

26 March 2020

BACKLOG CLEARANCE PROGRAM COMMUNICATION

Dear Industry Partners,

As we are all aware of the current situation relating to COVID19, the President has announced a national lockdown on 23 March 2020. The Lockdown is effective from midnight on 26 March 2020 until midnight on 16 April 2020. With the number of people tested positive for the coronavirus (COVID-19) both globally and in South Africa, this is the best strategy for avoid the spread of the infection. The global mortality rate is now well over 16 000 and the current COVID-19 positive cases in South Africa are estimated at 709.

With the above being said, SAHPRA will comply with the pronouncement by the President. Be advised that the SAHPRA Reception (Building 38) will be closed during the lockdown and backlog applications will only be submitted electronically. The following procedures will be implemented:

1. New Registrations

The backlog new registration resubmission windows (RW) will be postponed as indicated in Appendix 1 due to the current lockdown:

- The upcoming RW 6 applications (Respiratory system diseases) will only be resubmitted to SAHPRA from **4 May 2020**.

SAHPRA will continue to accept responses to queries during the lockdown period.

- The responses to queries should be submitted through a via document upload solution, File Transfer Protocol (FTP). Look out for a separate SAHPRA communication on remote document upload solution.
- Responses to queries issued between **1 March 2020 and 16 April 2020** (end of the lockdown period) should be submitted to SAHPRA by 31 May 2020.
- All queries to applicants received after the lockdown period must be responded to within the stipulated response period, unless a specific request for longer periods have been approved by SAHPRA.

2. Variations

The backlog variation applications resubmission windows will be postponed by one (1) month. During the lockdown, SAHPRA will only be accepting urgent variation applications (stock out and tender) which should be submitted electronically.

- SAHPRA is postponing RW 2 variation applications by a month and will start accepting these applications on **1 June 2020**
- SAHPRA will merge RW 7 and RW 8 variation applications for these two (2) windows to be submitted in October 2020. Please attached see the revised variation resubmission windows (Appendix 2).

Your co-operation and continued support is highly appreciated.

Regards,

SAHPRA

Appendix 1: Revised Resubmission windows for generic new applications

Resubmission window	Therapeutic area / type of medicine	Opening date	Closing date
1	HIV	01 Aug 2019	30 Sep 2019 Closed
	TB		
	Hepatitis		
	Vaccines		
2	Oncology	01 Oct 2019	31 Oct 2019 Closed
3	Mental and behavioural disorders	01 Nov 2019	29 Nov 2019 Closed
4	Infectious / parasitic diseases	03 Feb 2020	28 Feb 2020 Closed
5	Maternal and newborn health	02 Mar 2020	31 Mar 2020
	Diabetes		
	Malaria		
	Priority APIs		
6	Respiratory system diseases	04 May 2020	29 May 2020
7	Cardiovascular disease	01 Jun 2020	30 Jun 2020
8	Haematological / immunological diseases	01 Jul 2020	31 Jul 2020
	Analgesics & NSAIDs ¹		
9	Genitourinary system diseases	03 Aug 2020	31 Aug 2020
	Nervous system diseases		
10	Endocrine, nutritional and metabolic diseases	01 Sep 2020	30 Sep 2020
	Digestive system diseases		
11	Musculoskeletal system and connective tissue diseases	01 Oct 2020	30 Oct 2020
	Skin and subcutaneous tissue diseases		
	Eye and adnexa diseases		
	Ear and mastoid diseases		
12	Other	02 Nov 2020	30 Nov 2020

Appendix 2: Revised Resubmission windows for variation applications

Resubmission window	Therapeutic area / type of medicine	Opening date	Closing date
1	HIV	02 Mar 2020	31 May 2020
	TB		
	Hepatitis		
	Oncology		
	Mental and behavioural disorders		
2	Infectious / parasitic diseases	01 June 2020	30 Jun 2020
3	Maternal and new-born health	01 Jul 2020	31 Jul 2020
	Diabetes		
	Malaria		
	Respiratory system diseases		
4	Cardiovascular diseases	01 Aug 2020	31 Aug 2020
5	Analgesics & NSAIDs	01 Sep 2020	31 Sep 2020
	Haematological / immunological diseases		
	Genitourinary system diseases		
6	Nervous system diseases	01 Oct 2020	30 Oct 2020
	Endocrine, nutritional and metabolic diseases		
	Digestive system diseases		
7	Musculoskeletal system and connective diseases	01 Nov 2020	30 Nov 2020
	Skin and subcutaneous tissue diseases		
	Ear and mastoid diseases		
	Eye and adnexa diseases		
	Other		