

Questions and answers about the online application for narcotic drugs order forms narcoreg.be

1. Will there be a transition period during which people can choose between paper narcotic drugs order forms and the digital narcotic drugs order forms system?
From 1 July 2023 to 31 August 2023, there will be a transition period during which the new system will be accessible to all operators. During this period, it remains a legal requirement to continue to use paper forms and provide monthly sales records to the FAMHP. The transition period is intended to become familiar with the new system and the procedure, as well as to verify that the data provided by operators is received and processed correctly. Data entry into the new system will then be on a voluntary basis.
From 1 September 2023, the digital system will be mandatory and paper forms will belong to the past. This also means that monthly sales records will no longer have to be provided to the FAMHP by email.
2. As a wholesaler-distributor, do I only have to record my narcotic drug purchases (which used to require a form) or also my sales?
You must record both purchases and sales.
3. As a pharmacist, do I only have to register my narcotic drug purchases or also my sales (e.g. in case of a return to my wholesaler)?
You must register purchases, sales (helping out other pharmacies in urgent cases) or returns to wholesalers. Sales to patients should not be recorded.
Please note that the return of a **wrong delivery** by the wholesaler should **not** be recorded **in the system**.
4. When should registration be done?
No later than 30 days after receipt or shipment of the goods.
5. Declarations must be submitted monthly: does this mean that all products received in that particular month should be registered at the end of that month? Or does one effectively have one month from the day a product is received?
You have up to one month from the day a product is received/shipped. A customer can only register in the system if he or she has received the products (receipt date is required). Verification by the FAMHP is thus done a posteriori.
6. As a wholesaler, should I verify that my customers have coded their purchase before I can deliver the narcotic drugs to them?
No, verification is done a posteriori by the FAMHP.
7. What should be submitted when the narcotics are received?
Both purchases and sales must be registered into the system.
8. Who can do the registration?
For a pharmacy, the pharmacist-in-charge, deputy pharmacist-in-charge or substitute pharmacist can submit a declaration in the system. For authorisation holders, those indicated by the primary access manager may do so.
9. Do I still have to keep an in/out register (Royal Decree of September 6, 2017, Article 25, § 1)?
Yes, this is mandatory for substances named in Annexes I, II, III and IV.
10. Do I still have to provide a monthly record of supplies of products in Annexes IA, IB, II and IVB (Article 25, § 5) to the FAMHP?
No.
11. Should I register imports and/or exports ?
No, only the delivery and receipt **in Belgium** must be registered.
12. What do I risk if I forget to register?
To be determined.
13. How can I rectify the situation in case of an oblivion?
It is possible to submit entries a posteriori.
14. What in case of a return from a pharmacy?
This is entered into the system as a sale by the pharmacy and a purchase by the wholesaler.

Please note that the return of a **wrong delivery** by the wholesaler should not be recorded in the system.

15. In case of incomplete delivery, the system keeps the order in status "incomplete". When the rest of the order is delivered and it is complete, the order is filed away and a delivery date is assigned to the entire order. Is there a problem that products with the same CNK code from the same order, but received on a different day (i.e. received in two pieces) are still recorded in one line ? Or should they effectively be recorded by receipt date?

These will need to be recorded by receipt date.

16. Should I still check the activity license if I see that the purchasing wholesaler is in the system?

Yes, the control of the licensed substances/notice framing the authorisation is not carried out by the system.

17. What in case of delivery to a pharmacy with IMP site not located at the pharmacy's address?

The wholesaler should look at the exploitation license and should register sales on the pharmacy's APB number.