**CRITICAL EVALUATION OF THE DRUG PROMOTIONAL LITERATURE**

|  |  |  |  |
| --- | --- | --- | --- |
| **S.NO** | **OBJECTIVE** | **DOMAIN** | **LEVEL** |
| **1** | At the end of the session, a phase-II student must be able to describe drug promotion, correctly. | **K** | **KH** |
| **2** | At the end of the session, a phase-II student must be able to enumerate what a prescriber should look for in drug promotion literature, correctly. | **K** | **K** |
| **3** | At the end of the session, a phase-II student must be able to enumerate parts of an ideal check list used for critically appraising promotional drug literature, correctly. | **K** | **K** |
| **4** | At the end of the session, a phase-I student must be able to perform critical evaluation of the given drug promotional literature, correctly. | **S** | **P** |

Pharmaceutical marketing is an important strategy adopted by the companies to promote their drugs. The World Health organization (WHO) defines ‘promotion’ as ‘all informational and persuasive activities by manufacturers and distributors, the effect of which is to induce the prescription, supply, purchase and/or use of medicinal drugs.

All promotion making claims concerning medicinal drugs should be reliable, accurate, truthful, informative, balanced, up-to-date, and capable of substantiation. They should not contain any misleading or unverifiable statements or omissions likely to induce medically unjustifiable drug use or to give rise to undue risks.

Drug advertisement using promotional literature is a persuasive communication and forms an integral part of pharmaceutical marketing. Drug promotional literature(DPL) includes product characteristics, side effects, dosage regime, contraindications and various marketing claims with references which at times, may be inadequate, deceptive and of poor educational value.

Pharmaceutical companies supply the promotional material in the form of flip charts, brochures and leaflets. The material is attractive and catches the eye due to its designs, colors and images. Advertiser uses images and/ or words that appeal to the desires of prescribers.

**What should a prescriber look for in drug promotional literature?**

1. The disease
2. The need
3. The patient
4. The comparator
5. What was the outcome(efficacy)
6. Number of subjects and statistics
7. How is the treatment expressed?
8. Relative risk reduction (RRR) is the percent reduction in even in the treated group compared to the control group even rate.
9. A better statistic is the absolute risk reduction (ARR) which is the difference in the outcome even trait between the control group and the experimental treated group.
10. Inverse of the ARR gives the number needed to treat (NNT) that is how many patients must be treated with the new treatment for one patient to benefit more than if the patient had been treated with the standard treatment. The NNT is a simple statistic that could be easily interpreted bye by the physician as well as patients.

Risk associated with the use of new drug(safety):

As no drug is without risks, the physician should consider the side effect and not get overwhelmed by efficacy outcomes. The physician should prepare for this key information. the risk benefit ratio should always be weight before prescribing the drug to any patient.

Complains of the new drug:

It indicates if the new drug effects the compliances of the patient. It can be estimated by comparing the spectrum of side-effect of the new drug with the standard drug. It can also be seen by looking at the dropout rates of the trials of the drug. It will also be affected by the type of formulation and frequency of Administration.

Cost(price):

Cost of the new treatment is an important consideration for starting the treatment. As new drugs usually have high cost of treatment, it would be inappropriate to prescribe costlier drugs, especially when cheaper and effective alternative exist. Cost becomes an important consideration for treatment, particularly in a country like ours.

FDA has released a draught guidance for good reprint practices. The salient features include-

* Organizational publications which are Peer reviewed and not funded by the manufacturers of the product in the manuscript.
* The manufacturer should not influence directly, or any individual involving in the writing, editing, or publishing of the scientific information.
* The information in the scientific or Medical Journal or reference Publications should not be false or misleading and should be derived from adequate and well-controlled clinical investigations.
* The information should not pose a significant risk to the public health. Publications which do not qualify for dissemination to Healthcare professionals include letters to editors, abstracts of publications, results of phase 1 trials and publications without relevant investigations or data.
* Scientific information should not be presented in a form that might bias the judgement of the physician and should be accompanied by the approved labelling of the drug or the device.
* It should be distributed separately from information that is promotional in nature.

The validity of references could be determined by answering following 6 questions:

**Major criteria:**

1. Was assignment of the patients to the treatments randomized?
2. Were are all the patients who entered study accounted for at the end of the study?
3. Were the patients were analyzed in the group in which they were randomized?

**Minor criteria:**

1. Was study blinded?
2. Except for the treatment provided were the group comparable in all other aspects?
3. Were study groups similar at the start of the trial?

An important aspect is to review the disclaimers and acknowledgements of the original study to determine whether a pharmaceutical company founded the study. This is important as published studies that are sponsored by pharmaceutical companies are more likely to have outcomes having the sponsor’s product.

Ethical guidelines for medicinal drug promotion per published by WHO in 1988 to address the issues of unethical drug promotional activities. In India, the uniform code of pharmaceutical marketing practices was notified by the department of pharmaceuticals under Ministry of chemicals and fertilizers of Government of India which has the guiding principles for Ethical drug promotional activities.

**Sample check list for critically appraising promotional drug literature:**

1. The name(s) of the active ingredient(s) using other international nonproprietary names (INN) or the approved generic name of the drug.
2. The brand name.
3. **Pharmacological data**: a brief description of the pharmacological effects and the mechanism of action.
4. **clinical information:**

**-Indications**: whenever appropriate, simple Diagnostic criteria should be provided.

-**Dosage regimen and the relevant pharmacokinetic data**:

(a)Average and range for adults and children;

(b) dosing interval;

(c) average duration of treatment;

(d) special situations, e.g.: renal, hepatic, cardiac, or nutritional insufficiencies that require either increased or reduced dosage.

-Contraindications

-Precautions and warnings (reference to pregnancy, lactation, etc.,)

-Adverse effects (quantify by category, if possible)

-Drug interactions (include only if clinically relevant; drugs used for self-medication to be included)

-**Overdosage**:

* Brief clinical description of symptoms
* Non-drug treatment and supportive therapy
* Specific antidotes

**5.Pharmaceutical information:**

(a) Dosage form

(b) Strength of dosage form

(c) Excipients

(d) Storage conditions and shelf life (expiry date)

(e) Pack sizes

(f) Description of the product and package

(g) Legal category (narcotic or other controlled drug, prescription or non-prescription)

(h) Name and address of manufacturer(s) and importer(s)