**

List the other countries where the product is registered and is currently marketed:

\_\_\_\_\_  
\_\_\_\_\_

VI. **Finished product specifications**

- British Pharmacopoeia; edition \_\_\_\_\_
- US Pharmacopoeia; edition \_\_\_\_\_
- International Pharmacopoeia; edition \_\_\_\_\_
- Other: \_\_\_\_\_

Please attach a copy of the finished product specification, if different from the British Pharmacopoeia, US Pharmacopoeia or International Pharmacopoeia specification.

Limits expressed as percentages for the assay of active ingredient(s):

- 95–105%     90–110%     Other: \_\_\_\_\_

Additional specifications to those in the pharmacopoeia (e.g. *dissolution*, *syringeability*):

\_\_\_\_\_

*Attach a copy of the model certificate of analysis for batch release.*

Are you willing to provide necessary information (analytical method) to enable the tests to be replicated by another quality control laboratory?

- Yes     No

VII. **Stability**

Stability testing data available:     Yes     No

If yes, type and conditions of testing:

- accelerated testing
- 40°C/ 75% relative humidity for 6 months
- other

In the same packaging as specified in point I (p. 1)

- Yes     No

real time testing

Temperature:     ambient     25°C     30°C     other

Relative humidity:     not controlled     45%     65%     other

Period of time:     1 year     2 years     3 years     other

In the same packaging as specified in point I (p. 1)

- Yes     No

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Can a stability report be forwarded within one week of being requested?

Yes       No

Was the stability testing done on a product of the same formula, manufactured on the same site and packed in the same packaging material as that for the product that will be supplied?

Yes       No

VIII. **Label and insert information**

Shelf-life:  2 years     3 years     4 years     5 years  
other: \_\_\_\_\_

Storage conditions (e.g. "Do not store above 30°C — protect from light"):

\_\_\_\_\_  
\_\_\_\_\_

Language used on label:  Bilingual English/French  
 English     French     Other: \_\_\_\_\_

Package insert:  Yes (*attach a copy*)     No

IV. **Samples**

Can free non-returnable samples be obtained upon request within one week of being requested?

Yes     No

X. **Therapeutic equivalence**

demonstrated

by in vivo bioequivalence studies

Reference product: \_\_\_\_\_

Number of volunteers: \_\_\_\_\_

Country of study: \_\_\_\_\_

Year performed: \_\_\_\_\_

by another method claimed to be suitable by the supplier/manufacturer (please describe briefly):

\_\_\_\_\_

by in vitro dissolution tests

Reference product: \_\_\_\_\_

not demonstrated

not relevant

unknown

Can a copy of the report be obtained upon request within one week of being requested?

Yes     No

Is the product used in the trial or test essentially the same as the one that will be supplied (i.e. same materials from the same suppliers, same formula, same manufacturing method)?

Yes     No

XI. **Active pharmaceutical ingredient(s) (APIs)**

*(If more than one active ingredient is used, please supply answers to this question separately for each active ingredient used.)*

Specifications and standard test methods exist for each API and excipient:

Yes     No

Each API used (give INN where this exists):

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has a Certificate of suitability to the European Pharmacopoeia (CEP)

Certificate no.: \_\_\_\_\_

The CEP is in our possession (including annex if any).

The CEP is in the possession of the manufacturer of the finished product (including annex if any).

has a Drug Master File (DMF) registered in (country): \_\_\_\_\_

The full or open part of the DMF is in our possession.

The full or open part of the DMF is in the possession of the manufacturer of the finished product.

Quality standard:

BP     USP     EP     International Pharmacopoeia

Other (e.g. "in-house"); specify: \_\_\_\_\_

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No pharmacopoeia monograph exists\*

\*If there is no monograph in a recognized pharmacopoeia, then the following information should be provided and evaluated:

**Chemical structure**

If relevant,

- state the isomeric nature of the active ingredient, including stereochemical configuration (e.g. acemate, pure (*S*)-isomer, 50/50 mixture of (*Z*)- and (*E*)-isomers);
- the solubility of the active ingredient in water at 25°C or 35°C;
- the solubility of the active ingredient in other solvents such as ether, ethanol, acetone and buffers, if different pH (if the active ingredient is acidic or basic);
- other relevant physicochemical characteristics of the active ingredient such as partition coefficient (usually octanol/water) and the existence of polymorphs;
- copies of infrared, nuclear magnetic resonance (proton and C<sub>13</sub>), ultraviolet and mass spectra; and
- information on the chemical stability of the API, and on physicochemical stability if relevant (e.g. formation of a hydrate, change of polymorphic form).

Manufacturer (name, physical address and country):

GMP certified:  Yes (*attach a copy of the GMP certificate if any*)

Certified by: \_\_\_\_\_

No

Unknown

XIII. **Commitment**

I, the undersigned, \_\_\_\_\_,  
(*position in the company, e.g. General Manager, Authorized Person, Responsible Pharmacist*), acting as responsible person for the company \_\_\_\_\_ (*name of the company*), certify that the information provided (above) is correct and true

(*if the product is marketed in the country of origin, tick the appropriate box below*)

and I certify that the product offered is identical in all aspects of manufacturing and quality to that marketed in \_\_\_\_\_

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(*country of origin*), including formulation, method and site of manufacture, sources of active pharmaceutical ingredients and excipients, quality control of the product and starting material, packaging, shelf-life and product information

and I certify that the product offered is identical to that marketed in \_\_\_\_\_ (*name of country*), except:

\_\_\_\_\_  
\_\_\_\_\_  
*(e.g. formulation, method and site of manufacture, sources of active pharmaceutical ingredients and excipients, quality control of the finished product and starting material, packaging, shelf-life, indications, product information)*

Date: \_\_\_\_\_ Signature: \_\_\_\_\_

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## SELECTED WHO PUBLICATIONS OF RELATED INTEREST

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**The international pharmacopoeia**, third edition.

Volume 1: general methods of analysis. 1979 (223 pages)

Volume 2: quality specifications. 1981 (342 pages)

Volume 3: quality specifications. 1988 (407 pages)

Volume 4: tests, methods, and general requirements: quality specifications for pharmaceutical substances, excipients and dosage forms. 1994 (358 pages)

Volume 5: tests and general requirements for dosage forms. Quality specifications for pharmaceutical substances and dosage forms. 2003 (371 pages)

**Basic tests for drugs: pharmaceutical substances, medicinal plant materials and dosage forms.**

1998 (94 pages)

**Basic tests for pharmaceutical dosage forms.**

1991 (134 pages)

**Quality assurance of pharmaceuticals: a compendium of guidelines and related materials.**

Volume 1: 1997 (244 pages)

Volume 2: good manufacturing practices and inspection. 2004 (236 pages)

**Quality control methods for medicinal plant materials.**

1998 (123 pages)

**WHO Expert Committee on Specifications for Pharmaceutical Preparations.**

Thirty-sixth report.

WHO Technical Report Series, No. 902, 2002 (215 pages)

**International nonproprietary names (INN) for pharmaceutical substances. Cumulative list no. 10.**

2002 (available in CD-ROM format only)

**The use of essential drugs.**

Ninth report of the WHO Expert Committee (including the revised Model List of Essential Drugs).

WHO Technical Report Series, No. 895, 2000 (66 pages)

**WHO Expert Committee on Biological Standardization.**

Fiftieth report.

WHO Technical Report Series, No. 904, 2002 (113 pages)

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Further information on these and other WHO publications can be obtained from  
Marketing and Dissemination, World Health Organization, 1211 Geneva 27, Switzerland.

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This report presents the recommendations of an international group of experts convened by the World Health Organization to consider matters concerning the quality assurance of pharmaceuticals and specifications for drug substances and dosage forms. Of particular relevance to drug regulatory authorities and pharmaceutical manufacturers, this report discusses the latest volume of *The International Pharmacopoeia* and quality specifications for pharmaceutical substances and dosage forms, as well as quality control of reference materials, good manufacturing practices (GMP), inspection, distribution and trade and other aspects of quality assurance of pharmaceuticals, and regulatory issues.

The report is complemented by a number of annexes, including recommendations on good trade and distribution practices for pharmaceutical starting materials, guidelines on the WHO scheme for the certification of pharmaceutical materials moving in international commerce, draft procedures for assessing quality control laboratories and procurement agencies for use by United Nations agencies, and guidelines for preparing a laboratory information file and a procurement agency information file.



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ISBN 92 4 120917 8