ELSEVIER

International Journal of Pharmaceutics 184 (1999) 263–264

international journal of pharmaceutics

Letter to the editor

Potency and bioavailability of therapeutic formulations during their field usages

To the Editor:

Traditionally, quantification of active ingredients of therapeutic agents is carried out in laboratories designed to carry out complex assay procedures like liquid chromatography, tandem mass spectroscopy, infra-red absorption spectroscopy, thin layer chromatography with silica gel or gas chromatography. Assay of γ-butyric acid level in brain is possible using a 2.1-T magnetic resonance image spectrometer and an 8-cm surface coil (Petroff et al., 1996). The laboratory facilities for carrying out such assays are very limited in developing countries, where even the storage facilities for therapeutic agents tend to be unsatisfactory and poor.

There have been reports on poor quality of therapeutics being used by patients in Asia and Africa. During an analysis of 137 brands of paracetamol, ampicillin, cotrimoxazole, and vitamin B preparations being used in Bangladesh, there were 37 substandard batches being used by patients. Of the 16 brands of paracetamol and ten brands of ampicillin that were found to be substandard during analysis, 11 and six brands, respectively, had already been assessed to be standard by the regulatory authorities (Roy et al., 1997). Quantification of active ingredients of field samples of therapeutics in use in Nigeria and Thailand was no better. An analysis of chloroquine, amoxycillin, tetracycline, cotrimoxazole, and ampiclox, revealed 36.5% samples to be substandard. Moreover, in six samples of chloroquine, there was no active ingredient left (Shakoor et al. (1997).

The scourge of poor quality therapeutics could be blunted through availability of one- to two-step assay procedures for quantification of the residual ingredients in tablets, infusions, syrups and injection preparations. A semi-quantitative paracetamol specific spot test for screening paracetamol in the field (Roy et al., 1997), is very promising. Screening of 38 brands of paracetamol enabled spotting of three spurious and 11 border line brands of paracetamol in the field itself.

Simple tests for therapeutic interventions against infections, neoplastic or degenerative diseases would assist in detection and elimination of spurious or poor quality drugs. They would be an asset to national or international programmes against tuberculosis, AIDS, epilepsy or cardiovascular diseases. The resultant elimination of poor quality drugs from pharmacy and non-pharmacy distribution centres, would, apart from therapeutic failures in patients, as well prevent selection of subpopulations of microbes that were likely to propagate in higher concentrations of antimicrobial agents.

The manufacturers of therapeutics should spare funds towards standardisation of simplified assay procedures (Roy et al., 1997) to quantify active ingredients of their products. Similar tests to

PII: S0378-5173(99)00108-8

monitor drug concentrations in different tissues or body fluids would be useful to monitor bioavailability of drugs prescribed with other drugs. The extra financial input by the manufacturers would eliminate numerous ethical, legal or allied issues linked with inadvertent usage of poor quality drugs (Roy, 1994; Shakoor et al., 1997).

References

Petroff, O.A., Rothman, D.L., Beher, K.L., Lamoureux, D., Mattson, R.H., 1996. The effect of gabapentin on brain gamma-aminobutyric acid in patients with epilepsy. Ann. Neurol. 36, 95–99.

Roy, J., 1994. The menace of sub-standard drugs. World Health Forum 15, 406–407.

Roy, J., Saha, P., Sultana, S., Kenyon, A.S., 1997. Rapid screening of marketed paracetamol tablets: use of thin layer chromatography and a semiquantitative spot tester. Bull WHO 75, 19–22.

Shakoor, O., Taylor, R.B., Behrens, R.H., 1997. Assessment of the incidence of substandard drugs in developing countries. Trop. Med. Int. Hlth. 2, 839–845.

Subash C. Arya
Centre for Logistical Research and Innovation,
M-122 (of part 2),
Greater Kailas-II,
New Delhi 110048,
India
Fax: +91-11-6494361