**Product Evaluation and Registration Unit**

**Date:** 31/12/2021

**Product Evaluation and Registration Unit**

**Minutes of the fourth quarter meeting**

**Time:** 09:00 - 10:30 AM

**Participants**

1. Azania Werede
2. Hermella Yemane
3. Meron Tesfagaber
4. Sirak Tesfamariam

**Agenda of meeting**

* **Progress report of planned activities of the fourth quarter**
* **Report of unplanned activities**
* **New year wishes and ways forward**

**Rapporteur**

Sirak Tesfamariam

—————————

The third quarter meeting was conducted on Friday, 31st of December. The meeting was moderated by Sirak and every member of the unit presented the progress of planned and unplanned activities. The progress report of each member is provided below:

**AZANIA WEREDE**

**Executed activities**

* **Submit list of registered products to Director and editorial board of medicines information bulletin**

This task was executed and the updated list of registered products was communicated to the editorial board of the medicines information bulletin to be included in the upcoming publication.

* **Update and archive individual staff profile (CVs, job descriptions)**

The CV of the new PERU staff recruited on July has been updated and documented.

**Ongoing activities**

* **Develop Medicines Variation Evaluation Guideline**

No new progress has been made from the last quarter.

* **Update statements in Proclamation No.36/1993 related to market authorization of medical products**

There was no update in the fourth quarter, but the NMFA is planning to revise the proclamation in 2022 as highlighted in the development of Institutional Development Plan (IDP) (2022 – 2024).

**Unexecuted activities**

* **Develop MOU with PHARMECOR and PMU to accelerate registration status of manufacturers**

There was no progress regarding the development of the MOU with PHARMECOR and PMU. The NMFA, however, has developed an IDP; and registering all medical products that enter to the Eritrean market by the end of 2023 was set as a goal for the PERU. To achieve this goal, the NMFA had sent an official letter to Pharmecor, a procuring agent and central ware house, that imposed registration of all medical products prior to bidding.

**SIRAK TESFAMARIAM**

**Executed activities**

* **Define PERU into different sections with clear responsibilities to conduct registration or MA activities and Develop and print PERU organogram**

Using the structure of different NRA’s as a reference, the PERU is segmented into five sections namely Pharmaceuticals section, Biologicals section, Medical devices section, Planning and evaluation section, and Training, education, and development section. The organogram has also been drafted and communicated to the PERU team for comments. Final approval from the Director of the NMFA is remaining prior to its implementation.

**Partially executed activities**

* **Develop MOU with Inspection and Pharmacovigilance Units**

A draft MOU with both Inspection and Pharmacovigilance units has been prepared by the PERU. The draft still awaits input from the respective units.

**Ongoing activities**

* **Develop and deploy a fully-functional medical product registration software**

In the last quarter, the PERU team has prepared the user stories of release 4, and templates of release 3 and 4. In-depth discussion with the developers and demonstration of the first two release was also conducted. Additionally, additional network materials were purchased by the WHO.

The development of the four releases is completed with the exception of final release i.e. setting network infrastructure and deployment of the software along with a website. Delay in the delivery of the IT materials and unavailability of secured internet connection were the main obstacles to due delivery.

* **Encourage prequalification holding companies to register in Eritrea through proactive measures with the help of PQT**

No new company has expressed interest to register products in Eritrea.

* **Collaborate on the development of the NMFA website**

A team composed of five members from various NMFA units was formed to work on the NMFA’s website with the software development team. The skeleton of the website has been completed and efforts are being made to populate the necessary information to be displayed online. The task, however, is on hold until the completion of the database so as to be incorporated on the website. Thus, its development will start soon after the deployment of the software.

* **Risk categorization of pharmaceutical products for MA**

There was no progress in the last quarter.

**MERON TESFAGABER**

**Executed activities**

* **Define PERU into different sections with clear responsibilities to conduct registration or MA activities and Develop and print PERU organogram (**\*described above**)**

**Partially executed activities**

* **Drafting a guidance document for waiver of registration of medical products for market authorization**

The draft guidance document for waiver of registration still awaits review comments from the NMFA staff.

**Ongoing activities**

* **Risk Categorization of Pharmaceutical Products for market authorization (**\*described above**)**

**Unexecuted activities**

* **Develop MOU with PHARMECOR and PMU to accelerate registration status of manufacturers (**\*described above**)**
* **Develop medical product registration policy**
* **Set continuing e-learning programs on dossier evaluation to PERU and Registration Committee**

**HERMELLA YEMANE**

**Partially executed activities**

* **Develop MOU with Inspection and Pharmacovigilance Units (**\*described above**)**

**Ongoing activities**

* **Risk Categorization of Pharmaceutical Products for market authorization (**\*described above**)**

**Additional activities of the PERU**

* **Dossier Assessment**

In the last quarter, due to delayed access to MedNet and unavailability of WHO assessment reports, the PERU team has decided to change the review procedure of the 12 products of Serum Institute of India from fast-track review through the WHO-CRP to standard pathway. In response to this unprecedented event, the unit conducted dossier evaluation retreat to clear the backlog from 08 to 26 November. The assessment of the above products is in-progress and it is summarized in the table below.

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **S.N** | **Product Name** | **Preliminary Screening** | **First Query Sent** | **Second Query**  **Sent** | **Assessors** |
| 1 | Men-A 5 dose | - | 12 November | 29 December | Meron & Hermella |
| 2 | Men-A 10 dose | - | 12 November | 29 December | Meron & Hermella |
| 3 | MR 5 dose | - | 12 November | 29 December | Azania & Sirak |
| 4 | MR 10 dose | - | 12 November | 29 December | Azania & Sirak |
| 5 | BCG | - | 29 December | - | Meron |
| 6 | Pentavalent | - | 29 December | - | Hermella |
| 7 | Rabies vaccine | - | 29 December | - | Azania |
| 8 | Rotavirus vaccine | - | 29 December | - | Sirak |
| 9 | bOPV | 29 October | - | - | Sirak |
| 10 | IPV 5 dose | 29 October | - | - | Meron |
| 11 | IPV 10 dose | 29 October | - | - | Hermella |
| 12 | Tetanus diphteria | 29 October | - | - | Azania |

Moreover, the assessment of Artesunate powder for injection Ph. Int 60mg from Macleods Pharmaceuticals Ltd has started on 23/11/2021 through Fast track (WHO – CRP) review process and it is undergoing.

* **Meetings attended**

The PERU staff attended training sessions on Quality Management System for Laboratory (ISO/IEC 17025/ 2017) (December 21, 2021) and Evaluation of Analytical Method Validation (December 27 – 28, 2021) given by a WHO consultant, Mr. Colin Shamhuyarira.

* **Unplanned activities**

**Conducting WHO-GBT self-benchmarking and drafting an iIDP**

The PERU team participated in the development of the iIDP at NMFA level that took place at Crystal Hotel between October 4, 2021 and October 16, 2021.

**Data collection of KAP survey on Falsified medical products**

The PERU team participated in the data collection process of a national KAP survey conducted from 2nd to 17th of December. The aim of the study was to assess the knowledge, attitude, and practice of Eritrean healthcare professionals on falsified medical products and identify the barriers to reporting.

**Ways forward**

* Reach quick regulatory decision on the registration application of LET-400 and Metrozole (250 & 500 mg)
* Send an official letter to WHO-PQT to communicate the issue on LET-400 (absence of GMP certificate of an intermediate manufacturer) and inquire guidance.
* Schedule a PERC meeting in the coming month

**Second Semi-annual Strategic Plan 2021**

|  |  |  |  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **#** | **Activity** | **Time frame** | | | | | | | | **Responsible person** | **Status** |
| **Jul** | **Aug** | | **Sep** | **Oct** | **Nov** | | **Dec** |
| 1 | Develop and deploy a fully-functional medical product registration software |  |  | |  |  |  | |  | **Sirak** | Ongoing |
| 2 | Develop MOU with PHARMECOR & PMU to accelerate registration status of manufacturers |  |  | |  |  |  | |  | **Azania and Meron** | Not executed |
| 3 | Set continuing e-learning programs on dossier evaluation to PERU and Registration Committee |  |  | |  |  |  | |  | **Meron** | Not executed |
| 4 | Encourage Prequalification holding companies to register in Eritrea through proactive measures with the help of Prequalification Team |  |  | |  |  |  | |  | **Sirak** | No new notification |
| 5 | Arrange regular meetings for discussion with the Registration Committee |  |  | |  |  |  | |  | **Secretary of PERC** | There was no meeting |
| 6 | Provide training on dossier assessment for new recruits |  |  | |  |  |  | |  | **PERU Staff** | One recruit was trained |
| 7 | Update Proclamation No.36 1993 (related to medical products Market Authorization) |  |  | |  |  |  | |  | **Azania** | Ongoing |
| 8 | Submit list of registered products to Director and editorial board of medicines information bulletin |  |  |  | |  | |  |  | **Azania** | Executed |
| 9 | Define PERU into different sections with clear responsibilities to conduct registration or MA activities |  |  |  | |  | |  |  | **Sirak & Meron** | Executed |
| 10 | Develop and print PERU organogram |  |  |  | |  | |  |  | **Sirak** | Awaiting approval |
| 11 | Develop MOU with Inspection and Pharmacovigilance Units |  |  |  | |  | |  |  | **Sirak & Hermella** | Partially executed |
| 12 | Prepare guidance document for waiver of registration applications of medical products for marketing authorization |  |  |  | |  | |  |  | **Meron** | Partially executed |
| 13 | Collaborate on the development of the NMFA website |  |  |  | |  | |  |  | **Sirak** | Ongoing |
| 14 | Update SOPs in line with transparency and accountability |  |  |  | |  | |  |  | **Hermella** | Pending |
| 15 | Develop Medical Product Registration Policy |  |  |  | |  | |  |  | **Meron** | Not executed |
| 16 | Develop Medicines Variation Evaluation Guideline |  |  |  | |  | |  |  | **Lead: Azania**  ***PERU Staff*** | Ongoing |
| 17 | Risk categorization of pharmaceutical products for marketing authorization |  |  |  | |  | |  |  | **Lead: Sirak**  ***Meron & Hermella*** | Ongoing |