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.

- 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.
- The wrong narcotic drugs have been delivered to me. Should I also submit this as a transfer declaration in the system?
 No, the return of a wrong delivery should not be recorded in the system.
- 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.
- 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.
- Who can record a transfer declaration in the system? Any user for whom the access has been configured according to the <u>user guide</u>, can submit a transfer declaration.
- 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? This is no longer mandatory as from 1 September 2023.
- 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 forgetfulness? It is possible to submit entries a posteriori.
- 14. What to do in case of a return? This should be registered in the system as a sale by the returning party and a purchase by the party receiving the return. Please note that the return of a **wrong delivery** should not be registered 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 registered by receipt date.

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

Yes, the check 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.

- 18. Who is the principal access manager (PAM) for my organisation? The name of the person holding that position is mentioned in the Crossroads Bank for Enterprises (<u>CBE</u>). The principal access manager can appoint you as access manager (AM) or user.
- 19. How to designate the principal access manager (PAM) in CSAM if he or she does not have the Belgian nationality and therefore does not have a national register number? If the legal representative does not have a national register number, they can use the bis number. To do so, follow the instructions in the <u>user guide</u> (§ 2.2.3.2.2.).
- 20. Can our distributor continue to submit transfer declarations in our stead as was previously the case with the paper narcotic drugs order forms? The distributor also has a person 'on site' in charge of our activity licence.

Yes, that person can continue to do so. Your organisation needs to appoint a principal access manager (PAM) in CSAM (your organisation's legal representative). Afterwards, the PAM can designate an access manager (AM) or a user from amongst your distributor's staff to be responsible for your transfer declarations. You can then continue to access these transfer declarations on Narcoreg. Please note that access to Narcoreg for staff members of your organisation must also be configured according to the user guide so that they can continue to access the transfer declarations.

21. Can I also access my colleague's transfer declarations?

Yes, anyone with access to Narcoreg on behalf of the organisation can access his or her colleague's transfer declarations.

22. Should I enter both the narcotic code and the CNK code when submitting my transfer declaration?

No, filling in one of both fields is enough to submit a transfer declaration. The system automatically completes the other field. However, both fields can be filled in manually.

23. Are the 'headers' in the template of the CSV file required? Yes, the CSV file, and therefore the transfer declarations, cannot be uploaded without 'headers'.

Specific questions and answers for pharmacists

24. 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.

- 25. I am an adjunct pharmacist, why can't I log in to Narcoreg? Please contact the NIHDI by sending an email to <u>dossierpharma@riziv-inami.fgov.be</u> to verify your details as an adjunct pharmacist.
- 26. Can only the registered pharmacist-in-charge record transfer declarations? No, both adjunct pharmacists and substitute pharmacists of a pharmacy open to the public can get access to Narcoreg. However, substitute pharmacists need to be configured in CSAM by the principal access manager (PAM) before they can log in.

The <u>user guide</u> (§ 2.2.3.2.1., followed by §2.2.7.1.) describes the configuration procedure step by step.

- 27. I am the pharmacist-in-charge and have a foreign nationality. I do not have an ID card and cannot log in to Narcoreg. What do I need to do to be able to log in? You can designate a principal access manager (PAM) using the exception procedure. To do so, follow the instructions in the user guide (§ 2.2.3.2.2.).
- 28. I can only select my previous employer's profile even though I now work for a different pharmacy. How to make the necessary changes? Please contact the NIHDI by sending an e-mail to <u>dossierpharma@riziv-inami.fgov.be</u> stating that you are no longer employed by your former employer. The NIHDI can then make the necessary changes in coBRHA. This is important as our application retrieves its data from coBRHA.
- 29. The address of my pharmacy is incorrect in Narcoreg. How can it be changed? Please contact the NIHDI by sending an email to <u>dossierpharma@riziv-inami.fgov.be</u>.
- 30. As a pharmacy, we sell anaesthetics to veterinarians. Should this be recorded in Narcoreg?

No, neither party has to report that in Narcoreg. The order form is still being used to that end.

31. As a pharmacist, do I have to record only my drug purchases or also my sales (e.g., in case of a return to my wholesaler)? You must record 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**.

Specific questions and answers related to veterinary use

32. As a veterinarian, I buy anaesthetics from a pharmacy. Should this be recorded in Narcoreg?

No, neither party has to report that in Narcoreg. The order form is still being used to that end.

- 33. As a veterinary wholesaler, we purchase anaesthetics from veterinary manufacturers. Should this be recorded in Narcoreg? Yes, the veterinary wholesaler records the purchase through Narcoreg, the veterinary manufacturer records the sale through Narcoreg.
- 34. As a veterinary wholesaler, we sell anaesthetics to pharmacists. Should this be recorded in Narcoreg?

Yes, the veterinary wholesaler records the sale through Narcoreg, the pharmacist records the purchase through Narcoreg.

35. As a veterinary wholesaler, we sell anaesthetics to other veterinary wholesalers. Should this be recorded in Narcoreg?

Yes, the purchasing wholesaler records the purchase through Narcoreg, the selling wholesaler records the sale through Narcoreg.