



## FAQs about the supply of unlicensed pharmaceutical products

Index

### When must an application be submitted?

1. How can I determine whether a pharmaceutical product is registered in the Netherlands or the EU?
2. Are there circumstances in which permission is not required from the IGJ (Health and Youth Care Inspectorate)?
3. Is it ever legal to supply an unlicensed pharmaceutical product without prior permission?
4. If there is a shortage of a particular product registered in the Netherlands, can I order and supply a comparable product imported from another EU member state?
5. What should I do if the European Commission has issued a marketing authorisation for a particular pharmaceutical product, but the commercial sales packaging is not yet available in the Netherlands?
6. What should I do if I want to supply a pharmaceutical product intended for clinical research to a patient who is not participating in a trial?

### Compassionate use

7. What is a compassionate use programme?
8. What is the difference between a compassionate use programme and supplying an unlicensed product under a doctor's declaration?
9. What action will the IGJ take if an application may qualify as compassionate use?

### Submitting an application

10. Which parties can apply for permission from the IGJ to supply an unlicensed pharmaceutical product under a doctor's declaration?
11. How can I apply for permission to supply an unlicensed pharmaceutical product under a doctor's declaration?
12. How can I get my permission renewed?
13. Under what conditions can I submit an urgent application?

### Documentation

14. Which documents should accompany an application for permission to supply an unlicensed pharmaceutical product?
15. What documents must I submit when renewing my application for permission?
16. Why does a doctor's declaration need to be included and what is its purpose?
17. What is the term of validity of a doctor's declaration?
18. What is a pharmacovigilance statement?
19. How can I substantiate that no suitable alternative medication is available, or that such an alternative cannot be used?
20. Why do I need to include documentation showing that the unlicensed product has been produced under GMP conditions?

### Vaccine, blood product, Opium Act

21. What action must I take before supplying an unlicensed vaccine or blood product?

22. What action should I take before supplying an unlicensed product that is controlled under the Opium Act?

### **The permission**

23. For how long is permission valid?
24. For how many patients is permission valid and what does the IGJ do with the data about the number of patients treated with an unlicensed product?
25. Is it possible to obtain permission to supply an unlicensed pharmaceutical product to treat several indications?

### **After the permission and the administrative records**

26. Do I need a completed and signed doctor's declaration for each individual patient?
27. What should I do with the individual doctor's declarations and the substantiating documents?
28. What action should I take when side effects are reported?
29. Am I required to submit regular reports of side effects?

### **Ordering, importing, delivery**

30. Where may I order an unlicensed pharmaceutical product?
31. Does the IGJ issue import permits for unlicensed pharmaceutical products?
32. How should I inform third parties that I am able to supply an unlicensed pharmaceutical product?
33. Can one pharmacy supply (i.e. physically deliver) an unlicensed pharmaceutical product to another?
34. Can a pharmacy participating in the Automated Dose Dispensing System (Geautomatiseerd Geneesmiddeldistributiesysteem, GDS) order an unlicensed pharmaceutical product on behalf of another pharmacy, package it and then supply it to that pharmacy?
35. Can a GDS pharmacy repackage and/or relabel an unlicensed pharmaceutical product?
36. How does the IGJ's permission affect the reimbursement of an unlicensed product?

## 1. How can I determine whether a pharmaceutical product is registered in the Netherlands or the EU?

If a pharmaceutical product is already registered in the Netherlands or the EU, you cannot submit an application for it as an unlicensed product.

The [Medicines Information Bank](#) maintained by the Medicines Evaluation Board (MEB) lists whether a product is licensed. If a pharmaceutical product has been duly registered in the Netherlands, the MEB will have issued a marketing authorisation for that product to the applicant. If a pharmaceutical product has been registered in all EU member states, the European Commission will have issued a marketing authorisation for that product.

A registered pharmaceutical product is identified by a registration number starting with the letters 'RVG' or 'EU'. This number is stated on the packaging of the product. A registration number starting with 'RVG' means that the MEB issued the marketing authorisation. A registration number starting with 'EU' means that the European Commission issued the marketing authorisation.

### More information

- [European Medicines Agency – Medicines](#)
- [EC database](#)

## 2. Are there circumstances in which permission is not required from the IGJ?

- Article 40, paragraph 3a of the Dutch Medicines Act (Geneesmiddelenwet, GnW) allows the unsupervised supply of 'magistral' and 'officinal' prescriptions. These are preparations made in small quantities by a pharmacist for their own patients. However, the supply of such preparations to any third party is covered by the provisions of the circular entitled '[Enforcement in cases of preparations provided by pharmacists](#)'.
- Investigational pharmaceutical products. Further to Article 40, paragraph 3c of the Medicines Act and its elaboration in Article 3.17 of the Medicines Act Regulations (Regeling Geneesmiddelenwet, RGnW), permission is not required to supply a pharmaceutical product for the purposes of clinical research, where such research has been approved under the provisions of the Medical Research (Human Subjects) Act (Wet medisch-wetenschappelijk onderzoek met mensen, WMO). See '[Investigational pharmaceutical products](#)'.
- A further exemption exists for pharmaceutical products that are supplied as part of a compassionate use programme (CUP, the term used internationally for particularly distressing/painful cases). Compassionate use programmes are defined by the MEB pursuant to Article 40, paragraph 3f and elaborated further in Article 3.18 of the Medicines Act Regulations. For further information, see the [MEB website](#).

### More information

- [Medicines Act](#)
- [Medicines Act Regulation](#)

## 3. Is it ever legal to supply an unlicensed pharmaceutical product without prior permission?

No, except in the circumstances described in Question 2. Supplying unlicensed pharmaceutical products without prior permission constitutes a violation of Article 40 of the Medicines Act.

## 4. If there is a shortage of a particular product registered in the Netherlands, can I order and supply a comparable product imported from another EU member state?

There are many products registered in different EU member states that have the same active ingredients and the same pharmaceutical form, and that are prescribed for the same indications.

In the case of a shortage of a particular product registered in the Netherlands, a comparable product registered in another EU member state may therefore be used as an alternative, as such products are registered independently in different countries.

A proprietary pharmaceutical product registered in another EU member state may only be supplied further to a doctor's declaration if the IGJ has granted a competent party in the Netherlands permission to do so (i.e. a pharmacist, a general practitioner owning a pharmacy, a wholesale distributor or a manufacturer).

#### **5. What should I do if the European Commission has issued a marketing authorisation for a particular pharmaceutical product, but the commercial sales packaging is not yet available in the Netherlands?**

It is possible that the European Commission has registered a particular pharmaceutical product, but that no sales packaging for the Dutch market is available (i.e. sales packaging in Dutch, in accordance with the applicable requirements for the Netherlands as stated in the registration dossier). In this situation, sales packaging for use in another EU member state may already be available. In that case, the marketing authorisation holder may [contact the IGJ](#) and request permission for the temporary supply of a specific quantity of these non-Dutch packages for a specific period.

This is a different procedure to the one for supplying an unlicensed product under a doctor's declaration. Such permission cannot be requested from the Inspectorate by a pharmacy or wholesale distributor; this can only be done by the marketing authorisation holder of the pharmaceutical product.

#### **6. What should I do if I want to supply a pharmaceutical product intended for clinical research to patients who are not able to participate in a trial?**

In some cases, a patient with a specific indication may not be able to participate in a clinical trial, while the physician may nevertheless wish to treat them for this indication with the unlicensed pharmaceutical product in question. This situation can occur if the patient does not meet all the inclusion criteria for the study, for instance. In that case, the physician may ask a Netherlands-based manufacturer, wholesale distributor or a hospital-based or other pharmacist to submit an application to the IGJ. Permission can be requested in this way to supply the product outside the context of a clinical trial, under a doctor's declaration. The physician can submit this request to the manufacturer, wholesale distributor or hospital-based or other pharmacist who supplies the trial medication for clinical research purposes.

#### **7. What is a compassionate use programme?**

This is a programme in which pharmaceutical products can be delivered to alleviate pain and suffering. Compassionate use programmes (CUPs) are [defined by the Medicines Evaluation Board \(MEB\)](#).

#### **8. What is the difference between a compassionate use programme and supplying an unlicensed product under a doctor's declaration?**

- The IGJ is responsible for processing requests to supply an unlicensed product under a doctor's declaration.
- The MEB is responsible for processing requests for compassionate use programmes.
- Supplying pharmaceutical products under a doctor's declaration involves individual patients treated at the physician's initiative because an alternative registered product cannot or can no longer be used to treat that patient.
- The terms 'Named Patient Product' and 'Named Patient Programme' are also used to describe the supply of unlicensed pharmaceutical product under a doctor's declaration, requiring authorisation from the IGJ.

- If it is a severe condition for which no alternative pharmaceutical product is on the market and the as yet unregistered product could be granted a licence in the future, the manufacturer of the pharmaceutical product can submit a request to the MEB for eligibility for use in a compassionate use programme.
- The MEB can give permission for as yet unregistered pharmaceutical products to be put on the market for distressing cases, i.e. a compassionate use programme. A manufacturer can make these pharmaceutical products available for that group of patients. For further information about requesting a CUP, please refer to the [MEB website](#).

### **9. What action will the IGJ take if an application may qualify as compassionate use?**

If the pharmaceutical product may meet the eligibility criteria for a compassionate use programme, the IGJ will contact the MEB. The IGJ will inform you in writing that, in the first instance, your application will not be processed by the IGJ because it may be eligible for an MEB compassionate use programme. If MEB nevertheless declines to grant you, as the future marketing authorisation holder, permission to supply the product under a compassionate use programme (CUP) or if the patient concerned cannot be included in an approved CUP, you can resubmit your application to the IGJ to supply the product under a doctor's declaration.

### **10. Which parties can apply for permission from the IGJ to supply an unlicensed pharmaceutical product under a doctor's declaration?**

Under Article 3.17 of the Medicines Act Regulations (RGnW), one of the following persons and legal entities may be given permission to supply an unlicensed pharmaceutical product; the applicant must be domiciled in the Netherlands, and must possess a valid permit or be registered in the Register of Pharmacists.

- manufacturer
- wholesale distributor
- hospital and other pharmacists
- dispensing general practitioners

Once a manufacturer or wholesale distributor has obtained permission to supply an unlicensed pharmaceutical product under a doctor's declaration, it is no longer necessary for the pharmacist or dispensing general practitioner to submit an application themselves to the IGJ. The pharmacist or dispensing general practitioner must provide the manufacturer or wholesale distributor with the doctor's declaration or a copy thereof.

### **11. How can I apply for permission to supply an unlicensed pharmaceutical product under a doctor's declaration?**

The application for permission to supply an unlicensed pharmaceutical product must be submitted using the [digital application form](#). You can also use the same form for applying for a renewal of your request. When a new application is being submitted, additional documents are needed to complete your request. Make sure that you have these documents ready to hand when you start your application process. Please refer to Question 14 for this.

The law gives the IGJ eight weeks to process your application and give a response.

If it is not possible to use the digital form (e.g. if there is a technical fault or an error message in the digital form), you can call the IGJ reporting centre on 0031 88 120 50 00.

### **12. How can I get my permission renewed?**

If you obtain permission to supply an unlicensed pharmaceutical product, it will state how long the permission is valid for. You can extend the duration of validity. The request to do that can be submitted using our [digital application form](#). You may only submit a request for an extension if your existing permission is still valid. When submitting a renewal request, allow for the fact that the IGJ has a maximum of eight weeks' time for processing an application.

If your permission expires and you have not yet had a response to your request for a renewal of the validity period, you may no longer supply the pharmaceutical product.

If the validity period of your current permission has expired, you can submit a new request.

### **13. Under what conditions can I submit an urgent application?**

The law gives the IGJ eight weeks to process your application for supplying an unlicensed pharmaceutical product and to give a response. It is possible that there may be a critical situation for the patient for whom you are requesting the pharmaceutical product. Those are the only cases in which you can state on the form that the situation is urgent. You are then given an opportunity to indicate the latest time by which you need to have received permission. The IGJ will take this into consideration as much as possible.

The urgent procedure does not apply for renewal requests.

### **14. What documents should accompany an application for permission to supply an unlicensed pharmaceutical product?**

You can submit your application for permission using the [digital application form](#). The IGJ requires the following documentation to assess if your application meets the requirements laid down in Article 3.17 of the Medicines Act Regulations (RGnW):

1. A recently completed and signed [doctor's declaration](#).
2. Substantiation of the unavailability of suitable alternative medication.
3. Information about the product, such as the patient information leaflet (PIL) or the summary of product characteristics (SPC) (or the IB-1 text). If the PIL or SPC are not available in Dutch, English or German, you must include the Dutch or English translation of the document in question.
4. Evidence that the product has been produced under GMP conditions, for example:
  - a. If the manufacturer is based within the EEA or in a country with which the EU has concluded a Mutual Recognition Agreement (MRA) and the product is registered in that country: the name and registered address of the manufacturer (or a copy of the manufacturer's licence).
  - b. If the manufacturer is based outside the EEA (the EU member states plus Iceland, Norway and Liechtenstein) or in a country with which the EU has not concluded an MRA: a valid GMP certificate issued by a competent EU authority or a ['certificate of a pharmaceutical product'](#) issued by the country of origin.
5. A declaration that all reported side effects will be recorded: the [Pharmacovigilance declaration](#).

If a GMP certificate has been issued by a competent EU authority, this is stated in the [EudraGMDP website](#). This information must be included with your application. The documentation mentioned above can be uploaded at the end of the digital form.

If it is not possible to use the digital form (e.g. if there is a technical fault or an error message in the digital form), you can call the IGJ reporting centre on 0031 88 120 50 00.

### **15. What documents must I submit when renewing my application for permission?**

You can use the digital application form to submit an application to renew your current permission. The IGJ requires the following documentation to assess if your application meets the requirements laid down in Article 3.17 of the Medicines Act Regulations:

1. A renewal request using the [digital application form](#).

If applicable:

2. A new completed and signed [pharmacovigilance declaration](#) if the person at the company or pharmacy who is responsible for pharmacovigilance has changed.

3. Overview of new scientific insights into the treatment of the illness or condition for which the unlicensed product is prescribed.
4. Any changes in the registration status of the unlicensed product in another country.

Once a product has been registered, permission to supply the product under a doctor's declaration expires. This also applies if suitable alternative medication has since become available.

## **16. Why does a doctor's declaration need to be included and what is its purpose?**

The IGJ wishes to assess the need for treatment prior to granting any authorisation. The IGJ uses a completed and signed doctor's declaration for this purpose. The legal basis for the doctor's declaration is Article 40, paragraph 3c of the Medicines Act, and it is also defined in Article 3.17 of the Medicines Act Regulations. The template doctor's declaration prescribed by the IGJ must be used for this purpose (as per Article 3.17, paragraph 1c of the Medicines Act Regulations).

In a doctor's declaration, the responsible physician declares that they are aware that the pharmaceutical product that they wish to prescribe to a patient is an unlicensed product that has not been assessed in terms of quality, safety and efficacy by the MEB or the Committee for Medicinal Products for Human Use (CHMP) / EMA. An unlicensed product therefore carries certain risks, and the physician must be aware of them and carefully assess the availability of suitable Dutch-registered alternatives before prescribing the product to a patient.

The doctor's declaration must be included with the application submitted to the IGJ for permission to supply the unlicensed product concerned for a specific indication. Once the IGJ has granted such permission, each subsequent doctor's declaration for the product in question and the indication should also be submitted to the party that obtained permission (manufacturer, wholesale distributor or pharmacist / dispensing general practitioner). That party can then check if the application to supply the product meets the conditions concerned, and can assess if the physician has considered the availability of a registered alternative. A fully completed doctor's declaration must be submitted for each patient treated with the unlicensed pharmaceutical product in question. The IGJ requests that no patient details should be stated on the doctor's declaration, but that a patient code should be used that allows the organisation to trace it back (internally) to the patient concerned.

### **More information**

- [Doctor's declaration](#)
- [Medicines Act \(in Dutch\)](#)
- [Medicines Act Regulations](#)

## **17. What is the term of validity of a doctor's declaration?**

A completed and signed doctor's declaration remains valid for one year. If a patient is treated with an unlicensed product, the IGJ believes it is necessary to assess regularly whether the treatment is working or if the patient is for instance suffering from any side effects. Such an evaluation may result in a decision to stop or continue treatment. If treatment is continued, the physician must confirm this by completing and signing a new doctor's declaration. To ensure periodic evaluation of treatment with an unlicensed product, the IGJ has decided that the doctor's declaration remains valid for a maximum period of one year.

## **18. What is a pharmacovigilance statement?**

A pharmacovigilance statement is a formal statement in which you declare that you record all side effects reported when using the unlicensed product. You are legally required to do this under Article 3.17 of the Medicines Act Regulations. An example of such a statement is given below, though you may change the wording to suit your situation. Your application must be accompanied by this declaration. The pharmacovigilance declaration is valid for one year after the date of signature.

## More information

- [Pharmacovigilance declaration](#)
- [Medicines Act Regulations](#)

### **19. How can I substantiate that no suitable alternative medication is available, or that such an alternative cannot be used?**

Supplying unlicensed pharmaceutical products is only permitted if no suitable alternative is available in the Netherlands for the patient concerned, or if such an alternative product cannot or can no longer be used to treat that patient (Article 3.17, paragraph 1b of the Medicines Act Regulation). The IGJ assumes in every case that any registered product will have been considered and/or used first.

Evidence for this must be provided, for instance by demonstrating that patients have previously used registered products, but that these alternatives were not (sufficiently) efficacious. Patients may also have suffered side effects following the use of such registered alternatives. These are just some of the reasons why a patient may be dependent on unlicensed products for the treatment of their illness. If suitable existing alternatives are available in the Netherlands, the accompanying documents submitted must include a list of the registered products that can be used to treat the indication.

In addition, you must state the reasons why these registered products cannot be prescribed in this case. The accompanying documents must also include clinical information substantiating the expectation that the unlicensed product will be beneficial to the intended patient or patient group. Please note that non-medical reasons such as patient convenience (e.g. a pharmaceutical form or strength that differs from the registered alternative medication) or financial considerations are not regarded as sufficient justification for using an unlicensed product.

### **20. Why do I need to include documentation showing that the unlicensed product has been produced under GMP conditions?**

Documentation demonstrating that the manufacturer's products were produced under Good Manufacturing Practice (GMP) conditions assures the pharmaceutical quality of the unlicensed product. It is all the more important to obtain assurance for the pharmaceutical quality of unlicensed products, as the quality, safety and efficacy of such products have not been assessed by a registration authority. If the manufacturer is domiciled in a member state of the European Economic Area (EEA), you must state the name and registered address of the manufacturer. The manufacturer's name may be stated in the summary of product characteristics (SPC) and/or patient information leaflet (PIL) of the unlicensed product that is to be supplied.

In some cases it is impossible to ascertain the manufacturer. This does not present a problem for your application if the product in question has been registered in one or more EU member states. If the manufacturer is not domiciled in the EEA, you must state the manufacturer's name and registered address and submit a valid GMP certificate issued in an EU member state. If a valid GMP certificate is not available, you must submit a 'Certificate of a Pharmaceutical Product'. If the application concerns a pharmaceutical product registered in a country with which the EU has concluded a [Mutual Recognition Agreement](#), no GMP Certificate or Certificate of a Pharmaceutical Product needs to be submitted together with your application.

### **21. What action must I take before supplying an unlicensed vaccine or blood product?**

The application must be accompanied by a 'certificate of suitability' issued by an authorised body – an Official Medicines Control Laboratory (OMCL) located within the European Economic Area (EEA). For the Netherlands, this is the Dutch [National Institute for Public Health and the Environment](#) (RIVM). This is a separate procedure.



If no Certificate of Suitability issued by an OMCL is available, you should contact the IGJ reporting centre:

- Tel: 0031 88 120 50 00
- E-mail: [meldpunt@igj.nl](mailto:meldpunt@igj.nl)

If a batch of the product has been issued a certificate of suitability by an OMCL in another EU member state, you can submit that certificate with your application to the IGJ.

## **22. What action should I take before supplying an unlicensed product that is controlled under the Opium Act?**

A pharmacist wishing to supply an unlicensed medicine that is defined as a 'controlled substance' under the provisions of the Opium Act must approach a manufacturer or wholesale distributor to facilitate the import of the pharmaceutical product.

The manufacturer or wholesale distributor must hold an official Opium Act exemption in respect of the specific substance concerned. Such exemptions can be requested from [CIBG/Farmatec](#) (the Central Information Point for Healthcare Professions).

The manufacturer, wholesale distributor or pharmacy, must also ask the IGJ for permission to supply an unlicensed pharmaceutical product under a doctor's declaration.

## **23. For how long is permission valid?**

In principle for a period of one year. The IGJ may vary this period in individual cases; this will be clearly stated in the authorisation. If the IGJ grants permission to supply an unlicensed pharmaceutical product in connection with a shortage of the registered product that is normally used, that permission remains valid until the registered product is available again, should that moment be earlier than the date stated in the decision.

## **24. For how many patients is permission valid and what does the IGJ do with the data about the number of patients treated with an unlicensed product?**

Article 3.17 of the Medicines Act Regulations (RGnW) is intended for the treatment of individual patients in exceptional cases. The IGJ is therefore reluctant to grant permission to supply unlicensed products.

Article 40, paragraph 3c of the Medicines Act (worked out in further detail in Article 3.17 of the Medicines Act Regulations) makes it possible to treat patients who are dependent on unlicensed products.

The application of these rules is expressly not intended to circumvent the obligation to obtain marketing authorisation. The IGJ monitors compliance with Article 3.17 of the Medicines Act Regulations (RGnW).

In cases where permission is granted, the IGJ gives it in principle at the individual level (for one or more doctor's declarations that have been submitted to the IGJ). When assessing an application, the IGJ can also consider issuing permission for a patient group with a specific indication as stated in the documents substantiating the application. The number of patients to which the permission applies depends on the patient group. However, applicants are then required to maintain records of the individual doctor's declarations (which must be completed in full for each patient treated with the pharmaceutical product concerned) to allow the IGJ to check these documents during any inspection. These administrative records may be implemented digitally, as long as the entire text of the doctor's declaration is used and the digital system is suitably qualified (as per Article 3.17, paragraph 1c of the RGnW).

The IGJ asks manufacturers, wholesale distributors and hospital-based and other pharmacists who have received permission from the IGJ to supply unlicensed pharmaceutical products under a doctor's declaration to annually submit an overview of the number of patients treated with such products. If this number is too high, the IGJ expects the relevant party to submit a registration application to the Medicines Evaluation Board or the EMA.

**25. Is it possible to obtain permission to supply an unlicensed pharmaceutical product to treat several indications?**

Yes. In that case, the IGJ would like to receive a separate, full application for each indication. Substantiating evidence that no suitable registered alternative is available must be provided for each indication. A completed and signed doctor's declaration is also needed for each indication to enable proper assessment.

**26. Do I need a completed and signed doctor's declaration for each individual patient?**

Yes. The supplier has to keep records of the fully completed individual doctor's declarations to allow the IGJ to check these documents during any inspection.

**27. What should I do with the individual doctor's declarations and the substantiating documents?**

After receiving an individual doctor's declaration and the substantiating documents, the manufacturer, wholesale distributor or hospital-based or other pharmacist (the 'supplier') must check if treatment of this patient meets the conditions of the permission granted by the IGJ. The aforementioned substantiating documents must provide evidence that an alternative registered product has been considered and/or used first. The manufacturer, wholesale distributor or hospital-based or other pharmacist must keep records of the doctor's declarations that have been received.

**28. What action should I take when side effects are reported?**

Article 3.17, paragraph 1f of the Medicines Act Regulations requires a manufacturer, distributor or pharmacist who has received permission from the IGJ to supply an unlicensed product for a specific indication (named patient use) to record all reported adverse drug reactions (ADRs).

All reports of suspected ADRs from named patient use should be reported to the Netherlands Pharmacovigilance Centre Lareb ([www.lareb.nl](http://www.lareb.nl)). These reports should include a notification that it concerns an unlicensed pharmaceutical product supplied under named patient use. The following terms apply for reporting:

- serious adverse drug reactions should be submitted within 15 calendar days;
- non-serious adverse drug reactions should be submitted within 90 calendar days.

The legal entity that received permission from the IGJ to supply an unlicensed product under named patient use must report any ADRs not only to the Netherlands Pharmacovigilance Centre Lareb, but also to the pharmaceutical company concerned. Lareb will forward all received ADRs to EudraVigilance. The legal entity that received permission from the IGJ to supply an unlicensed product under a named patient use or the pharmaceutical company concerned do not have to report ADRs to EudraVigilance.

**More information**

- [Medicines Act Regulations](#)
- [Netherlands Pharmacovigilance Centre Lareb](#)

### **29. Am I required to submit regular reports of side effects?**

No. If you have been granted permission by the IGJ to supply an unlicensed pharmaceutical product, you must however maintain full records of all reported side effects. The IGJ may wish to examine these administrative records during an inspection visit.

### **30. Where may I order an unlicensed pharmaceutical product?**

A Netherlands-based pharmacy can order pharmaceutical products that have not been licensed in the Netherlands from a wholesale distributor based in an EU member state, or from a manufacturer based in an EU member state or a non-EU member state. However, this product may not be supplied until the IGJ has given permission to do so under a doctor's declaration. Stocks may only be kept for patients for whom a doctor's declaration has been received.

### **31. Does the IGJ issue import permits for unlicensed pharmaceutical products?**

No. An import permit is not required if the IGJ has granted you permission pursuant to Article 40, paragraph 3c to supply an unlicensed pharmaceutical product further to a doctor's declaration.

### **32. How should I inform third parties that I am able to supply an unlicensed pharmaceutical product?**

Advertising of pharmaceutical products covers "any form of influencing with the apparent objective of encouraging the prescribing, provision or use of a pharmaceutical product, or giving instructions to that end" (see Article 1, paragraph 1 sub xx of the Medicines Act). Advertising can be distinguished by its commendatory nature, generally pointing out the positive characteristics of the pharmaceutical product or leaving out the negative characteristics.

The format in which that expression is presented is not a decisive factor; both written and verbal expressions can constitute advertising, such as publications on paper, on websites or in social media, as a stand owner at events or in presentations at congresses. Providing samples of pharmaceutical products is also a form of advertising.

Advertisements for pharmaceutical products that are not licensed is never permissible, either aimed at professional practitioners (such as doctors and pharmacists) or aimed at the general public (such as the patient).

The provider of an unlicensed pharmaceutical product may present generalised commercial advertising for its services unless this also means advertising specific pharmaceutical products either directly or indirectly. You may provide information such as the trade name, packaging format, dosage and price of the pharmaceutical products that may be obtained from you. You may only provide written information (e.g. in a letter or e-mail) if the recipient has expressly asked you to do so. You may not suggest that someone should contact you for information. Expressions that are purely informative in nature are not covered by the Medicines Act

### **33. Can one pharmacy physically supply an unlicensed pharmaceutical product to another?**

This is prohibited under Article 18 of the Medicines Act.

### **34. Can a pharmacy participating in the Automated Dose Dispensing System (GDS) order an unlicensed pharmaceutical product on behalf of another pharmacy, package it and then supply it to that pharmacy?**

Yes. This is only permitted if the relevant GDS pharmacy has obtained separate permission from the IGJ to supply the unlicensed pharmaceutical product further to a doctor's declaration (in accordance with Article 40, paragraph 3c of the Medicines Act). The GDS pharmacy in question must submit an application to the IGJ for permission. See [Question 14](#) in this FAQ section for questions about submitting an application for permission.

If the IGJ grants permission, the notification in question will state explicitly that the unlicensed product may be packaged and supplied to other pharmacies.

After obtaining permission from the IGJ, the GDS pharmacy must continue to meet the conditions stated in Article 3.17 of the Medicines Act Regulations. This could for instance include the condition that the GDS pharmacy must have a completed doctor's declaration for each patient treated with the unlicensed product. See [Question 26](#) and [Question 28](#) in this FAQ for further information.

### **35. Can a GDS pharmacy repackaging and/or relabel an unlicensed pharmaceutical product?**

It is the policy of the IGJ that unlicensed pharmaceutical products must be supplied in the packaging in which they are sold in the country of origin. In principle, repackaging and relabelling products is therefore not permitted.

A GDS pharmacy may only open packaging for repackaging and relabelling purposes if the '[Norm for an automated dose-dispensing system of the KNMP](#)' (Royal Dutch Pharmacists Association) field standard is met, and if the GDS pharmacy itself has obtained separate permission from the IGJ to supply an unlicensed pharmaceutical product further to a doctor's declaration. The decision document giving permission must then explicitly state this.

### **36. How does the IGJ's permission affect the reimbursement of an unlicensed product?**

If the IGJ has given permission to supply an unlicensed product further to a doctor's declaration, this does not necessarily mean that the product will be reimbursed.

The IGJ has no role in the process of reimbursement for an unlicensed pharmaceutical product. Its role is limited to granting permission to manufacturers, wholesale distributors, pharmacists and general practitioners who own a pharmacy for the supply of an unlicensed product further to a doctor's declaration.

This information belongs with '[Delivering under a doctor's declaration](#)' on [www.igj.nl](http://www.igj.nl).