



25 July 2014

FDA ADVISORY

No. **2014-057**

SUBJECT: PATIENT COUNSELLING BY PHYSICIANS AND PHARMACISTS

Last 30 April 2014, the Food and Drug Administration (FDA) conducted a public hearing on doctors as non-consumer users of vaccines and other biologic products. Likewise, last 30 May 2014, another public hearing was conducted for healthcare professionals, oncologists, and members of medical specialty societies regarding accessibility and affordability of anti-cancer drugs. Several meetings, round table discussions, and consultations consistently revealed that one of the major contributors to the irrational use of drugs and safety issues with drugs is the lack of patient counseling and education from prescribing physicians and from pharmacists who dispense medicines, as well as other healthcare professionals who are involved in the use and administration of the drug products. Serious complications are known to occur to patients who fail to complete the prescribed dosage of drug during therapy. This is an arising concern in the country with the increasing prevalence of antimicrobial resistance (AMR) due to non-compliance to the prescribed treatment regimen.

More than any legal obligation or accepted practice, it is an ethical and moral responsibility of all healthcare professionals to ensure that patients receive the highest possible level of care. It is in this context that the FDA hereby encourages all physicians and pharmacists to practice patient counseling with the use of drug products.

On the part of physicians, patients should receive counseling on taking the right dose and proper administration of prescribed drugs, as well as potential adverse drug reactions or events that may occur. Any interactions with certain food, drug, or laboratory or diagnostic tests should be explained. The physician should explain the importance of seeking immediate medical attention for serious adverse drug reactions that the patient may experience during treatment, and reporting of these reactions to FDA. For other instructions, physicians are encouraged to make notes to the pharmacist on which areas to focus during their patient counseling.



Pharmacists should provide patient counseling that focuses on proper use of drug products they dispense to achieve optimal therapy. Pharmacists should explain, if not supplement the information found package inserts or patient information leaflets and should clarify any instructions given by the physician. Emphasis should be given to complete the treatment regimen, as well as reporting of any adverse drug reaction.

Other healthcare professionals are expected to provide information or assistance to the patient based on approved product information for the promotion of rational drug use.

For information and compliance.


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