Pharmaceutical product procurement and storage: rifampicin and allergy medication

1. Purpose

This Standard Operating Procedure (SOP) describes the procedure for procurement and storage of pharmaceutical products needed for SDR-PEP implementation (rifampicin and medication for allergy).

2. Scope

This procedure applies to the procurement and storage of rifampicin and medication against allergies in the context of SDR-PEP implementation.

3. Target group

This SOP applies to all staff working on the procurement, storage and logistics, and quality assurance of pharmaceutical products.

4. Procedure

4.1. Rifampicin

For the administration of SDR-PEP, 150mg rifampicin and 300mg rifampicin capsules are required (if available also rifampicin 600mg for adults and rifampicin syrup/suspension for children; rifampicin tablets if capsules are not available).

The purchase of rifampicin needs to be coordinated with the implementing team. The procedure of comparing pharmaceutical suppliers and purchasing rifampicin needs to follow purchase regulations in the context in which the intervention is implemented. Dealing with the suppliers includes ensuring the necessary documents are made available, e.g.: donation letters, the supplier's information, quality reports, etc. If importation of rifampicin is required, the required documents need to be obtained, such as governmental approval letters. Take into account that the production and import of rifampicin can take up to 4-6 months, therefore, monitoring, forecasting and ordering in time is important. The in-country distribution of rifampicin needs to be coordinated through the existing national logistic channels. For more information on supply chain management with regard to rifampicin, refer to the 2020 WHO Technical Guidance - Leprosy/Hansen disease: contact tracing and post-exposure prophylaxis (1).

4.2. Medication against allergy

It is advised to have at least a few dosages of anti-allergy medication available, including anti-histamine and corticosteroid dosages, in case someone develops an allergic reaction. It can be useful to include these medicines in a separate allergy kit. An allergic reaction is very rare after rifampicin, but it is important to always be prepared for allergies for safety reasons. Please use the national anti-allergy guidelines (e.g. regarding dosage) when administering anti-allergy medication, monitor the vital functions of the patient, and refer the patient quickly if needed. In addition, any adverse event should be reported according to the national guidelines. For more detail on pharmacovigilance refer to ***'SOP 4: SDR-PEP administration'.***

- Examples of anti-histamines are: cetirizine (Zyrtec®, Benadryl®), loratadine (Clarityn®) or desloratadine (Clarinex), fexofenadine (Allegra®), diphenhydramine, chlorpheniramine,

levocetirizine (Xyzal®), loratadine (Alavert®, Claritin®), clemastine (Tavegil®), chlorphenamine maleate (Piriton®), hydroxyzine, promethazine hydrochloride (Phenergan®), cyproheptadine hydrochloride (Periactin®). When giving anti-histamines, make sure that that 'drowsiness' as possible side-effect is mentioned to the recipient, including the remark that driving motorized vehicles or working with machines is contra-indicated after taking anti-histamines.
- (Cortico)steroids (e.g. prednisolone, prednisone, cortisone, hydrocortisone, triamcinolone, dexamethasone) are also possible to give in case of an allergic reaction, and can be used besides anti-histamines. Be careful / monitor closely in case of possible contra-indications against steroids (e.g. stomach problems, diabetes, immunosuppression, inflammatory bowel disease).
- If medication as epinephrine/adrenaline is needed/given, please contact a health facility with urgent care facilities. Ongoing vital function monitoring and urgent referral may be needed.
- Anti-itchiness ointment (e.g. calamine, camphor, menthol, class-1 steroids) can be given in case of urticaria/hives.

In case additional or invasive (intravenous/ intramuscular) medication is needed (e.g. adrenalin), this needs to take place in coordination with a health facility, by an authorized health professional, according to national guidelines.

4.3. Procurement guidelines

Proper procurement of pharmaceutical products and (price) agreements and contracts with the pharmaceutical supplier need to be ensured. The procurement of pharmaceutical products should be aligned with and/or based on context-specific guidelines, taking into account the following aspects:

- Reliability of suppliers and quality of products. For more information, refer to the WHO's guidelines on Good Manufacturing Practices, Certificates of pharmaceutical products and the WHO Prequalified Manufacturers' Lists (2–4);
- Comparing quotations of different pharmaceutical suppliers;
- Ask for quality reports. Make sure these laboratory reports also include acceptable nitrosamine (4-methyl-1-nitrosopiperazine, MeNP) levels;
- Check expiry dates;
- National importation procedures and guidelines, if importing medication is required;
- Delivery times, transportation services, storage conditions, shelf life / expiration date and quality assurances activities.

4.4. Product storage and logistics

All procedures for medication management, storage and logistics should be aligned with national guidelines and practices.

When pharmaceutical products are delivered, check for damage/broken seals, the product's count, amount, batch numbers, expiry dates, etc. If necessary, quality assurance tests may be performed. A stock register should be maintained to monitor the quantity and expiring dates of the pharmaceutical products.

Pharmaceutical products may deteriorate on exposure to high temperature and/or high humidity and moisture. To maintain their integrity and potency, it is important to store the products in conditions as specified by the manufacturer. Some of the factors that may be considered regarding the storage room conditions are:

- Appropriate temperature and humidity, away from direct sunlight;
- Availability of temperature and manometers to monitor the temperature and humidity;
- Free of pests and rodents;
- Free of flammable materials and heaters/stoves;
- Possibility to restrict access to those authorized only.

5. Definitions and abbreviations

An overview of all definitions and abbreviations can be found in the document ***'Introduction, content and definitions'.***

6. Related SOPs

- *SOP 4: SDR-PEP administration*
- *SOP 8: Skin medication*

7. References

1. World Health Organization; Regional Office for South-East Asia. Leprosy/Hansen disease: contact tracing and post-exposure prophylaxis. Technical guidance. 2020.

2. World Health Organization. Model certificate of a pharmaceutical product [Internet]. [cited 2023 May 12]. Available from: https://www.who.int/teams/regulation-prequalification/regulation-and-safety/regulatory-convergence-networks/certification-scheme/model-certificate-of-a-pharmaceutical-product

3. World Health Organization. Health products policy and standards - Good Manufacturing Practices [Internet]. [cited 2023 May 12]. Available from: https://www.who.int/teams/health-product-policy-and-standards/standards-and-specifications/gmp

4. World Health Organization. Prequalified Lists [Internet]. [cited 2023 Oct 4]. Available from: https://extranet.who.int/prequal/medicines/prequalified-lists