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FSCA Ref: CR260118\_FSCA\_initial

Date: 17.04.2026

**Urgent Field Safety Notice**  
**Bronwel Night (cough syrup)**

For Attention of\*: Apotek Hjärtat and Apotea AB (Swedish pharmacies) as customers of the distributor Perrigo to inform end consumers of named device (lay persons).

| Contact details of local representative (name, e-mail, telephone, address etc.)*                                                                                                                                              |
|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| Perrigo Sverige AB<br>Box 7009<br>164 07 Kista<br>+468-59002900<br><a href="mailto:swedeninfo@perrigo.com">swedeninfo@perrigo.com</a><br><a href="mailto:CHCINordicQA-Safety@perrigo.com">CHCINordicQA-Safety@perrigo.com</a> |

**Urgent Field Safety Notice (FSN)****Bronwel Night (cough syrup)****Packages intended for the Danish and Norwegian market delivered to two Swedish Pharmacies, lacking the Swedish language**

| 1. Information on Affected Devices* |                                                                                                                                                                                                                                                                                                                                                                                                                      |
|-------------------------------------|----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 1                                   | 1. Device Type(s)*                                                                                                                                                                                                                                                                                                                                                                                                   |
| .                                   | MD Nite (trade name in Sweden: Bronwel Night) is a class IIa medical device, - a cough syrup intended for treatment and relief of dry and productive cough as well as hoarseness, scratching of the throat, urge to clear the throat and difficulty swallowing, especially at night. The product contains Icelandic moss extract hyaluronic acid and xanthan. As primary packaging a glass bottle of 120 ml is used. |
| 1                                   | 2. Commercial name(s)                                                                                                                                                                                                                                                                                                                                                                                                |
| .                                   | Bronwel Night                                                                                                                                                                                                                                                                                                                                                                                                        |
| 1                                   | 3. Unique Device Identifier(s) (UDI-DI)                                                                                                                                                                                                                                                                                                                                                                              |
| .                                   | Complete when this becomes available.                                                                                                                                                                                                                                                                                                                                                                                |
| 1                                   | 4. Primary clinical purpose of device(s)*                                                                                                                                                                                                                                                                                                                                                                            |
| .                                   | Treatment of any cold related cough at nighttime. MD Nite is intended for the treatment of any cold-related cough as well as hoarseness, sore throat, scratching of the throat, urge to clear the throat and difficulty swallowing, especially at night. It is intended for use by lay persons.                                                                                                                      |
| 1                                   | 5. Device Model/Catalogue/part number(s)*                                                                                                                                                                                                                                                                                                                                                                            |
| .                                   | 9532311                                                                                                                                                                                                                                                                                                                                                                                                              |
| 1                                   | 6. Software version                                                                                                                                                                                                                                                                                                                                                                                                  |
| .                                   | Only where relevant.                                                                                                                                                                                                                                                                                                                                                                                                 |
| 1                                   | 7. Affected serial or lot number range                                                                                                                                                                                                                                                                                                                                                                               |
| .                                   | Lots 5G1492 and 5G1493                                                                                                                                                                                                                                                                                                                                                                                               |
| 1                                   | 8. Associated devices                                                                                                                                                                                                                                                                                                                                                                                                |
| .                                   | Within context of the FSCA eg for IVD reagents and platforms.                                                                                                                                                                                                                                                                                                                                                        |

| 2 Reason for Field Safety Corrective Action (FSCA)* |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |
|-----------------------------------------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
| 2                                                   | 1. Description of the product problem*                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| .                                                   | The labelling (outer packaging, bottle label, and instructions for use of the affected batches are not provided in Swedish language, since these were intended to be delivered to the Danish and Norwegian markets. Shipment from Kwizda (contract manufacturer) to the distributor (Perrigo) was made with the wrong EAN code on the shipping carton. After relabelling with the correct EAN, the goods were mistakenly stored in the incorrect SAP location, resulting in delivery to Sweden instead of DK/NO.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| 2                                                   | 2. Hazard giving rise to the FSCA*                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| .                                                   | The IFU must be provided in Swedish language on the Swedish market. - Packages from two batches of the country variant for the Danish and Norwegian market were delivered to two pharmacies in Sweden. Therefore, the labelling (outer packages, bottle and IFU) was not available in Swedish. No complaints have been received by HÄLSA Pharma GmbH from the Swedish market to date, although a first shipment has been delivered in December 2025. All sales are blocked since calendar week 3/2026. - Risk of users taking higher/lower dose is very low as the Scandinavian languages provided (DK/NO) are similar enough to Swedish to be understandable for users. The dosage instructions are in numerical text. - Moreover, according to the clinical evaluation, no health risks are associated with a possible overdose of the product for the users/patients. Hypersensitivity reactions, which could occur in isolated cases due to the incomprehensibility of warnings and instructions in the IFU (in Danish or Norwegian), are assessed as "remote" without mitigating by providing sufficient information in the IFU, i.e. more frequent than any 100,000th application. If access to the correct labeling in the respective national language, and in particular to the instructions for use, is ensured, this risk decreases to |

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|---|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|
|   | “improbable,” with a probability of harm of less than one in 100,000 uses. – This is confirmed by the fact that no complaints have been received from end consumers.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |
| 2 | 3. Probability of problem arising                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
| . | see above                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                        |
| 2 | 4. Predicted risk to patient/users                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| . | In the risk analysis, different risks are assessed in the section “hazards by information”, e.g. relating to overdosage or insufficient dosage, wrong indication, intended use, insufficient information about contraindication/side-effects, etc. The maximal severity and the maximal probability of these risks are assessed as “2” (e.g. severe allergic reaction: S2, P2). This risk usually is mitigated by providing the respective warnings and contraindications in the IFU to “S2, P1”, which is not true in this case as the labelling of the sold products is not given in Swedish. However, the Scandinavian languages provided (DK/NO) are similar enough to Swedish to be understandable for users.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                               |
| 2 | 5. Further information to help characterise the problem                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                          |
| . | In respect of the labelling of the products in Danish and Norwegian, the main risk from the product might relate to (severe) allergic reactions. There is no direct safety-relevant hazard, as product quality, dosage and composition are unchanged. The primary risk is a language barrier. No complaints regarding the package leaflet in a foreign/unintelligible language have been received to date, but special attention is being paid to potential complaints of this kind. Based on the clinical evaluation, there are no health risks associated with a possible overdose of the product. Hypersensitivity reactions, which could occur in isolated cases due to the incomprehensibility of warnings and instructions in the IFU, are generally very rare. In addition, the ingredients are almost identical in the specified languages and therefore very easy to identify by the user.                                                                                                                                                                                                                                                                                                                                                                                                                                              |
| 2 | 6. Background on Issue                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                           |
| . | <p>Eg how the manufacturer became aware; brief details of relevant incidents; root cause if known; rationale for containment of problem to only affected devices; other risk mitigation or longer-term preventative action etc. Shipment from the contract manufacturer to the distributor was made with the wrong EAN code on the shipping carton. After relabelling with the correct EAN code, the products were mistakenly stored in the incorrect SAP location, resulting in delivery to Sweden instead of DK/NO. On 12 January 2026, Perrigo as the distributor was informed by a customer (pharmacy Apotek Hjärtak) that products with the DK/NO artworks have been delivered. The stock was immediately blocked by the customer Apotek Hjärtak and Apotea.</p> <p>There is no health risk associated with a possible overdose of the product. Hypersensitivity reactions, which could occur in isolated cases due to the incomprehensibility of warnings and instructions in the IFU, are generally rare. In addition, the ingredients are almost identical in the specified languages and therefore very easy to identify by the user.</p> <p>No complaints regarding the package leaflet in a foreign/unintelligible language have been received to date, but special attention is being paid to potential complaints of this kind.</p> |
| 2 | 7. Other information relevant to FSCA                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                            |
| . | This field may only contain additional information that is deemed necessary by the manufacturer to supplement information relevant to the FSCA.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  |

| 3. Type of Action to mitigate the risk* |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                             |                                                   |
|-----------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|---------------------------------------------------|
| 3.                                      | <b>1. Action To Be Taken by the User*</b><br><br><input checked="" type="checkbox"/> Identify Device <input type="checkbox"/> Quarantine Device <input checked="" type="checkbox"/> Return Device <input checked="" type="checkbox"/> Destroy Device<br><br><input type="checkbox"/> On-site device modification/inspection<br><br><input type="checkbox"/> Follow patient management recommendations<br><br><input type="checkbox"/> Take note of amendment/reinforcement of Instructions For Use (IFU)<br><br><input type="checkbox"/> Other <input type="checkbox"/> None<br><br>Note: Identification of the affected products, return of medical devices from the pharmacies' warehouses to Perrigo, as well as destruction of products from pharmacies' shelves has already taken place (as confirmed by the pharmacies and Perrigo as distributor).                                                                                                                                                                                                                                                   |                                                   |
| 3.                                      | 2. By when should the action be completed?                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | 2026-03-31                                        |
| 3.                                      | 3. Particular considerations for: Choose an item.<br><br>Is follow-up of patients or review of patients' previous results recommended?<br>No<br><br>There is no health risk associated with a possible overdose of the product. Hypersensitivity reactions, which could occur in isolated cases due to the incomprehensibility of warnings and instructions in the IFU, are generally rare. In addition, the ingredients are almost identical in the specified languages and therefore very easy to identify by the user.                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                   |                                                   |
| 3.                                      | 4. Is customer Reply Required? *<br>(If yes, form attached specifying deadline for return)                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | No                                                |
| 3.                                      | <b>5. Action Being Taken by the Manufacturer</b><br><br><input type="checkbox"/> Product Removal <input type="checkbox"/> On-site device modification/inspection<br><input type="checkbox"/> Software upgrade <input type="checkbox"/> IFU or labelling change<br><input checked="" type="checkbox"/> Other <input type="checkbox"/> None<br><br>Based on the delivery of products to Sweden, which were intended (and carried the labelling) for the Danish and Norwegian markets, HÅLSA Pharma GmbH as the legal manufacturer of the cough syrup initiated a non-conformity procedure (NC26006).<br>Within this NC procedure, the following CAPAs were defined:<br>CAPA 26018: Clarification with Kwizda (as the contract manufacturer and IP holder) as well as Perrigo as distributor, that the current version of Swedish IfU is available on the websites of Swedish pharmacies.<br>CAPA 26019: NC Report from Perrigo regarding wrong delivery of DK/NO packages to SE<br>CAPA 26020: Confirmation from Perrigo that all DK/NO packages (collected from pharmacies) have left the Swedish pharmacies |                                                   |
| 3                                       | 6. By when should the action be completed?                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                  | Specify where critical to patient/end user safety |

|                                |                                                                                                                                                                   |                                                        |
|--------------------------------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------|
| 3.                             | 7. Is the FSN required to be communicated to the patient /lay user?                                                                                               | No                                                     |
| 3                              | 8. If yes, has manufacturer provided additional information suitable for the patient/lay user in a patient/lay or non-professional user information letter/sheet? |                                                        |
|                                | Choose an item. Choose an item.                                                                                                                                   |                                                        |
| <b>4. General Information*</b> |                                                                                                                                                                   |                                                        |
| 4.                             | 1. FSN Type*                                                                                                                                                      | New                                                    |
| 4.                             | 2. For updated FSN, reference number and date of previous FSN                                                                                                     | Provide reference and date of previous FSN if relevant |
| 4.                             | 3. For Updated FSN, key new information as follows:                                                                                                               |                                                        |
|                                | Summarise any key difference in devices affected and/or action to be taken.                                                                                       |                                                        |
| 4.                             | 4. Further advice or information already expected in follow-up FSN? *                                                                                             | No                                                     |
| 4                              | 5. If follow-up FSN expected, what is the further advice expected to relate to:                                                                                   |                                                        |
|                                | Eg patient management, device modifications etc                                                                                                                   |                                                        |
| 4                              | 6. Anticipated timescale for follow-up FSN                                                                                                                        | For provision of updated advice.                       |
| 4.                             | 7. Manufacturer information<br>(For contact details of local representative refer to page 1 of this FSN)                                                          |                                                        |
|                                | a. Company Name                                                                                                                                                   | <b>HÄLSA Pharma GmbH</b>                               |
|                                | b. Address                                                                                                                                                        | <b>Maria-Goeppert-Str. 5, 23562 Lübeck, Germany</b>    |
|                                | c. Website address                                                                                                                                                | <b>www.haelsa.de</b>                                   |
| 4.                             | 8. The Competent (Regulatory) Authority of your country has been informed about this communication to customers. * - Yes.                                         |                                                        |
| 4.                             | 9. List of attachments/appendices:                                                                                                                                | If extensive consider providing web-link instead.      |
| 4.                             | 10. Name/Signature                                                                                                                                                | <b>Dr. Bettina Hofer</b>                               |

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| <b>Transmission of this Field Safety Notice</b> |                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                                |
|                                                 | <p>This notice needs to be passed on all those who need to be aware within your organisation or to any organisation where the potentially affected devices have been transferred. (As appropriate)</p> <p>Please note: The impacted two pharmacies have already been informed. They have reached out to the end consumers and provided a digital IFU in Swedish or informed all of its pharmacies, respectively. The products have been removed from shelves immediately. Please maintain awareness on this notice and resulting action for an appropriate period to ensure effectiveness of the corrective action.</p> <p>Please report all device-related incidents to the manufacturer, distributor or local representative, and the national Competent Authority if appropriate, as this provides important feedback.*</p> |

Note: Fields indicated by \* are considered necessary for all FSNs. Others are optional.