



**GUIDANCE DOCUMENT ON IMPLEMENTATION OF THE
POINT SYSTEM: LICENSING & ADVERTISING COMMITTEE**

EFFECTIVE DATE: 16 DECEMBER 2024

Medicines Control Authority of Zimbabwe

106 Baines Avenue

P O Box 10559

Harare

Email: mcaz@mcaz.co.zw

Website: www.mcaz.co.zw

Reviewed by:

Signature

Date

Checked by HoD/HoU:

Signature

Date

Authorised for use by:
Quality Manager

Signature

Date

Approved by:
Director-General

Signature

Date

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1.0 APPLICATION

This guideline is a decision-making tool to be used by the Committee for the determination of the gravity offences. The tool is focused on premises and persons licensed by the Authority. Points accrued would remain valid on file for a period of up to three (3) years.

2.0 PURPOSE

To be a decision-making tool to be used by the Committee for the determination of the gravity of offences.

3.0 BACKGROUND / INTRODUCTION

3.1 INTRODUCTION

This guideline has been drawn up to enable the Licensing and Advertising Committee to make consistent decisions for contraventions of the Medicines and Allied Substances Control Act [Chapter 15:03], the Dangerous Drugs Act [Chapter 15:02] and the accompanying regulations. This administrative tool is aimed at ensuring consistency, transparency and objectivity when dealing with contraventions.

The point system is designed in such a way that a licensee accrues points for transgressions and such points accumulate over time. Fixed points will be issued for specific transgressions but however, some points will be subtracted or added based on mitigating or aggravating circumstances respectively. For example, points could be subtracted for first offenders and for the level of risk posed by the transgression, if the risk is low e.g. previously registered medicines from a trusted source, although unregistered, should attract a less penalty than unregistered medicines from an unknown or untrusted source.

3.2 BACKGROUND

The Authority has in the past, issued warnings for a variety of contraventions based on the severity of the offence and precedence from similar cases. The decisions are generally at four levels which are warnings, strong warnings, final warnings and cancellations of licenses for up to a maximum of three (3) years. The final warnings are usually reserved for serious contraventions which, upon successful prosecution, would likely result in a conviction for a level 12 offence by a Magistrates Court or a 2-year prison sentence. The offences for which final warnings are issued, even on first offence include the following but not limited to:

- 3.2.1 Poor supervision
- 3.2.2 Buying and selling unregistered medicines
- 3.2.3 Selling expired medicines
- 3.2.4 Poor record keeping of dangerous drugs

4.0 DEFINITIONS

- 4.1 **Aggravating Factor:** Evidence or circumstance that intensifies the gravity of an offence.
- 4.2 **Mitigating Factor:** Evidence or circumstance that mitigates or reduces the intensity of the gravity of an offence.

5.0 GUIDELINES

5.1 Application of the Point System

The schedule of offences and applicable base line points accrued are listed in Section 5.5.

- 5.1.1 According to the point system, contraventions attract a maximum of 20 points that are valid for 3 years.
- 5.1.2 Different contraventions carry different weights, thereby attracting different points and the clock starts ticking when the first offence is committed. However, in the beginning the system will only focus on the most serious offences as indicated in 3.0 above.
- 5.1.3 Offences that would pose serious *and immediate danger* to public health would attract more points i.e. 10 points e.g. operating a pharmacy without the continuous personal supervision of a licensed pharmacist, selling expired medicines. These are the most serious offences.
- 5.1.4 In the case of Specially Restricted Medicines (SR) offences base points of 20 shall be used
- 5.1.5 In the case of poor record keeping and shortages of Dangerous Drugs, supervisors should sit for and pass a forensics exam unless the response to inspection report satisfactorily addresses any shortages or poor record keeping practices.
- 5.1.6 As a matter of policy, holders of premises licences and permits will be held vicariously responsible for the conduct of their employees. Directors must therefore work diligently to ensure that their employees, particularly supervisors of licensed and approved premises, comply with all the legal requirements provided for in the relevant statutes.
- 5.1.7 Where different rules apply to licensees and supervisors, this will be spelt out in the relevant sections below. It is therefore possible that the licensee and the supervisor will get different sanctions for the same offence, depending on the circumstances.

5.2 The consequences of the mitigation and aggravation points will be as follows:

- 5.2.1 Where after application of the point system, the total number of points accrued are above 40, the Committee shall show intent to cancel the relevant licence, whether the offender is a first-time offender or otherwise.
- 5.2.2 Where the points are 40 and below, but above 20, the Committee shall issue the offender a final warning, and alert the same offender to the risks of committing another serious offence within the following three (3) years, regardless whether the offence is different from the first one, as that will likely carry the offender beyond the 40-point threshold.
- 5.2.3 Where the points accrue are 20 and below, but above 10, the Committee shall issue a strong warning.

- 5.2.4 Where the points accrue are 10 and below, the Committee shall issue a warning.
 - 5.2.5 With respect to subsequent offences, the previously accrued points count towards the decision of the Committee. For example, where a licensee had previously accrued 10 points and been issued a warning, and subsequently accrues 11 points due to a later transgression, the total number of points becomes 21 (10+11), and therefore such a licensee would attract a final warning, since the total would now be above the threshold of 20 points.
 - 5.2.6 It is however also possible for one who already sits on a final warning to accrue further points without crossing the 40-point threshold. For example, one who has accrued 20 points and gets a final warning, but subsequently accrues a further 5 points. In this case, no other warning is issued, but attention will be drawn to the consequence of breaching the 40-point threshold, and that licensee will be reminded of the previously issued final warning.
 - 5.2.7 It should be noted that the warnings issued under this system serve only the purpose of alerting the affected person of the gravity that the Authority attaches to their offence, the important measure however remains the points themselves, as it is the threshold that determines whether further action will be taken with regards to the cancellation, suspension or variation of the relevant licence.
- 5.3 This Guideline is a living document and will be updated as time progresses. In the beginning, the guideline focused on the most serious offences as already indicated. With time other offences will be included as the Committee gets comfortable with the process.
- 5.4 Depending on the circumstances, points can be adjusted downwards where there are mitigating circumstances or adjusted upwards where there are aggravating circumstances e.g. first offenders for certain transgressions will accrue less points but repeat offenders will accrue more. The mitigation/aggravation process was developed to include a level of equity in the point system, so that the circumstances prevailing at the time a contravention occurred would be taken under consideration. There are however certain transgressions where mitigation does not apply, so this principle will only be used where applicable. It is also critical to note that points are cumulative. The calculation of points is as elaborated in section 5.5 tables.

5.5 Details of Offences

- 5.5.1 Evaluation of the points will be done upon receipt of responses to the inspection reports and letters of intent to cancel respective licences.
- 5.5.2 Inspectorate shall review all responses from licence or permit holders and apply mitigation or aggravation on the merits or demerits of each of the contraventions to which the point system applies.
- 5.5.3 Comments shall be added to each of the respective forms to support mitigation or aggravation applied.

5.5.1 OFFENCES RELATED TO SUPERVISION OF LICENSED PREMISES (LEF 82a)

Licence/Permit Holder:

OFFENCE: Failure to provide continuous personal supervision of licensed premises		STATUTORY REFERENCE: Section 55(1)(b) as read with section 55(5) of MASCA		STATUTORY PENALTY: Level 12 fine or 2 years imprisonment			
A. BASE POINTS: 10		B. PREVIOUS SANCTION:					
		Warning []	Strong warning []	Final warning []	None []		
		Points					
Reference (insert minute reference)							
(tick and indicate points where applicable)							
C. MITIGATION	POINTS SUBTRACTED	TALLY	COMMENTS TO SUPPORT MITIGATION	D. AGGRAVATION	POINTS ADDED	TALLY	COMMENTS TO SUPPORT AGGRAVATION
First offence	2			Second offence	5		
Supervisor returned prior to finalisation of closure procedures by inspectors	5			Where there is no supervisor of record, for example, where the previous supervisor resigned and was not replaced.	5		
Where the Licensee (the holder of the premises licence) has demonstrable and robust rules and systems in place to prevent incidences of poor supervision but supervisor AND other staff members disregarded those rules.	5 (mitigation applies only to the Licensee)			Where a complaint is received that the premises are operating without a supervisor and this is confirmed through an inspection of the premises.	5		
Where the supervisor left the premises closed but staff opened premises against instructions not to.	5 (mitigation applies only to the supervisor)			Where an unlicensed person employed by directors of the licensee masquerades as a pharmacist	2		

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First Offense in more than 10 years of experience	5			Where medicines were sold during the absence of a pharmacist	2		
				Misrepresentation of facts, for example when the pharmacist provides misleading information.	3		
				When a person fails to respond	5		
				When the supervisor/directors disregard the Authority's instruction to close.	10		
Total point in MITIGATION				Total points in AGGRAVATION			
Total points accrued by Licensee				Formula: Base points (A) + points in aggravation (D) + points from previous transgressions (B) - points in mitigation (C). Total = A+D+B-C (show how the figures are arrived at in the space below). A ... + D + B ... - C = ...	TOTAL		
			Is there another offence committed at the same time? Yes ☐ No ☐ If yes, is the form with the computation attached? Yes ☐ Form Reference Number No ☐	*If a separate offence was committed and the points tallied added to (A), the form must be appended, and the computation must reference the other offences.			

5.5.2 OFFENCES RELATED TO BUYING AND SELLING OF UNREGISTERED MEDICINES (LEF 82b)

Licence/Permit Holder:

OFFENCE: Selling Unregistered Specified medicines		STATUTORY REFERENCE: Section 29(1) (a) of the Act	STATUTORY PENALTY: Level 12 fine or 2 years imprisonment				
A. BASE POINTS:							
10							
B. PREVIOUS SANCTION:							
Warning []		Strong warning []	Final warning []				
Points							
(tick and indicate points where applicable)							
Reference (insert minute reference)							
C. MITIGATION	POINTS SUBTRACTED	TALLY	COMMENTS TO SUPPORT MITIGATION	D. AGGRAVATION	POINTS ADDED	TALLY	COMMENTS TO SUPPORT AGGRAVATION
First offence	2			Second offence	5		
Previously registered medicine	2			Product that has never been registered in Zimbabwe, but from a trusted source	2		
Innocuous, high therapeutic index, low risk product-	2			Product that has never been registered in Zimbabwe, from an Unknown source	5		
OTC product(s)	2			Low therapeutic index, prescription preparation for chronic conditions or injectables	3		
Unregistered medicine procured from an approved source. For example, an unregistered medicine procured from an approved wholesale dealer	2			Evidence of Intention to misrepresent, mislead or conceal an unregistered medicine, for example, by repacking an unregistered medicine in a container of a registered medicine to pass it off as a registered medicine	10		
				A large number of unregistered medicine being offered for sale (more than 5 different types) in significant quantities (the significance of the quantities to	4		

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					be determined on a case by case basis)				
					Substandard Medicines (to be confirmed after testing)		5		
Sample analysis confirming that the product is not falsified	5				Failure to pay for samples analysis to confirm that the product is not falsified		10		
Total point in MITIGATION					Total points in AGGRAVATION		0		
Total points accrued by Licensee					Formula: Base points (A) + points in aggravation (D) + points from previous transgressions (B) - points in mitigation (C). Total = A+D+B-C (show how the figures are arrived at in the space below). $A + D + B - C = 2$		TOTAL		
					Is there another offence committed at the same time? Yes [x] No [] If yes, is the form with the computation attached? Yes [] No [] Form Reference Number LEF 82i, LEF 82f				

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*If a separate offence was committed and the points tallied added to (A), the form must be appended, and the computation must reference the other offences.

5.5.3 OFFENCES RELATED TO SELLING OF EXPIRED MEDICINES (LEF 82c)

Licence/Permit Holder:

OFFENCE: Selling of Expired Medicines		STATUTORY REFERENCE: Section 51 of SI 150 of 1991 as read with Section 38 (3) of the Act		STATUTORY PENALTY: Level 12 fine or 2 years imprisonment			
A. BASE POINTS: 10		B. PREVIOUS SANCTION:					
		Points	Warning []	Strong warning []	Final warning []		
					None []		
		(tick and indicate points where applicable)					
Reference (insert minute reference)							
C. MITIGATION	POINTS SUBTRACTED	TALLY	COMMENTS TO SUPPORT MITIGATION	D. AGGRAVATION	POINTS ADDED	TALLY	COMMENTS TO SUPPORT AGGRAVATION
First offence	2			Second offence	5		
Where satisfactory evidence is presented that although the product was on the shelf, it had not been dispensed to a customer.	2			Where there is evidence that an expired medicine was dispensed to a customer.	5		
Where an expired medicine is found on the shelf within 30 days of expiry	2			Where an expired medicine is found on the shelf beyond 30 days of expiry but not more than six months.	2		
Where quantity is less than five (5)	2			Where an expired medicine is found on the shelf beyond a period of six (6) months	5		
				Misrepresentation, i.e. obliteration of expiry dates	5		
				Quantity of medicines, i.e. large number of expired medicines (more than five different types) in significant quantities (the significance of the quantities to be	5		

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5.5.4 OFFENCES RELATED TO POOR RECORD KEEPING OF DANGEROUS DRUGS (LEF 82d)

Licence/Permit Holder:

OFFENCE: Poor record keeping of Dangerous Drugs Regulations Act (1975)		STATUTORY REFERENCE: Section 42-43 of the Dangerous Drug Regulations Act (1975)		STATUTORY PENALTY: Level 12 fine or 2 years imprisonment									
A. BASE POINTS: 10		C. PREVIOUS SANCTION:											
B.		<table border="1"> <tr> <td>Warning []</td> <td>Strong warning []</td> <td>Final warning []</td> <td>None []</td> </tr> <tr> <td>Points</td> <td>.....</td> <td>.....</td> <td>.....</td> </tr> </table>				Warning []	Strong warning []	Final warning []	None []	Points			
Warning []	Strong warning []	Final warning []	None []										
Points													
		(tick and indicate points where applicable)											
		Reference (insert minute reference)											
C. MITIGATION	POINTS SUBTRACTED	TALLY	COMMENTS TO SUPPORT MITIGATION	D. AGGRAVATION	POINTS ADDED	TALLY	COMMENTS TO SUPPORT AGGRAVATION						
First offence	2			Second offence	5								
Scripts tallying with stock, but records not captured correctly, for example, genuine errors in the records	4			Stock shortages concurrent with poor record keeping	5								
All the requisite requirements in place but records not captured within the required timelines.	2			Evidence of stock abuse, for example, supplying to an addict without authorisation or omission or records.	10								
Excess stock on hand, but within acceptable limits (sometimes due to errors from the manufacturer)	2			Illegible records, obliterations in the dangerous drugs registers	3								
				Poorly Secured dangerous drugs, for example storage of dangerous drugs in a place without a lock and key	2								

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Total point in MITIGATION		Total points in AGGRAVATION	
Total points accrued by Licensee		Formula: Base points (A) + points in aggravation (D) + points from previous transgressions (B) - points in mitigation (C). Total = A+D+B-C (show how the figures are arrived at in the space below). A ... + D + B ... - C = ...	TOTAL
Is there another offence committed at the same time? Yes ☐ No ☐ If yes, is the form with the computation attached? Yes ☐ Form Reference Number..... No ☐		*If a separate offence was committed and the points tallied added to (A), the form must be appended, and the computation must reference the other offences.	

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5.5.5 INSUFFICIENT PATIENT DETAILS (LEF 82e)

Licence/Permit Holder:

OFFENCE: Capturing insufficient patient details		STATUTORY REFERENCE: Section 63 of the Act		STATUTORY PENALTY: Level 12 fine or 2 years imprisonment											
A. BASE POINTS: 5		B. PREVIOUS SANCTION:													
		<table border="1"> <tr> <td>Points</td> <td>Warning []</td> <td>Strong warning []</td> <td>Final warning []</td> <td>None []</td> </tr> <tr> <td>.....</td> <td>.....</td> <td>.....</td> <td>.....</td> <td>.....</td> </tr> </table> (tick and indicate points where applicable)				Points	Warning []	Strong warning []	Final warning []	None []					
Points	Warning []	Strong warning []	Final warning []	None []											
.....															
Reference (insert minute reference)															
C. MITIGATION	POINTS SUBTRACTED	TALLY	COMMENTS TO SUPPORT MITIGATION	D. AGGRAVATION	POINTS ADDED	TALLY	COMMENTS TO SUPPORT AGGRAVATION								
First offence	2			Second offence	5										
Low risk product	2			High risk products	2										
All the requisite requirements in place but records not captured within the required timelines.	1			Frequency ≥ 10	1										
Total point in MITIGATION				Total points in AGGRAVATION											
Total points accrued by Licensee				Formula: Base points (A) + points in aggravation (D) + points from previous transgressions (B) – points in mitigation (C). Total = A+D+B-C (show how the figures are arrived at in the space below). A ... + D + B ... - C = ...	TOTAL										
Is there another offence committed at the same time? Yes [] No [] If yes, is the form with the computation attached? Yes [] No [] Form Reference Number.....				*If a separate offence was committed and the points tallied added to (A), the form must be appended, and the computation must reference the other offences.											

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5.5.6 PURCHASING FROM OR SELLING TO UNAUTHORISED SOURCES (LEF 82f)

Licence/Permit Holder:

OFFENCE: Purchasing from or selling to Unauthorised Sources		STATUTORY REFERENCE: Section 17a and 18 respectively of the SI 150 of 1991		STATUTORY PENALTY: Level 12 fine or 2 years imprisonment									
A. BASE POINTS: 5 <table border="1" style="border-collapse: collapse;"> <tr> <td style="width: 10%;">Warning []</td> <td style="width: 10%;">Strong warning []</td> <td style="width: 10%;">Final warning []</td> <td style="width: 10%;">None []</td> </tr> <tr> <td style="text-align: center;">Points</td> <td style="text-align: center;">.....</td> <td style="text-align: center;">.....</td> <td style="text-align: center;">.....</td> </tr> </table> (tick and indicate points where applicable)						Warning []	Strong warning []	Final warning []	None []	Points			
Warning []	Strong warning []	Final warning []	None []										
Points													
B. PREVIOUS SANCTION:													
Reference (insert minute reference)													
C. MITIGATION	POINTS SUBTRACTED	TALLY	COMMENTS TO SUPPORT MITIGATION	D. AGGRAVATION	POINTS ADDED	TALLY	POINTS TO SUPPORT AGGRAVATION						
First offence	2			Second offence	3								
				High risk products	2								
				Frequency of ordering or selling ≥ 3	2								
				Failure to disclose source of medicines	5								
Total point in MITIGATION				Total points in AGGRAVATION									
Total points accrued by Licensee				Formula: Base points (A) + points in aggravation (D) + points from previous transgressions (B) – points in mitigation (C). Total = A+D+B-C (show how the figures are arrived at in the space below).		TOTAL							
Is there another offence committed at the same time? Yes [] No [] If yes, is the form with the computation attached? Yes [] Form Reference Number.....			A ... + D + B ... - C ... = ... *If a separate offence was committed and the points tallied added to (A), the form must be appended, and the computation must reference the other offences.										
No []													

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5.5.7 DISPENSING PRESCRIPTION PREPARATION WITHOUT PRESCRIPTION (LEF 82g)

Licence/Permit Holder:

OFFENCE: Dispensing PP without prescriptions		STATUTORY REFERENCE: 9 th Schedule of SI 150 of 1991		STATUTORY PENALTY: Level 12 fine or 2 years imprisonment									
A. BASE POINTS: 10		B. PREVIOUS SANCTION:											
		<table border="1"> <tr> <td>Warning ☐</td> <td>Strong warning ☐</td> <td>Final warning ☐</td> <td>None ☐</td> </tr> <tr> <td>Points</td> <td>.....</td> <td>.....</td> <td>.....</td> </tr> </table> (tick and indicate points where applicable)				Warning ☐	Strong warning ☐	Final warning ☐	None ☐	Points			
Warning ☐	Strong warning ☐	Final warning ☐	None ☐										
Points													
Reference (insert minute reference)													
C. MITIGATION	POINTS SUBTRACTED	TALLY	COMMENTS TO SUPPORT MITIGATION	D. AGGRAVATION	POINTS ADDED	TALLY	COMMENTS TO SUPPORT AGGRAVATION						
First offence	2			Second offence	3								
Dispensing PP 10 medicines only	2			Dispensing PPs known to be substances of abuse like Narcotics (like Codeine containing syrups), Psychotropic substances, Misoprostol etc	5								
Frequency of such dispensing of less than 10 occasions within a period of 3 months	2			Frequency of such dispensing of more than 10 occasions within a period of 3 months	5								
Total point in MITIGATION				Total points in AGGRAVATION									
Total points accrued by Licensee				Formula: Base points (A) + points in aggravation (D) + points from previous transgressions (B) – points in mitigation (C). Total = A+D+B-C (show how the figures are arrived at in the space below). A ... + D ... + B ... - C = ...	TOTAL								
Is there another offence committed at the same time? Yes ☐ No ☐ If yes, is the form with the computation attached? Yes ☐ Form Reference Number				*If a separate offence was committed and the points tallied added to (A), the form must be appended, and the computation must reference the other offences.									

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5.5.8 SELLING OF MEDICINES BY WHOLESALE WITHOUT A WHOLESALE DEALERS PERMIT (LEF 82h)

Licence/Permit Holder:

OFFENCE: Selling medicines by wholesale without a wholesale dealer's permit		STATUTORY REFERENCE: Section 17(b) of the SI 150 of 1991		STATUTORY PENALTY: Level 7 fine or 2 imprisonment for a period not exceeding six months									
A. BASE POINTS: 5		B. PREVIOUS SANCTION:											
		<table border="1"> <tr> <td>Warning []</td> <td>Strong warning []</td> <td>Final warning []</td> <td>None []</td> </tr> <tr> <td>Points</td> <td>.....</td> <td>.....</td> <td>.....</td> </tr> </table>				Warning []	Strong warning []	Final warning []	None []	Points			
Warning []	Strong warning []	Final warning []	None []										
Points													
Reference (insert minute reference)													
C. MITIGATION	POINTS SUBTRACTED	TALLY	COMMENTS TO SUPPORT MITIGATION	D. AGGRAVATION	POINTS ADDED								
Product registered in Zimbabwe	2			Product not registered in Zimbabwe	2								
Total point in MITIGATION				Total points in AGGRAVATION									
Total points accrued by Licencee				Formula: Base points (A) + points in aggravation (D) + points from previous transgressions (B) – points in mitigation (C). Total = A+D+B-C (show how the figures are arrived at in the space below). A ... + D + B ... - C = ...	TOTAL								
Is there another offence committed at the same time? Yes [] No [] If yes, is the form with the computation attached? Yes [] Form Reference Number		*If a separate offence was committed and the points tallied added to (A), the form must be appended, and the computation must reference the other offences.											
No []													

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5.5.9 FAILURE TO PROVIDE ADEQUATE REFRIGERATION FOR COLD CHAIN MEDICINES (LEF 82i)

Licence/Permit Holder:

OFFENCE: Failure to provide adequate refrigeration for cold chain medicines		STATUTORY REFERENCE: Section 2(d) of the Third Schedule of SI 150 of 1991		STATUTORY PENALTY: Level 7 fine or 2 years imprisonment for a period not exceeding six months									
A. BASE POINTS: 10		<table border="1"> <tr> <td colspan="2">B. PREVIOUS SANCTION:</td> <td colspan="2">Warning ☐ Strong warning ☐ Final warning ☐ None ☐</td> </tr> <tr> <td colspan="2"></td> <td colspan="2">Points</td> </tr> </table>				B. PREVIOUS SANCTION:		Warning ☐ Strong warning ☐ Final warning ☐ None ☐				Points	
B. PREVIOUS SANCTION:		Warning ☐ Strong warning ☐ Final warning ☐ None ☐											
		Points											
Reference (insert minute reference)													
C. MITIGATION	POINTS SUBTRACTED	TALLY	COMMENTS TO SUPPORT MITIGATION	D. AGGRAVATION	POINTS ADDED								
First offence	2			Second offence	2								
				Temperature measured and found outside 2-8°C	5								
				No back-up power in cases of power cuts	3								
				No or inadequate temperature monitoring device	3								
				No or inadequate temperature monitoring records	2								
				Falsifying temperature records	10								
Total point in MITIGATION				Total points in AGGRAVATION									
Total points accrued by Licensee				Formula: Base points (A) + points in aggravation (D) + points from previous transgressions (B) – points in mitigation (C). Total = A+D+B-C (show how the figures are arrived at in the space below). A+ D + B- C = ...	TOTAL								
Is there another offence committed at the same time? Yes ☐ No ☐ If yes, is the form with the computation attached? Yes ☐ No ☐ Form Reference Number.....		*If a separate offence was committed and the points tallied added to (A), the form must be appended, and the computation must reference the other offences.											

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5.5.10 BUYING AND SELLING OF SPECIALLY RESTRICTED PREPARATIONS BY UNAUTHORISED PERSONS (82j)

Licence/Permit Holder:

OFFENCE: Handling SR preparations without authorisation		STATUTORY REFERENCE: 8 th Schedule of SI 150 of 1991		STATUTORY PENALTY: Level 7 fine or 6 months imprisonment									
A. BASE POINTS: 20													
B. PREVIOUS SANCTION: <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 20%; text-align: center;">Warning ☐</td> <td style="width: 20%; text-align: center;">Strong warning ☐</td> <td style="width: 20%; text-align: center;">Final warning ☐</td> <td style="width: 20%; text-align: center;">None ☐</td> </tr> <tr> <td style="text-align: center;">Points</td> <td style="text-align: center;">.....</td> <td style="text-align: center;">.....</td> <td style="text-align: center;">.....</td> </tr> </table> (tick and indicate points where applicable)						Warning ☐	Strong warning ☐	Final warning ☐	None ☐	Points			
Warning ☐	Strong warning ☐	Final warning ☐	None ☐										
Points													
Reference (insert minute reference)													
C. MITIGATION	POINTS SUBTRACTED	TALLY	COMMENTS TO SUPPORT MITIGATION	D. AGGRAVATION	POINTS ADDED	TALLY	COMMENTS TO SUPPORT AGGRAVATION						
First offence	2			Second offence	5								
The medicine was acquired from an authorised source	2			Authorisation letters that were cleared by MCAZ and ZIMRA not available for the unregistered medicines.	5								
				The medicine was acquired from an unknown and undisclosed source	5								
				Evidence of dispensing without a prescription	5								
				A complaint or adverse event was received at the Authority	10								
Total point in MITIGATION				Total points in AGGRAVATION									
Total points accrued by Licensee				Formula: Base points (A) + points in aggravation (D) + points from previous transgressions (B) - points in mitigation (C). Total = A+D+B-C (show how the figures are arrived at in the space below). A ... + D + B ... - C = ...									
Is there another offence committed at the same time? Yes ☐ No ☐ If yes, is the form with the computation attached? Yes ☐ Form Reference Number.....				*If a separate offence was committed and the points tallied added to (A), the form must be appended, and the computation must reference the other offences.									
No ☐													

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5.5.11 FAILURE TO NOTIFY THE AUTHORITY UPON IMPORTATION OF MEDICINES (LEF 82k)

Licence/Permit Holder:

OFFENCE: Failure to notify the authority upon importation of medicines		STATUTORY REFERENCE: Section 12 of SI 57 of 2008		STATUTORY PENALTY: Level 7 fine or 6 months imprisonment	
E. BASE POINTS: 10		F. PREVIOUS SANCTION:			
		Warning ☐ ☐ Strong warning ☐ ☐ Final warning ☐ ☐ None ☐ ☐		Points (tick and indicate points where applicable)	
Reference (insert minute reference)					
G. MITIGATION	POINTS SUBTRACTED	TALLY	COMMENTS TO SUPPORT MITIGATION	H. AGGRAVATION	POINTS ADDED
First offence	2	2	First Offence	Second offence	5
The medicines were consistent with the permits issued	2	2	The medicines noted during the inspection were consistent with the issued permits.	Medicines found on the premises inconsistent with those on the permit.	5
Evidence of clearance of the consignment by port officials	2			Port of entry of consignment not disclosed to the Authority	3
Total point in MITIGATION	4			Total points in AGGRAVATION	3
Total points accrued by Licensee				Formula: Base points (A) + points in aggravation (D) + points from previous transgressions (B) – points in mitigation (C). Total = A+D+B-C (show how the figures are arrived at in the space .).	TOTAL 9
Is there another offence committed at the same time? Yes ☐ No ☐ If yes, is the form with the computation attached? Yes ☐ Form Reference Number..... No ☐		*If a separate offence was committed and the points tallied added to (A), the form must be appended, and the computation must reference the other offences.			

5.6 Management of the System

- 5.6.1 The Regulatory Officer-Administrative in the LED will electronically update the point system database after every Committee meeting.
- 5.6.2 The database will capture all the points accrued as well as the names and details of the affected licence holders and track the validity of the points. The database will be available and accessible to Committee members at all Committee meeting where it shall be used as a reference. Minute references will also be captured to ensure that all points can be easily tracked to the meetings where they were issued.
- 5.6.3 A reminder with points accrued will be attached to licences and permits upon renewal.
- 5.6.4 The Chief Regulatory Officer Enforcement with the aid of inspectors will calculate the points for each case ahead of the Licensing and Advertising Committee meeting, and a presentation will be made to the Committee with a recommendation, with justifications, regarding the points both in aggravation and mitigation.
- 5.6.5 The Committee is at liberty to amend the rules as far as the applicable points are concerned, which means the system shall be allowed to evolve, and any precedence can be invalidated by future decisions regarding the application of this system. **The rules of precedence will however generally apply.**
- 5.6.6 Effectiveness of the system will be periodically reviewed during divisional meetings and an update shall be tabled before the Licensing and Advertising Committee.
- 5.6.7 The point system is a transparent system, which means the affected persons will have the same access to this document as the Licensing & Advertising Committee and MCAZ Secretariat. This document will be available on the MCAZ website and shall be promptly updated when any amendments are made to it.

6.0 KEY RELEVANT DOCUMENTS

- 6.1 Medicines and Allied Substances Control Act (Chapter 15:03)
- 6.2 Medicines and Allied Substances Control (General) Regulations, 1991, SI 150 of 1991
- 6.3 Dangerous Drugs Act (Chapter 15:02)
- 6.4 Dangerous Drugs Regulations, 1975, Rhodesia Government Notice No. 1111 of 1975

DOCUMENT HISTORY		
Revision Number	Date Approved	Reason for Change and Amendments
0	March 2019	State the reason(s) for change Documenting the guideline in a standard template <u>Description of changes</u> <u>Revision Status</u> Rev 0_ March 2019 to Rev 1_ December 2019 <u>Added</u> 5.1.1 A re-evaluation of the points will be done upon receipt of satisfactory responses to the letters of intent to cancel respective licences. (313th Licensing and Advertising Committee meeting) Two aggravations in table 5.5.1 - Where medicines were sold during the absence of a pharmacist – Points Added : 2 (314th Licensing and Advertising Committee Meeting) - Misrepresentation of facts, for example when the pharmacist provides misleading information. Points added : 3 Two mitigations in table 5.5.3 - Where an expired medicine is found on the shelf beyond 30 days of expiry but not more than six months. (309th Licensing and Advertising Committee Meeting) - Where quantity is less than five (5). Points Added : 2 (309th Licensing and Advertising Committee Meeting) One aggravation in table 5.5.3 - Where an expired medicine is found on the shelf beyond a period of six (6) months. Points Added : 5 (309th Licensing and Advertising Committee Meeting) Tables 5.5.5. and 5.5.6 (22nd August 2019 – Point system Meeting) Table 5.5.7 319th Licensing and Advertising Committee Meeting 15th October 2019 Selling of medicines by wholesale without a wholesale dealer's permit

	<i>Foot note</i> Ignore aggravating factors for essential unavailable medicines. This is dealt with on a case by case basis. Proposed amendment to the point system 320th Licensing and Advertising Committee Meeting 5th November 2019 Omitted – 3.2 (last paragraph) The system will primarily focus on the above (3.2.1-3.2.4) four contraventions but will be expanded in time to deal with other offences 5.2.1 Changed from “Where after application of the point system, the total number of points accrued are above 20, the Committee shall show intent to cancel the relevant licence, whether the offender is a first-time offender or otherwise.” To “Where after application of the point system, the total number of points accrued are above 40, the Committee shall show intent to cancel the relevant licence, whether the offender is a first-time offender or otherwise.” 5.2.2 Changed from “Where the points are below 20, but above 10, the Committee shall issue the offender a <u>final warning</u>, and alert the same offender to the risks of committing another serious offence within the following three (3) years, regardless whether the offence is different from the first one, as that will likely carry the offender beyond the 20-point threshold.” To “Where the points are below 40, but above 20, the Committee shall issue the offender a <u>final warning</u>, and alert the same offender to the risks of committing another serious offence within the following three (3) years, regardless whether the offence is different from the first one, as that will likely carry the offender beyond the 40-point threshold.” 5.2.3 Changed from “Where the points accrue are below 10 but above 6, the Committee shall issue a <u>strong warning</u>.” To “Where the points accrue are below 20 but above 10, the Committee shall issue a <u>strong warning</u>.” Added Mitigation on Table 5.5.1 Mitigation Supervisor returned prior to finalisation of closure procedures by inspectors (Points increased from 2-5) New First offence is more than 10 years of experience (Points 5) Added New Table 5.5.7 321st Licensing and Advertising Committee Meeting 3rd December, 2019
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		<u>Added (4)Aggravation factors below:</u> Table 55.1 Offences related to supervision of licenced premises 1. When a person fails to respond: points 5 Table 55.2 Offences related to buying and selling of unregistered medicines 2. Substandard or falsified medicines : points 5 Table 55.3 Offences related to selling of expired medicines 3. Misrepresentation, ie obliteration of expiry dates: points 5 4. Quantity of medicines, ie large quantity of medicines (more than five different types) in significant quantities (the significance of the quantities to be determined on a case by case basis) : points 5 Added 6.0 KEY RELEVANT DOCUMENTS 6.1 Medicines and Allied Substances Control Act (Chapter 1503) 6.2 Section 51(1) (b) as read with section 55(5) of MASCA 6.3 Section 29(1) (a) of the Act 6.4 Section 51 of 1991 6.5 Section 51 of SI 150 of 1991 as read with Section 38(3) of the Act 6.6 Dangerous Drugs Regulations of 1975
1	December 2019	State the reason(s) for change Documenting the guideline in a standard template and Rolling Review Rev 1_ December 2019 to Rev 2_ April 2022 (NEW) Reviewed all the tables in Section 5.5 Details of Offences

2	April 2022	<u>Continuous Improvement</u> Added Aggravation on Table 5.5.1 (LEF 82a) New When the supervisor/directors disregards the Authority's instruction to close. (Points 10) Added New Table 5.5.9 Point system form for FAILURE TO PROVIDE ADEQUATE REFRIGERATION FOR COLD CHAIN MEDICINES (LEF 82i) <i>350th Licensing and Advertising Committee Meeting, 4th October, 2022</i> Table 5.5.6 Changed from "Purchasing from unauthorised sources (LEF 82f)" To "Purchasing from or supplying to unauthorised sources (LEF 82f)" Table 5.5.6 Changed from "Frequency of ordering ≥ 5" To "Frequency of ordering or supply ≥ 3"
3	November 2022	Reason for change To incorporate outcomes of the 357th Licensing and Advertising Committee Meeting, held on the 6th of June, 2023 and 359th Licensing and Advertising Committee Meeting, held on the 1st of August, 2023. Added New Table 5.5.10 Point system form for BUYING AND SELLING OF SPECIALLY RESTRICTED PREPARATIONS BY UNAUTHORISED PERSONS (LEF 82j) <i>(357th Licensing and Advertising Committee Meeting, 6th of June, 2023)</i> Section 5.1.4 and 5.1.5 was added 5.1.4 In the case of Specially Restricted Medicines (SR) offences base points of 20 shall be used. 5.1.5 In the case of poor record keeping and shortages of Dangerous Drugs, supervisors should sit for and pass a forensics exam unless the response to inspection report satisfactorily addresses any shortages or poor record keeping practices.

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		Section 5.5 Details of offences was added 5.5.1 Evaluation of the points will be done upon receipt of responses to the inspection reports and letters of intent to cancel respective licences. 5.5.2 Inspectorate shall review all responses from licence or permit holders and apply mitigation or aggravation on the merits or demerits of each of the contraventions to which the point system applies. 5.5.3 Comments shall be added to each of the respective forms to support mitigation or aggravation applied. Amended all tables to add two columns as follows: Comments to support mitigation Comments to support aggravation Table 5.5.9 Point system form for FAILURE TO PROVIDE ADEQUATE REFRIGERATION FOR COLD CHAIN MEDICINES (LEF 82i) Column on Aggravating factors Added: <u>Temperature measured and found outside 2-8°C</u> <i>359th Licensing and Advertising Committee Meeting, 1st of August, 2023</i>
4	August 2023	Reason for change To incorporate outcomes of the 374th Licensing and Advertising Committee Meeting, held on the 3rd of December, 2024. Amended Table 5.5.2 Section which states that: “Product that has never been registered in Zimbabwe, but from a trusted source” changed from a mitigation factor to aggravation factor Addition on Mitigation Column: Sample analysis confirming that the product is not falsified Aggravation Column: “Substandard or falsified Medicines” changed to “Substandard Medicines (to be confirmed after testing)” Aggravation Column: Evidence of Intention to misrepresent, mislead or conceal an unregistered medicine, for example, by repacking an unregistered medicine in a container of a registered medicine to pass it off as a registered medicine- points added changed from 5 to 10 Addition on Aggravation Column: Failure to pay for samples analysis to confirm that the product is not falsified

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		Added Table 5.5.11 Failure to notify the AUTHORITY upon Importation of medicines (LEF 82k)
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