From Chairman's Desk

Clinical Research

Post-marketing surveillance or phase-IV clinical trial is an important determinant whether a drug shall survive in the market place or become stillborn. Research in terms of contribution from hospital and community Pharmacists based on genuine information/authentic and unbiased data collection, collation and compilation from individual patients is an important input to assess occurrences and possibilities of adverse effects in actual clinical and therapeutic environment, which varies from patient to patient and clinician to clinician. In order to receive analysable and correlating data the researcher must record following historical information for the individual patient while dispensing the medication. Whether the patient

- smokes;
- drinks alcohol;
- has ever had an ulcer or bleeding in stomach;
- has liver disease;
- has kidney disease;
- has asthma;
- has congestive heart failure;
- has fluid retention;
- has heart disease;
- has high blood pressure;
- has coagulation disorder or taking an anticoagulant such as warfarin; or
- is taking a steroid medicine such as prednisone, methylprednisolone, prednisolone and others.

The researcher need to convince the patient to notify immediately if (s)he develops abdominal pain, tenderness, or discomfort; nausea; blood in vomit; bloody, black, or tarry stools; unexplained weight gain; swelling or water retention; fatigue or lethargy; a skin rash; itching; yellowing of skin or eyes; fever; or unusual bruising or bleeding, unusual color of urine. These symptoms could be early signs of dangerous side effects, which if ignored may prove hazardous. Thus every unusual experience by the patient during the course of therapy is essentially important. In research authenticity and foolproof data collection should be the main motto, so that the final outcome of data analysis stands all challenges and no drug is unnecessarily weeded out. This is important from clinical point of view to provide better therapy, economical therapy and safer therapy.

New drugs are necessity and not luxury. At the same time their safety, efficacy and economy are of prime importance from clinical, social and patient safety point of view. The main agenda of phase-IV clinical trial should be superiority of the new drug over existing therapeutic regimen and not simply another alternative in the wide range of drugs already available. Thus the medication must be more specific in action, well and better tolerated and distinctly less harmful. This phase of trial provides ample opportunity to adjudge all these parameters in large number of patients distributed in various regions and genetically different. Therefore, it needs to be conducted very carefully and in absolutely pious manner, because every useful and superior drug deserves promotion in greater public interest. In order to meet this genuine research objective it is all the more necessary that more and more third party involvement should be in such projects and such projects need not be funded by the sponsor of the drug. The Vioxx episode at least hints so.

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