

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18

Title page

DRAFT SPECIMEN FOR

Report on Disclosure of Transfer of Values (Expenditure Details) for the Year () in
Compliance to Ethical Marketing to Healthcare Professionals Rules, 2021

by

Company Name

Prepared by: Name of Senior Executive given the Responsibility

Contact details: email, phone

Verified by: Owner / Head of the Company

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25
26

CONTENTS

1. Statement of Commitment	3
2. Purpose of the report	3
3. Acronyms & Definitions	3
4. Scope of marketing or promotional activities:	3
4.1. Disclosed Here:	4
4.2. Not Disclosed Here:	4
4.3. Currency	4
4.4. Timing of ToV	4
4.5. Reportable date	4
4.6. Value Added Tax (VAT):	4
5. Transfer of value categories	5
5.1. Procedure for Organisation of Disclosure of ToVs	5
6. Summary of Procedure of Promotional Activities	6
6.1. Consulting Arrangement with HCPs	6
6.2. Sponsoring Third Party Educational Conferences	6
6.3. Carrying Out Training or Education Meetings	6
6.4. Sponsoring HCPs / Institutes for Training & Education	6
6.5. Carrying out Business Meetings	6
6.6. Grants and Donations	6
6.7. Providing Education Items	6
6.8. Providing Demonstration and Evaluation Products	6

1 **1. Introduction**

2 Related to the company history, manufacturing sites, scope of therapeutic goods, number of
3 HR, marketing and promotional activities

4 **2. Statement of Commitment [Rule 13(d)]**

5 Para to include statement from head of the company, senior executive for EMHP and marketing
6 team etc.

7 *(The commitment should be drafted in light of principles of transparency, d*
8 *documentation and separation in marketing and promotional activities)*

9 Hard copy of Certificate of Compliance (scanned copy attached Annexure-III) has been duly
10 signed and submitted to DRAP.

11 **3. Purpose of the report**

12 This document is intended to serve the purpose of a disclosure report for submission of
13 expenditure details as required under Rule 14(2) of the EMHP Rules 2021 for the (year), by
14 (company name). It also presents how the transfers of value are categorized and in what format
15 they are disclosed.

16 The report summarises the marketing and promotional activities of therapeutic goods by
17 (company name) in order to identify, collect and report ToVs for each disclosure category as
18 described in the EMHP Rules 2021.

19 **4. Acronyms & Definitions**

EMHP	Ethical Marketing to Healthcare Professionals
ToVs	Transfer of Value Includes direct or indirect transfer of value, whether in cash, in-kind or otherwise, made, whether for promotional purposes or otherwise, in connection with the development or sale of medicines. A direct transfer of value is one made directly by a company for the benefit of a recipient. An indirect transfer of value is one made on behalf of a company for the benefit of a recipient or through an intermediate and where the company knows or can identify the recipient that will benefit from the transfer of value.
...	Add more for clarification of terms and abbreviations used in your report
...	

20

21 **5. Scope of marketing or promotional activities:**

22 This report includes transfers of value processed by (Company Name) during the reporting
23 period for (year). The report may also include transfers of value initiated by (Any subsidiary)
24 during the same period.

Company Logo

1 5.1. Disclosed Here:

2 Define promotional activities the company carried out for the purpose of marketing.

3 5.2. Not Disclosed Here:

4 Define your activities not falling under marketing scope as per the EMHP Rules

5 e.g. medical samples purchase and sales of Medicinal Products by and between a Company and
6 an HCP or an healthcare institute

7 Transfers of Value (ToV) related to investigational compounds and biological samples

8 External and internal trainings where the company invites HCPs to participate (without any
9 additional money transfer or cover of expenses)

10 Where the company provides a benefit in kind to a healthcare institute e.g. loan of (laboratory)
11 equipment in connection with and for the purpose of conducting a clinical trial, such benefit in
12 kind is not disclosed.

13 5.3. Currency

14 TOVs are reported in local currency on the disclosure report. TOV s made in non-local currency
15 are converted to local currency prior to publication. The standard exchange rates for the TOV
16 on the day of payment are applied.

17 5.4. Timing of ToV

18 The disclosure report includes transactions which have a reportable date within the reporting
19 period being disclosed.

20 5.5. Reportable date

21 the dates to be considered for disclosure reports are as follows:

22 In Cash TOV's – the clearing date is the reportable date

23 In Kind TOV's – meeting or event: end date is the reportable date; benefit in kind donation:
24 start date is the reportable date

25 5.6. Value Added Tax (VAT):

26 Treatment of VAT depends on the TOV:

27 Where possible In kind related TOV's will be reported including tax

28 Where possible Direct payment TOV's will be reported excluding tax

29 5.7. Details of Beneficiaries:

30 Details of beneficiary Institutes and healthcare professionals during the year containing the
31 following information:

Sr#	HCP / Healthcare Institute	Identification number	registration number	address	benefit category & amount (Rs)
1.	Name	(NA for institutes)	HCPs from respective		

Name of document (year)

			councils or commissions Institutes from respective healthcare commission / health regulatory authority		
2.					

1

2 5.8. Documents / Records:

3 Documents such as correspondence / agreements / notifications / activity related reports /
4 invoices etc. have been kept for detailed reference and audit when required.

5 **6. Transfer of value categories**

6 6.1. Procedure for Organisation of Disclosure of ToVs

7 Detail about data collection, reconciliation, processing, analysis, compilation etc.

8 Details regarding beneficiary Healthcare Professionals and Institutes are available with the
9 company and will be shared with DRAP when needed.

10 The following table defines what transfers of value are reported in which EMHP Rules category
11 and subcategory.

EMHP Category	Subcategory	Example activities
Consulting arrangements	Fees for services in the scope of the contract ...	e.g. fees for Speaker engagements Study-related engagements General consulting / advising Etc.
Third party educational conferences	Sponsorship amount ...	Sponsoring an event Leasing booth space Satellite symposia etc
Training and Educational Meetings	...	e.g. Registration fees paid for the HCP/HCO to attend events travel accommodation speaker arrangements Meeting expenses Etc.

Business meetings	Meeting expenses	Expenditure on ...
Grants & Donations		Charitable Business Education grants Etc.
Educational items	Nature of Item given	Reference Books Software subscription etc
Demonstration & Evaluation products	Products given	Devices Sample medicines Etc.

1

2 Details of Expenditure given in Annexure-II & III have been submitted in excel form as well.

3 **7. Summary of Procedure of Promotional Activities**

4 7.1. Consulting Arrangement with HCPs

5 Procedure of getting a consultant, scope of activities / services required, payment procedure

6 7.2. Sponsoring Third Party Educational Conferences

7 Procedure for Sponsoring and Event /Conference, scope of participation in the event (only sponsoring,
8 participation by symposia / getting booth etc.)

9 7.3. Carrying Out Training or Education Meetings

10 How is training / education need assessed, how is planned to be carried out? How are HCPs or institutes
11 selected for the purpose etc.

12 7.4. Sponsoring HCPs / Institutes for Training & Education

13 Planning educational or training activities, selecting agenda, selecting target audience

14 7.5. Carrying out Business Meetings

15 Planning, agenda

16 7.6. Grants and Donations

17 Selection of beneficiaries, assessment of grant or donation amount to be provided, carrying out the
18 transaction or donation procedure

19 7.7. Providing Education Items

20 Selection of educational items to be provided, selection of HCPs / Institutes to whom items are provided

21 7.8. Providing Demonstration and Evaluation Products

22 selection of HCPs / Institutes to whom items are provided, any terms for providing products, procedure
23 and tenure for use and return

24 **Note: The statements under the headings have been added to give an idea about what can be**
25 **added as detail in the procedure under each activity. The company can provide summary of**
26 **the SOP developed for each category so that the procedure is clearly understood.**

SCHEDULE

[see rule 14(2)]

DETAILS OF EXPENDITURE

Company Name: _____ **Turnover:** (PKR)

Financial Year: _____

Sr.	Advertising		Physician's Sample	Promotional Printed Material	Give Aways	Expenditure on Seminar, Conference, Workshop, Exhibition	Sponsorship		Any Outsourcing Activities	Miscellaneous Expenses under the Rules	Total
	Electronic Media	Print Media					Local	Foreign			
(1)	(2)	(3)	(4)	(5)	(6)	(7)	(8)	(9)	(10)		
1.											

Signature & Stamp|

Promotional Expenditure Form

Serial				
1.	Company Name			
2.	Financial Year (July-june)	Select year		
3.	Turnover during the year		Rs	
Details of expenditure				
4.	Promotional Activities:		Expenditure (Rs)	
5.	Advertisement: Public & Healthcare Professionals (HCPs)	Media electronic Print Social media Digital media websites	Rs Rs Rs Rs	
6.	Physician's samples		Rs	
7.	Promotional printed material		Rs	
8.	Give aways	Educational items If any other (specify)	Rs Rs	
9.	Seminar, Conference, Workshop, Exhibition	Education training Business meeting If any other (specify)	Rs Rs Rs Rs	
10.	Sponsorship/ Third party education conference	Local Foreign (if any)	Rs Rs	
11.	Outsourcing activities	Consulting arrangements with HCPs If any other (specify)	Rs Rs	
12.	Miscellaneous expenditure	Grants and donations Demonstration & evaluation products Other (specify)	Rs Rs Rs	
13.	Total expenditure		(Autocalculate) Rs.	Percentage from turnover autocalculate
14.	Submitted by (company personnel's auto info)			
15.	Certification at the end of data submission in online software	Info provided is correct and as per actual figures verifiable with actual documentation and invoices with the company and those submitted to tax authorities (can be modified)		

Company Logo

Annexure-III

1
2
3
4
5
6
7
8
9
10
11
12
13
14
15
16
17
18
19
20
21
22
23
24
25

Certificate of Compliance to SRO 1472(I)/2021

We hereby undertake that we are compliant to the Ethical Marketing to Healthcare Professionals Rules, 2021(**SRO 1472(I)/2021**) and the provided data for the year ---- is correct to the best of our knowledge and belief.

The report containing disclosure of transfer of values in compliance to Rule 14(2) verified by the undersigned is enclosed.

Yours sincerely,

Company name

Signatures
Name of authorized senior executive for the purpose
Designation

Stamp

