SAHPRA
South African
Health Products
Regulatory Authority

SAHPRA Head Office
Building A
Loftus Park
2nd Floor
Kirkness Road
Arcadia
0083

PHARMACOVIGILANCE PROCESS OF ISSUING SAFETY RECOMMENDATIONS TO APPLICANTS/HCRS FOR IMPLEMENTATION

TO ALL APPLICANTS

Kindly note that this communication serves to communicate two (2) processes that the SAHPRA Pharmacovigilance (PV) unit has revised. You are urged to take note of these revisions.

1. **The process of issuing safety recommendations for implementation.**

- All safety-related issues received by the unit will be processed and **recommendations for implementation will be issued to market leader/ innovator applicant/s only on initial stages**.
- Innovator applicant/s will be given seven (7) calendar days to indicate whether they agree with the PV recommendation or not.
- In cases where the applicant is not in agreement with the recommendation**, the innovator/market leader applicant/s** will be given 30 calendar days to respond to the recommendation with a motivation supporting their disagreement.
- The motivation will be reviewed and discussed internally, and **the outcome will be communicated to the market leader/innovator applicant/s**.
- The **market leader or Innovator applicant/s should update the Professional Information (PI) and Patient Information Leaflet (PIL) and submit to the Clinical Post-Registration unit** via the relevant portal and inform the Pharmacovigilance unit.
- The Clinical Post-Registration unit will review the submission and communicate with the market leader or innovator applicant/s until finalisation.
- Once finalised, the Post-Registration unit will communicate final amendments to be effected in the PI & PIL with the PV unit.

Chairperson: Prof Helen Rees • Vice-Chairperson: Dr Obakeng Khaole • Prof Joyce Tsoka-Gwegweni
Prof Patrick Demana • Dr Xolani Khayelihle Ngobese • Adv Hasina Cassim • Ms Ditaba Lucy Maraka

- The Pharmacovigilance unit will prepare and issue recommendation letters to all the affected applicants and publish a communique in this regard on the SAHPRA website under Safety Information and Updates - **https://www.sahpra.org.za/safety-information-and-updates/**

2. Process for issuing a Dear Healthcare Professional Letter

- All safety-related issues received by the unit will be processed and **recommendations will only be issued to the innovator/market leader applicant/s**.
- The innovator/market leader applicant/s will be given seven (7) calendar days to highlight whether in agreement with the recommendation or not.
- In cases where the applicant is not in agreement with the recommendation, the applicant will be given 30 calendar days to respond to the recommendation with a motivation supporting their disagreement.
- The motivation will be reviewed and discussed internally, and **the outcome will be communicated to the innovator/market leader applicant/s** and the process will continue until a consensus is reached.
- **Once a consensus is reached, the Pharmacovigilance unit will publish a communique to all holders of certificate of registration (HCRs) or applicants of the affected molecule on the SAHPRA website indicating the need to issue a DHCPL as per the DHCPL guideline. This communique will be issued on the SAHPRA website under Safety Information and Updates - https://www.sahpra.org.za/safety-information-and-updates/**.
- For PI/PIL amendment, **only the innovator/market leader applicant/s must send the amended PI/PIL to the Clinical-Post-Registration unit for review**.
- **The Clinical Post-Registration unit will review the submission and communicate with the innovator/market leader applicant/s until finalisation.**
- Once finalised, the Post-Registration unit will communicate final amendments that must be effected in the PI & PIL with the Pharmacovigilance unit, which will prepare and issue recommendation letters to all the affected applicants.

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- Furthermore, the Pharmacovigilance unit will issue a communique about the recommendation on the SAHPRA website under Safety Information and Updates **-https://www.sahpra.org.za/safety-information-and-updates/**.

Please note that these processes will be implemented on an immediate basis.

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Dr Boitumelo Semete-Makokotlela
SAHPRA Chief Executive Officer
Date: ~~13 February 2024~~