THE NATIONAL DRUG POLICY AND AUTHORITY ACT.

Statutory Instrument 206—3.

The National Drug Policy and Authority (Issue of Licences) Regulations.

Arrangement of Regulations.

Regulation

THE NATIONAL DRUG POLICY AND AUTHORITY ACT.

Statutory Instrument 206—3.

The National Drug Policy and Authority (Issue of Licences) Regulations.

(*Under section 64 of the Act*.)

PART I—PRELIMINARY.

1. Citation.

These Regulations may be cited as the National Drug Policy and Authority (Issue of Licences) Regulations.

2. Interpretation.

In these Regulations, unless the context otherwise requires—

(a) "Act" means the National Drug Policy and Authority Act;

(b) any words used in these Regulations shall have the same meanings as assigned to them in the Act.

PART II—LICENCE TO SELL CLASS C DRUGS.

3. Issue of licence.

An applicant shall be issued with a licence to sell drugs if—

(a) the applicant holds a certificate of suitability of premises issued by the registrar of the National Drug Authority;

(b) the applicant has not been previously convicted of an offence involving wrongful or illegal dealing in supply or possession of drugs;

(c) the applicant is recommended by a member of the local authority or a prominent member of the local community; and

(d) he or she pays the prescribed fees.

4. Licence to sell only class C drugs.

(1) A licensed seller holding a valid licence issued under section 15 of the Act shall not sell any classified or restricted drugs except class C

licensed drugs as in the Third Schedule to the Act.

(2) Any person who fails to comply with subregulation (1) of this regulation commits an offence.

5. Requirements for persons engaged in the business of selling drugs and for shops selling class C drugs.

(1) Every person engaged in the business of selling drugs or at least one person in his or her employment shall hold a qualification in a relevant pharmaceutical, medical, veterinary, nursing or other paramedical field approved by the National Drug Authority.

(2) Every shop where class C drugs are sold shall—
(a) keep and use suitable containers and labels;
(b) ensure that the containers in which the drugs are kept are safe and in usable condition;
(c) keep records of all drugs procured by the seller;
(d) keep a copy of the National Drug Policy and Authority Act and any statutory instruments made under the Act; and
(e) comply with any other requirements as may be specified from time to time by the National Drug Authority.

6. Preservation of records.

(1) The records referred to in regulation 5(2)(c) of these Regulations shall include—
(a) the source of supply of the drugs;
(b) the date of purchase;
(c) the name and quantity of the medicine; and
(d) the batch number and expiry date.

(2) The records shall be retained for a minimum of two years and shall be available for inspection by an inspector of drugs at all reasonable times.

PART III—LICENCE TO OPERATE A RETAIL PHARMACY.

7. Licence to operate retail pharmacy.

(1) No person shall be issued with a licence to operate a retail

pharmacy unless he or she complies with the requirements in regulation 3(a), (b) and (d) of these Regulations.

(2) Every person holding a valid licence under section 14 of the Act to operate a retail pharmacy shall ensure—

(a) that at least one of the partners is a pharmacist resident in Uganda, if the business is carried on as a partnership; and

(b) in case of a body corporate, at least one of the directors must be a pharmacist resident in Uganda.

8. Dispensing of prescriptions and sale of pharmacy-only medicines.

(1) The dispensing of prescriptions and sale of pharmacy-only medicines shall be under the supervision of a named pharmacist provided that the pharmacist shall be an active member of the pharmaceutical society of Uganda.

(2) The pharmacy shall not dispense any prescription or sell any pharmacy-only drug when the pharmacist is not present.

(3) No prescription-only drug is to be dispensed except in compliance with a valid prescription written by a registered medical practitioner, dental surgeon or veterinary surgeon.

9. Equipment for dispensing.

(1) Every retail pharmacy shall keep and maintain adequate equipment for the dispensing being carried out, that is to say, there shall be sufficient balances and weights, measures, spatulas, ointment slabs, counting trays and a refrigerator in working order.

(2) The pharmacy shall keep and use suitable dispensing containers and labels, that is to say, the containers shall be capable of keeping the dispensed drugs in a safe and useable condition.

10. Reference books.

(1) The pharmacy shall keep and maintain a sufficient range of satisfactory reference books and, in particular, there shall be the latest or next to latest edition of the Uganda National Formulary, Martindales Extra Pharmacopoeia, a recent edition of the British National Formulary, or similar,

current editions of the Essential Drug List for Uganda, the Uganda National Standards Treatment Guidelines and a copy of the National Drug Policy and Authority Act together with any subsequent amendments and statutory instruments made under the Act.

(2) The pharmacy shall also keep a current gazetted list of medical, dental and veterinary practitioners.

11. Records of retail pharmacy.

(1) A suitable and adequate prescription/patient recording system shall be maintained which shall consist of a prescription record ledger well indexed and up-to-date and may be supplemented by patient profile cards, a computerised system or other approved recording system.

(2) Records of all stocks received, their source, batch number, expiry date and quantity received shall be maintained.

(3) All records shall be retained for a minimum of two years, and five years in the case of records of narcotic drugs.

(4) All records shall be available for inspection by an inspector of drugs at all reasonable times.

12. Compliance with other requirements.

The retail pharmacy shall comply with any other requirements as may be specified by the National Drug Authority, from time to time.

PART IV—LICENCE TO OPERATE WHOLESALE PHARMACY.

13. Licence to operate wholesale pharmacy.

(1) No person shall be issued with a licence to operate a wholesale pharmacy unless he or she complies with the requirements in regulation 3(a), (b) and (d) of these Regulations.

(2) Every person holding a valid licence under section 37 of this Act to operate a wholesale pharmacy shall—

(a) ensure that the importation and sale of pharmacy-only medicines is under the supervision of a named pharmacist who shall be an

active member of the pharmaceutical society of Uganda and registered to practise in Uganda;

(b) not sell prescription-only drugs or pharmacy-only medicines when the pharmacist is not present; and

(c) ensure that one of the partners is a pharmacist resident in Uganda in case the business is carried on as a partnership; and in the case of a body corporate, at least one of the directors must be a pharmacist resident in Uganda.

14. Deliveries of prescription and pharmacy-only drugs.

(1) Deliveries of prescription and pharmacy-only drugs may only be made to customers on the basis of previously placed orders.

(2) Selling from a delivery vehicle of prescription or pharmacy-only drugs is prohibited.

15. Records of wholesale pharmacy.

(1) Every wholesale pharmacy shall keep adequate records for prescription and pharmacy-only drugs.

(2) These records shall include—

(a) receipts, supplier, quantity, batch numbers, expiry dates, number and date of importation, verification certificate (if imported by wholesaler);

(b) in case of sales, the persons to whom drugs have been supplied, the quantity supplied, batch number and expiry date; and

(c) up-to-date records of stock on hand for each batch and consignment.

(3) Records of rejected and expired drugs must be kept for a minimum of five years.

16. Notification to inspector of drugs.

The chief inspector of drugs must be notified of all drugs destroyed or otherwise disposed of and the methods used.

17. Compliance with other requirements.

The wholesale pharmacy shall comply with any other requirements as may be specified by the National Drug Authority from time to time.

PART V—LICENCE TO OPERATE BUSINESS OF PHARMACEUTICAL MANUFACTURE.

18. Issue of licence to manufacture drugs.

No person shall engage in the business of manufacturing classified drugs unless he or she has obtained a licence to do so.

19. Persons authorised to supervise pharmaceutical manufacture.

(1) Manufacturing process shall be carried out under the direct supervision of a registered pharmacist with the support of suitably qualified personnel such as pharmacists, pharmacy technicians and dispensers.

(2) Quality control must be under the supervision of a qualified pharmacist or chemist with the support of suitably qualified personnel such as pharmacy technicians and chemists.

20. Administration and staff of pharmaceutical manufacture.

(1) The general manager of the business shall not be the manager of the production or quality control functions.

(2) Neither of the persons in charge of production and quantity control should be responsible to the other.

(3) All staff engaged in processing, packing and quality control shall have a preemployment medical check-up to ensure that they do not suffer from any contagious disease which could be transmitted in the course of their work.

(4) All staff should have periodic health check-ups.

(5) Records of the dates of health check-ups of individual employees must be available for inspection at all times.

(6) Staff engaged in production and packaging shall be provided with appropriate protective clothing, both for their own protection and to avoid

contamination of the products.

21. Records of a pharmaceutical manufacturer.

Every person carrying on the business of pharmaceutical manufacture shall keep records and, in particular—

(a) comprehensive records must be kept of all batches of starting materials and ingredients, including source, batch numbers, expiry dates, certificates of analysis and any other relevant documents, and samples of starting materials shall be retained;

(b) records of each batch of finished product shall include master formula and methodology check lists. Samples of each batch of finished product must be kept until six months after the expiry date;

(c) other records to be kept shall be of yield reconciliation, all analytical and quality control results, supplies to customers, quantities and batch numbers supplied on specified dates; and

(d) unless expressly specified, all other records must be kept for a minimum of five years and shall be available for inspection by the inspector of drugs at all reasonable times.

22. Quality control.

(1) The functions of quality control must be independent of the manufacturing function and must be adequately staffed with properly qualified personnel.

(2) All batches of starting materials shall be tested to ensure that they comply with the prescribed standards and limits.

(3) Quality control facilities shall have the necessary equipment and reagents to carry out all prescribed tests for the product produced.

(4) For products manufactured to a set standard of a recognised pharmacopoeia or pharmaceutical codex and so labelled, all tests and standards prescribed in the relevant monograph must be carried out and the results recorded.

(5) The possibility of cross contamination of products during processing and packing should be minimised, and, in particular, toxic or sensitising materials such as hormones, cytotoxics and antibiotics.

PART VI—LICENCE FOR IMPORTATION OF DRUGS.

23. Import licence.

(1) An import licence may be granted to a holder of a licence for operating a retail, wholesale or pharmaceutical manufacturing plant to import drugs into Uganda.

(2) An import licence will be valid until the end of the calendar year in which it is issued but may be cancelled at any time if the applicant's pharmaceutical operating licence is withdrawn by the authority for breach of any requirement specified by the National Drug Authority.

24. Verification certificate.

Each consignment of drugs to be imported must receive a verification certificate before importation.

25. Guidelines on packaging imported drugs to be followed by inspecting agency, customs and inspector of drugs.

(1) The inspecting agency, customs and inspectors of drugs shall follow the guidelines in this regulation for imported drugs.

(2) The immediate packaging of the drugs shall be clearly labelled in the English language with the following—

(a) the trade or brand name where appropriate;
(b) the clearly stated International Nonproprietary Name (INN) (generic) name;
(c) the quantities of active ingredients in the given formulation;
(d) the dates of manufacture and expiry;
(e) the batch or lot number;
(f) any special conditions of storage; and
(g) the name and address of manufacturer.

(3) Enclosed and accompanying literature shall be in the English language.

(4) Drugs labelled for sale only in specified countries must not be imported into Uganda unless it is one of the countries so specified.

(5) Pharmaceutical products with labels which show evidence of alteration will be regarded as fake or substandard and shall be shipped back to the manufacturer at the cost of the importer, and the alterations shall include—

(a) entire labels or parts with details such as batch numbers or dates of manufacture cut off;
(b) evidence of labels being removed and new ones attached or new labels being pasted over old ones; or
(c) details being erased or painted out and replaced with new details.

26. Seals.

(1) The inner, primary package should be sealed in such a way that the product cannot be reached or tampered with without damaging the seal.

(2) The verification certificate will be issued by the registrar of the National Drug Authority on behalf of the National Drug Authority Commission.

(3) An application for the certificate shall state, for each drug to be imported—

(a) the INN (generic) name of the drug and its strength, and in the case of a product containing more than one active ingredient, the name and strength of each shall be stated;
(b) the pharmacopoeial specification of the ingredient such as B.P. U.S.P.;
(c) the total quantity to be imported;
(d) the name of the supplier;
(e) the name of the manufacturer;
(f) the country of origin;
(g) the trade or proprietary name if appropriate; and
(h) the product registration number allocated by the National Drug Authority for drugs approved for importation in Uganda.

(4) The application shall be accompanied by—
(a) a copy of the pro forma invoice;
(b) a copy of the certificate of good manufacturing practice issued by the drug regulatory authority of the country of origin for the manufacturer; and
(c) a copy of the free sale certificate issued by the drug regulatory

authority of the country of origin for the specified product.

(5) The requirements for good manufacturing practice and the free sale certificate may be waived for certain manufacturers at the discretion of the National Drug Authority.

(6) On receipt, the drugs shall be accompanied by—

(a) a certificate of analysis relating to the specific batch received; and

(b) a clean preshipment report of findings issued by an agency selected for that purpose.

(7) Manufacturers shall be asked to seal their packs in conformity with subregulation (1) of this regulation.

PART VII—MISCELLANEOUS.

27. Miscellaneous.

(1) An application for a licence under regulations 3, 7, 13, 18, and 23 of these Regulations shall be in the appropriate Form 1, 2, 3, 4 or 5, as the case may be, of the Schedule to these Regulations.

(2) Any licence issued under these Regulations shall remain valid until the date stated on the licence.

(3) A licence issued under these Regulations may be revoked or suspended any time.

Schedule.

regs. 3, 27.

Forms.

Form 1.

Application for a Licence to Operate a Shop to Sell Class C Drugs.

The National Drug Policy and Authority Act.

Physical address of premises _____

_____

P.O. Box No. _____ Tel. _____ Fax _____

Full names of applicant _____

Qualifications—(pharmaceutical) _____

(Other) _____

Is the application made for—

an individual _____

a partnership _____

a company _____

If applying on behalf of a company—

Physical address of registered office _____

P.O. Box No. _____ Tel. _____ Fax _____

Full names of managing director _____

If applying on behalf of a company or partnership, give the following information for all partners or directors—

Name	Address	Qualification
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

Has the applicant or any partner or director been convicted within the past three years, within or outside Uganda, of any offence involving the wrongful or illegal dealing or supply or possession of drugs? Yes/No

If "Yes", give details _____
_____

Has any previous application by the applicant, or any partner or director, for a licence to operate any type of pharmaceutical business been refused or cancelled? Yes/No

If "Yes", give details _____
_____

Does the applicant or any partner or director currently hold a licence to operate any type of pharmaceutical business (including class C) at any other premises? Yes/No

If "Yes", give details _____
_____

Full names of in-charge person _____

Qualification/training _____

I have been informed of and understand the restrictions on the range of drugs and medicines which may be sold by a class C drug shop.

I certify that the above information is correct and apply for a licence to operate a shop for the sale of class C drugs at the above-named premises.

_____ _____
Signature of Applicant Date

Recommended by _____ (*name*)

_____ (*signature*)

Position in the local authority/community _____

For N.D.A. use:

Suitability of premises certificate checked Yes/No
_____ (*Signature*)

Applicant's information checked and verified Yes/No

_____(*signature*)

Distance from pharmacy and class C verified Yes/No

_____(*signature*)

Licence to operate a class C drug shop for selling of drugs included in the Third Schedule of the National Drug Policy and Authority Act.

Approved/Not approved _____ Secretary

If not approved, give reasons.

Notes—

1. This application must be accompanied by—
   (a) a certificate of suitability of premises issued by the secretary for National Drug Authority;
   (b) any other information which may be required by the National Drug Authority from time to time.
2. Any change relating to the ownership or supervision of the business must be notified to the secretary within seven days.
3. This application must be submitted in duplicate to:
   The Secretary
   National Drug Authority
   Butabika, Kampala

regs. 7, 27.

Form 2.

Application for a Licence to Operate a Retail Pharmacy.

The National Drug Policy and Authority Act.

Physical address of premises _____

_____

P.O. Box No. _____ Tel. _____ Fax _____

Full names of applicant _____

Qualifications—(pharmaceutical) _____

(Other) _____

Is the application made for—

an individual _____

a partnership _____

a company _____

If applying on behalf of a company—

Physical address of registered office _____

P.O. Box No. _____ Tel. _____ Fax _____

Full names of managing director _____

If applying on behalf of a company or partnership, give the following information for all partners or directors—

Name	Address	Qualifications
_____	_____	_____
_____	_____	_____
_____	_____	_____

Has the applicant or any partner or director been convicted within the past three years, within or outside Uganda, of any offence involving the wrongful or illegal dealing in or supply or possession of drugs? Yes/No

If "Yes", give details _____

_____

Has any previous application by the applicant, or any partner or director, for a licence to operate any type of pharmaceutical business been refused or

cancelled? Yes/No

If "Yes", give details _____
_____

Purposes for which premises are to be used (*tick proposed activities*)—
retail pharmacy _____ dispensing prescriptions _____
compounding for prescription _____
compounding for retail sale packing _____

Full names of supervising pharmacist _____

Registration number with Pharmaceutical Society of Uganda _____

I certify that the above information is correct and apply for a licence to operate a retail pharmacy at the above-named premises.

_____ _____
Signature of Applicant Date

Notes—

1. This application must be accompanied by—
   (a) a certificate of suitability of premises issued by the chief inspector of drugs;
   (b) a letter of confirmation from the pharmacist appointed to be responsible; and
   (c) any other information which may be required by the National Drug Authority from time to time.
2. An operating licence issued in respect of this application applies only to a retail pharmacy operation; a separate licence is required for wholesaling or manufacture.
3. An operating licence issued in respect of this application will remain valid until the date stated on the licence.
4. Any change relating to the supervising pharmacist or the ownership of the business must be notified to the secretary within seven days.
5. This application must be submitted in duplicate to:
   The Secretary
   National Drug Authority
   Butabika, Kampala

For N.D.A. use:

Suitability of premises certificate checked Yes/No
_____(*signature*)

Applicant's information checked and verified Yes/No

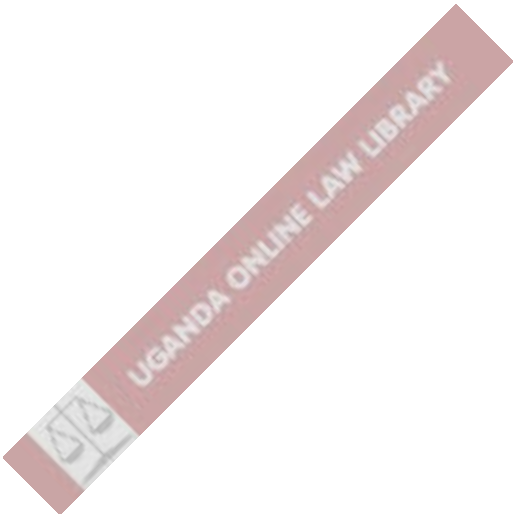
_____(*signature*)

Licence to operate a retail pharmacy

Approved/Not Approved _____
Secretary/NDA

Date _____

If not approved, give reasons.



regs. 13, 27.

Form 3.

Application for a Licence to Operate a Wholesale Pharmacy.

The National Drug Policy and Authority Act.

Physical address of premises _____

_____

P.O. Box No. _____ Tel. _____ Fax _____

Full names of applicant _____

Qualifications —(pharmaceutical) _____

(Other) _____

Is the application made for—

an individual _____

a partnership _____

a company _____

If applying on behalf of a company—

Physical address of registered office _____

P.O. Box No. _____ Tel. _____ Fax _____

Full names of managing director _____

If applying on behalf of a company or partnership, give the following information for all partners or directors—

Name	Address	Qualifications
_____	_____	_____
_____	_____	_____
_____	_____	_____

Has the applicant or any partner or director been convicted within the past three years, within or outside Uganda, of any offence involving the wrongful or illegal dealing in or supply or possession of drugs? Yes/No

If "Yes", give details _____

_____

Has any previous application by the applicant or any partner or director for a licence to operate any type of pharmaceutical business been refused or cancelled? Yes/No

If "Yes", give details _____
_____

Will a retail pharmacy be operated from the same premises? Yes/No

Does the applicant or any partner or director currently hold a licence to operate any type of pharmaceutical business (including class C) at any other premises? Yes/No

Will the business import its drugs from abroad? Yes/No

Will the business sell human drugs/veterinary drugs/both?

Full names of supervising pharmacist _____

Registration number with Pharmaceutical Society of Uganda _____

I certify that the above information is correct and apply for a licence to operate a wholesale pharmacy at the above-named premises.

_____ _____
Signature of Applicant Date

Notes—

1. This application must be accompanied by—
   (a) a certificate of suitability of premises issued by the secretary for the National Drug Authority; and
   (b) any other information which may be required by the National Drug Authority from time to time.
2. An operating licence issued in respect of this application applies only to a wholesale pharmacy operation; a separate licence is required for retailing or manufacture.
3. Any change relating to the supervising pharmacist or the ownership of the business must be notified to the secretary within seven days.
4. This application must be submitted in duplicate to:
   The Secretary
   National Drug Authority
   Butabika, Kampala

regs. 18, 27.

Form 4.

Application for a Licence to Operate a Pharmaceutical Manufacturing Business.

The National Drug Policy and Authority Act.

Physical address of premises _____

_____

P.O. Box No. _____ Tel. _____ Fax _____

Full names of applicant _____

Qualifications (pharmaceutical) _____

(Other) _____

Is the application made for—

an individual _____

a partnership _____

a company _____

If applying on behalf of a company—

Physical address of registered office _____

P.O. Box No. _____ Tel. _____ Fax _____

Full names of managing director _____

If applying on behalf of a company or partnership give the following information for all partners or directors—

Name	Address	Qualifications
_____	_____	_____
_____	_____	_____
_____	_____	_____

Has the applicant or any partner or director been convicted within the past three years, within or outside Uganda, of any offence involving the wrongful or illegal dealing in or supply or possession of drugs? Yes/No

If "Yes", give details _____

_____

Has any previous application by the applicant, or any partner or director, for a licence to operate any type of pharmaceutical business been refused or cancelled? Yes/No

If "Yes", give details _____
_____

Does the applicant or any partner or director currently hold a licence to operate any type of pharmaceutical business (including class C) at any other premises? Yes/No

If "Yes", give details _____
_____

Full names of the pharmacist in charge of manufacturing _____
_____

Registration number with Pharmaceutical Society of Uganda _____

Full names of pharmacist or chemist in charge of quality control _____
_____

Registration number with Pharmaceutical Society of Uganda _____
or details of qualifications as a chemist _____

Names and qualifications of any other pharmacists or chemists employed
_____
_____

I certify that the above information is correct and apply for a licence to operate a pharmaceutical manufacturing business at the above-named premises.

_____ _____
Signature of Applicant Date

For N.D.A. use:

Suitability of premises certificated checked Yes/No
_____(*signature*)

Applicant's information checked and verified Yes/No

_____(*signature*)

Licence to operate a pharmaceutical manufacturing business

Approved/Not Approved _____

Secretary/NDA

Date _____

If not approved, give reasons.

Notes—

1. This application must be accompanied by—
   (a) a certificate of suitability of premises issued by the chief inspector of drugs;
   (b) a letter of confirmation from the pharmacist appointed to be responsible for production; and
   (c) any other information which may be required by the National Drug Authority from time to time.
2. An operating licence issued in respect of this application applies only to a pharmaceutical manufacturing operation; a separate licence is required for importation, wholesaling and retailing.
3. Any change relating to the pharmacist in charge of manufacturing or the pharmacist/chemist in charge of quality control or the ownership of the business must be notified to the secretary within seven days.
4. This application must be submitted in duplicate to:
   The Secretary
   National Drug Authority
   Butabika, Kampala

regs. 23, 27.

Form 5.

Application for an Annual Importation Licence for Pharmaceuticals.

The National Drug Policy and Authority Act.

I apply for an annual importation licence for drugs and pharmaceutical products.

Name of applicant _____

Name of the business for which application is made _____
_____

Address/P.O. Box No. _____

This is a[1]—

retail pharmacy wholesale pharmacy
pharmaceutical manufactures other (*specify*) _____

Licence number _____ (National Drug Authority Operating Licence)

Name of the supervising pharmacist _____

I apply for the issue of an importation licence for—

(a) materials and ingredients for the production of pharmaceuticals and human medicines;
(b) materials and ingredients for the production of veterinary medicines;
(c) finished drugs and medicines for human use; and
(d) finished drugs and medicines for veterinary use.

I understand that a separate verification certificate must be obtained for each order placed.

I have received and understand a copy of the regulations/criteria relating to the importation of drugs and pharmaceutical substances into Uganda.

[1]Delete whatever is not applicable.

Signed _____ Date _____

This application to be sent together with the appropriate fee to:
The Secretary
National Drug Authority
Butabika, Kampala

For N.D.A. use only Application approved/rejected

If rejected, state reasons _____
_____
_____

Licence number _____ Issued on _____ (*Date*)

Signed _____ Secretary, NDA

Seal

History: S.I. 4/1995.

Cross References

British National Formulary.
Essential Drug List for Uganda.
Martindales Extra Pharmacopoeia.
Uganda National Formulary.
Uganda National Standards Treatment Guidelines.