



Medicines Control Authority of Zimbabwe

LEGAL & CORPORATE AFFAIRS UNIT

TITLE: Standard Operating Procedure for Drafting and Reviewing Legislation			
SOP Number: LC09		Revision Number: 5	Page 1 of 4
		Document Level: 3	
Date Issued for training: 6/3/2023		Effective Date: 13/04/2023	Review Date: 04/2025
Written by/Reviewed by:	R Sheebate Name	[Signature] Signature	12/04/2023 Date
Approved by HoU/HoD:	R.P Chimhenga Name	[Signature] Signature	12/04/2023 Date
Authorised for use by: (Quality Manager)	A. Chikwore Name	[Signature] Signature	13/04/2023 Date

1.0 PURPOSE

To outline the procedure for drafting and reviewing legislation.

2.0 SCOPE

Applies to all legislation drafted and reviewed by the Medicines Control Authority of Zimbabwe (MCAZ).

3.0 FREQUENCY

As and when legislation is drafted or reviewed.

4.0 LOCATION

- 4.1 The Master copy of this procedure shall be kept in the Quality Manager's office.
- 4.2 A copy shall be kept in the Legal Unit office.

5.0 DEFINITIONS

N/A

6.0 RESPONSIBILITY

The Regulatory Officers and the Legal Manager shall be responsible and accountable for the implementation and maintenance of this procedure.

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7.0 PROCEDURE

- 7.1 When the need arises, the Director-General shall call for input for the drafting or review of legislation from all Heads of Units/Divisions who shall submit their proposals within a reasonable time to the Legal Unit;
- 7.2 Input from the relevant Units/Divisions is then considered by the Legal Unit;
- 7.3 When drafting or reviewing legislation, the Legal Unit shall adopt the principles of Good Regulatory Practices into the draft legislation.
- 7.4 The Legal Unit shall make a draft of the proposed legislation within a period of thirty (30) working days and submit it to the Director-General for input.
- 7.5 The Director-General shall refer his input on the draft legislation to the Legal Unit, which input the Legal Unit shall incorporate into the draft legislation.
- 7.6 The Legal Unit shall refer the draft incorporating the Director-General's comments to Management for review within fourteen (14) working days and once approved, it is tabled before the Legal Drafting Sub-Committee;
- 7.7 Once the Legal Drafting Sub-Committee reviews the draft legislation, the Legal Unit shall make a recommendation for its adoption by the Legal Committee;
- 7.8 The draft legislation shall be tabled before the Legal Committee for adoption.
- 7.9 The Director-General shall seek the Minister's approval to consult stakeholders and Civil Society Groups on the draft legislation.
- 7.10 The Legal Unit shall consult stakeholders and Civil Society Groups for input, where necessary, on the proposed legislation, after which, a report of the proceedings shall be compiled and sent for review and signature to the Director-General or his representative.
- 7.11 The signed report and the draft legislation incorporating amendments proposed by the stakeholders shall be tabled before the Legal Committee for consideration and approval.
- 7.12 Within a period of seven (7) working days the Legal Unit shall incorporate, into the draft legislation, input from stakeholders and civil society groups which has been approved by the Legal Committee.
- 7.13 With the Approval of the Director-General, the Legal Unit shall prepare a memorandum and send it together with the draft legislation to the Minister of Health and Child Care for approval.
- 7.14 Once approved, the Minister of Health and Child Care shall send the draft legislation to the Attorney-General's (AG) Office.
- 7.15 The Legal Drafting Department in the AG's Office shall prepare the draft legislation for gazetting.
- 7.16 Once ready, the Legal Drafting Department shall send the legislation to the Minister of Health and Child Care.
- 7.17 The Minister of Health and Child Care shall send the legislation to MCAZ for gazetting.

Written by/Reviewed by: <i>R. Sheelate</i>	Approved by HoU/HoD <i>R. P. Chimhenger</i>	Authorised for use by QM: <i>pp Thuga</i>
Date: <i>12/04/2023</i>	Date: <i>12/04/2023</i>	Date: <i>11/13/04/2023</i>

- 7.18 Upon receipt of the legislation the Legal Unit shall check the legislation for errors within a period of seven (7) working days or send the draft to the relevant Units/Divisions within two (2) working days for proofreading.
- 7.19 The Legal Unit shall send the legislation to Printflow (Pvt) Ltd for a quotation;
- 7.20 Upon receipt of the quotation, the Procurement Management Unit shall raise a requisition for gazetting of the legislation and payment is done to Printflow (Pvt) Ltd.
- 7.21 Printflow (Pvt) Ltd shall publish the legislation and copies shall be sent to the Legal Unit;
- 7.22 Upon receipt of the gazetted legislation, the Legal Unit, within two (2) working days, shall send the gazetted legislation to the ICT Unit for uploading on the MCAZ website;
- 7.23 The Legal Unit shall keep a copy of the gazetted legislation and send an email to all staff on the gazetted legislation;
- 7.24 The Legal Unit shall train Staff on the newly gazetted legislation within a period of fourteen (14) days from the date of receipt of the gazetted legislation.
- 7.25 The Director-General may issue a circular on the new legislation.

8.0 APPENDICES/ ATTACHMENTS

N/A

9.0 RECORDS

Document Number	Title of Record	Retention Period
LCA 13	Legislation	5 years

10.0 REFERENCES

- 10.1 SOP MR 4.0 Writing Standard Operating Procedure
- 10.2 SOP MR 4.13 Control of Records

11.0 HISTORY

DOCUMENT HISTORY

Written by/Reviewed by: <i>R. Sherebate</i>	Approved by HoU/HoD <i>R. P. Chimhenga</i>	Authorised for use by QM: <i>PP Thungu</i>
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11.0 HISTORY

DOCUMENT HISTORY		
Revision Number	Date Approved	Reason for Change
0	April 2014	Rolling Review and System Improvement
1	January 2017	System Improvement
2	June 2018	
3	July 2020	Rolling Review and System Improvement
4	January 2022	Rolling Review and System Improvement

Reviewed by: <i>R. Sheeja</i>	Approved by HoU/HoD <i>R-P Chumhanga</i>	Authorised for use by QM:
Date: <i>12/04/2023</i>	Date: <i>12/04/2023</i>	Date: <i>pp [Signature] 13/04/2023</i>