International Journal of Basic & Clinical Pharmacology
Vyas AP et al. Int J Basic Clin Pharmacol. 2025 May;14(3):358-361
http://www.ijbcp.com
pISSN 2319-2003 | eISSN 2279-0780

DOI: https://dx.doi.org/10.18203/2319-2003.ijbcp20251060

Original Research Article

Analysis of the drug package inserts in India as per the CDSCO guidelines

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Received: 10 February 2025
Accepted: 13 March 2025

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ABSTRACT

Background: The package insert (PI) is provided along with the drug in its manufactured container by pharmaceutical companies. This is one of the ways to provide essential information related to drugs to healthcare professionals and patients. Pharmaceuticals follow the regulations mentioned in the drugs and cosmetics act (1940) and rules (1945) under Schedule D and the central drugs standard control organisation (CDSCO).
Methods: A cross-sectional, observational, prospective study was conducted at Shree Krishna Hospital, Anand, Gujarat. From December 2023 to January 2024, a total of 98 PIs were collected from pharmacy stores within the hospital. All PIs were analyzed according to CDSCO guidelines.
Results: A total of 98 PIs were analyzed. After the analysis,>90% of the information is present in half of the parameters. There is 25-65% information present regarding the drug details in the rest of the parameters.
Conclusions: Our study has revealed that the information on package inserts is currently inaccessible. If drug companies can present this crucial information in a manner that is easily accessible to patients, it has the potential to greatly improve compliance. In our country, where concerns regarding the quality of medicines arise, implementing high-quality package inserts can effectively address these concerns.

Keywords: Package inserts, Healthcare professionals, Central drugs standard control organisation guidelines, Accessibility, Knowledge

INTRODUCTION

There are various drug information tools are available, like package leaflets, prescription drug labels, and prescribing information also known as the package insert (PI).[1] This is one of the ways to provide information related to drugs to physicians, healthcare professionals, pharmacists, and patients. It is India's primary source of drug information, providing precise, authenticated, and reliable data. The PI provides essential information to the health care providers and the patients. It is a useful document to decrease and avoid medication errors by physicians, health care professionals, pharmacists, and patients, Because of this the quality and authenticity of the PI are vital in our country. All the drug details should be mentioned in the English language and an easily understandable language.

The package insert is a document provided along with the drug in its manufactured container by pharmaceutical companies. Most pharmaceutical companies follow the drugs act (1940) and cosmetics rules (1945) to provide drug information in the PI. The regulation of the PI is mentioned in the drugs and cosmetics act (1940) and Rules (1945) under sections 6.2 and 6.3 of Schedule D and the central drugs standard control organisation (CDSCO) is the regulatory authority for the PI in India.[2]

"Posology and method of administration, contra-indications, special warnings and special precautions for use, interaction with other medicaments and other forms of interaction, contraindication in pregnancy and lactation, effects on ability to drive and use machines, Undesirable effects/side effects, Antidote for overdosing are coming

under section 6.2. List of excipients, incompatibilities, shelf life in the medical product as packaged for sale, shelf life after dilution or reconstitution according to direction, shelf life after first opening the container, special precautions for storage, nature and specification of the container, instructions for use/handling are coming under section 6.3. Final amendment of drugs and cosmetics act 1940 and rules 1945 which was enforced in 1986".[2]

The purpose of the study is to find the deficiency in the PI which is available in the Indian market. There are national and international guidelines available for the PI but still, many deficiencies are present in the PI. This study assesses the PI according to the CDSCO guideline.[2]

METHODS

Collection of material i.e. package insert

A cross-sectional, observational, prospective study was conducted at Shree Krishna Hospital, located in the rural area of Karamsad in the Anand district. From December 2023 to January 2024, a total of 122 prescription inserts (PIs) were collected from different pharmacy stores within the hospital premises. Out of these, 24 PIs were found to be duplicates, resulting in a final analysis of 98 PIs.

Analysis of content of package insert

All PIs were analyzed as per sections 6.2 and 6.3 of Schedule D which is mentioned in the drugs and cosmetics act (1940) and Rules (1945) a total of 16 parameters are included under the 2 sections. Under section 6.2, a total of 8 parameters are included i.e., "Posology and method of administration. Contra-indications. Special warnings and special precautions for use, interaction with other medicaments and other forms of interaction. contra-indicated in pregnancy and lactation, effects on ability to drive and use machines; undesirable effects/side effects, antidote for overdosing". under section 6.3, a total of 8 parameters are included i.e., "the list of excipients, incompatibilities the shelf life in the medical product as packaged for sale.

Shelf life after dilution or reconstitution according to direction. Shelf life after first opening the container, special precautions for storage, nature and specification of the container; instructions for use/handling". All the data according to the parameters were tabulated in the Excel 2021 program.

RESULTS

Out of 98 PIs, under section 6.2 for posology and method of administration, contra-indications were present in all PIs (100%), special warnings and special precautions for use were present in 98% of PIs, interaction with other medicaments and other forms of interaction were present in 92% of PIs, contra-indicated in pregnancy and lactation were present in 95% of PIs, effects on ability to drive and use machines were present in 43% of PIs if contra-indicated, undesirable effects/side effects were present in 100% of PIs, antidote for overdosing were present in 91% of PIs (Table 1).

There are 8 parameters under section 6.3 which include the list of excipients that were present in 51% of PIs; Incompatibilities that were present in 49% of PIs, the Shelf life in the medical product as packaged for sale was present in 65% of PIs, special precautions for storage were present in 100% of PIs, nature and specification of the container were present in 25% of PIs, instructions for use or handling were present in 100% of PIs. Shelf life after dilution or reconstitution according to the direction and Shelf life after first opening the container regarding data are only 8% present in our study (Table 2).

Table 1: Evaluation of package inserts as per section 6.2 for therapeutic indications.

S. no.	Parameters	Present no. (%)	Absent no. (%)
1	Posology and method of administration.	98 (100)	00
2	Contra-indications	98 (100)	00
3	Special warnings and special precautions for use, if any.	96 (98)	2 (2)
4	Interaction with other medicaments and other forms of interaction.	90 (92)	8 (8)
5	Pregnancy and lactation, if contra-indicated.	93 (95)	5 (5)
6	Effects on ability to drive and use machines, if contra-indicated	42 (43)	56 (57)
7	Undesirable effects/side effects.	98 (100)	00
8	Antidote for overdosing	89 (91)	9 (9)

Table 2: Evaluation of package inserts as per section 6.3 for pharmaceutical information.

S. no.	Parameters	Present no. (%)	Absent no. (%)
1	List of excipients	50 (51)	48 (49)
2	Incompatibilities	48 (49)	50 (51)
3	Shelf life in the medical product as packaged for sale	64 (65)	34 (35)

Continued.

S. no.	Parameters	Present no. (%)	Absent no. (%)
4	Shelf life after dilution or reconstitution according to the direction	7 (8)	91 (92)
5	Shelf life after first opening the container	7 (8)	91 (92)
6	Special precautions for storage	98 (100)	00
7	Nature and specification of the container	24 (25)	74 (75)
8	Instructions for use/handling	98 (100)	00

Table 3: Comparison of therapeutic indications with other studies.

S. no.	Parameters	Present study (n=98) (%)	Chhaya et al[5] (n=100) (%)	Sudha et al[6] (n=110) (%)	Priyanka et al[7] (n=192) (%)	Govindadas et al[8] (n=263) (%)	Patel et al[9] (n=150) (%)
1	Posology and method of administration.	100	98	100	97.3	95	100
2	Contra-indications	100	96	90	93	93	97
3	Special warnings and special precautions for use, if any	98	89	52	91	85	97
4	Interaction with other medicaments and other forms of interaction	92	89	82	78	76	87
5	Pregnancy and lactation, if contra-indicated	95	89	76	77	75	90
6	Effects on ability to drive and use machines, if contra-indicated	43	16	12	19	19	32
7	Undesirable effects/side effects	100	97	NR	87	89	99
8	Antidote for overdosing	91	84	54	52	39	85

R: Not reported, values are in ([%]), (n=Total number of drug package inserts included in the study)

Table 4: Comparison of pharmaceutical information with other studies.

S. no.	Parameters	Present study (n=98) (%)	Chhaya et al[5] (n=100) (%)	Priyanka et al[7] (n=192) (%)	Govindadas et al[8] (n=263) (%)	Patel et al[9] (n=150) (%)
1	List of excipients	51	12	11	35	17
2	Incompatibilities	49	19	26	28	42
3	Shelf life in the medical product as packaged for sale	65	16	34	29	54
4	Shelf life after dilution or reconstitution according to the direction	8	NR	3	13	21
5	Shelf life after first opening the container	8	NR	5	10	27
6	Special precautions for storage	100	95	77	86	97
7	Nature and specification of the container	25	92	11	90	21
8	Instructions for use/handling	100	NR	25	29	55

NR: Not reported, values are in (%), (n=Total number of drug package inserts included in the study)

DISCUSSION

Patients require more information related to the drug they are consuming.[3] At present PIs need to improve the quality in terms of the information regarding drugs for a society where people crave better information. There is abundant availability of information from the internet and adding this information to the PIs will improve the patient's compliance in India.[4] In our study, posology and method of administration, contra-indications, special warning, and special precautions for use, interaction with other medicaments and other forms of interaction, contra-indicated in pregnancy and lactation, undesirable effects/side effects, antidote for overdosing were present in 100%, 100%, 98 %, 92%, 95%, 100% and, 91% respectively of the PIs compared with other studies by

Chhaya et al, Sudha et al, Priyanka et al, Govindadas et al, and Patel et al, an almost similar result was found between 80 to 100% (Table 3). [5-9] In our study, effects on the ability to drive and use machines, if contra-indicated were present only in 43% of the PIs compared with another study by Chhaya et al, Sudha et al, Priyanka et al, Govindadas et al, and Patel et al, an almost similar result was found between 10 to 30% (Table 3).[5-9]

In Sudha et al study special warnings and special precautions for the use and Antidote for overdosing were present in only almost 50% (Table 3).[6] In Priyanka et al and Govindadas et al studies, an Antidote for overdosing was present in only 39% and 52% respectively (Table 3).[7,8] In our study, all the parameters related to data pharmaceutical information except the Special precautions for storage of the majority of PIs, the same conclusion was found in compared studies like Chhaya et al, Sudha et al, Priyanka et al, Govindadas et al, and Patel et al (Table 4).[5-9]

In the current study, the list of excipients, incompatibilities, and shelf life in the medical product as packaged for sale were present in 51%, 49% & 65 % respectively of the PIs compared with other studies by Chhaya et al, Priyanka et al, Govindadas et al, and Patel et al, an almost similar result was found between 16 to 50% (Table 4).[5,7-9] In the present study, the shelf life after dilution or reconstitution according to the direction and shelf life after first opening the container was present in 8% of the PIs compared with other studies by Maheshi et al, Chhaya et al, Priyanka et al, Govindadas et al, and Patel et al, an almost similar result was found between 5 to 25% (Table 4). [5,7-9]

In our study, the Special precaution for storage was present in 100% of the PIs compared with other studies by Maheshi U. Chhaya et al, Priyanka et al, Govindadas et al, and Patel et al, an almost similar result was found between 77 to 97% (Table 4).[5,7-9] In the current study, the Instructions for use/handling were present in 100% of the PIs compared with other studies by Chhaya et al, Priyanka et al, Govindadas et al, and Patel et al, a different result was found between 25 to 55% only (Table 4).[5,7-9] All of the assessed PIs were found to be written in English, which is consistent with the compared studies.[5-9]

CONCLUSION

Although the present study has demonstrated some improvement compared to previous studies, further enhancements are still necessary. Our study has revealed that the information provided on drug inserts is currently inaccessible. However, if drug companies can present this crucial information in a manner that is easily accessible to patients, it has the potential to improve compliance greatly. To achieve this, it is recommended that drug package inserts include mandatory toll-free numbers and internet addresses. These contact details would allow patients to easily reach out to manufacturers for any queries regarding drug administration or to report adverse drug reactions (ADRs).

In the pharmaceutical industry, drug manufacturers mustn't treat PIs as a mere requirement. Rather, they should demonstrate a genuine commitment to enhancing the availability and quality of PIs. To achieve this, regulatory bodies need to monitor and evaluate the accessibility and standard of PIs consistently. Furthermore, it is crucial to establish legislative measures that impose suitable penalties on manufacturers who fail to meet these requirements to enforce compliance.

In a country such as ours, where concerns regarding the quality of medicines frequently arise, implementing high-quality PIs can effectively address these concerns. By doing so, our nation can advance and excel in the pharmaceutical industry.

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: The study was approved by the Institutional Ethics Committee

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Cite this article as: Vyas AP, Gor AP. Analysis of the drug package inserts in India as per the CDSCO guidelines. Int J Basic Clin Pharmacol 2025;14:358-61.