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Editorial

SHELF LIFE EXTENSION PROGRAM: REVALIDATING THE EXPIRY DATE

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From a Pharmacist's viewpoint expiry date is the time required for the drug content of a formulation to reduce to 90% of its labelled amount. Generally speaking, expiry date can be viewed as a guarantee from the manufacturer that drug formulation will maintain its potency within the specified period, in the storage condition recommended by them. The guarantee is conditional in as much as a drug formulation will maintain its potency within the period (Expiry date) if there has been no deviation from the recommended storage condition. The manufacturer's guaranteed life period of the products are disclosed to the consumers by printing the expiry date on the label¹.

In 1937 the sulfanilamide elixir disaster in the USA, the 1960 thalidomide tragedy in Europe and three consecutive toxicity reports of the date expired tetracycline in 1963-64 led to stringent regulations in drug marketing in terms of safety. Increasing consumer awareness and enactment of laws on consumer rights put pressure on the content and quality of marketed products. Law makers of countries across the globe thought it prudent to make amendments in Drug Laws and the mention of expiry date on primary and secondary packages of the product became mandatory. The responsibility of determining the expiry date of products was vested on the manufacturers who were supposed to fix the expiry period on the basis of stability studies conducted by them.

Mention of expiry date on the labels of all drugs was not mandatory in the law for a long time simply because the safety was not considered as a serious issue. The US Food and Drug administration made it mandatory to mention the expiry date on the labels of all drugs by promulgating regulations on September 29, 1978². Before that, since 1919, mention of expiry date was mandatory for biological products only. The US drug law under section 507 made it obligatory to mention expiry date on antibiotic and antibiotic containing formulations for human use in 1945. In the UK such amendment was made in the year 1976 and in India, it was made mandatory to mention expiry date on all drugs in 1986³.

Prior to the mandatory requirement, what happened to drug formulations which were consumed many years their manufacture? Did they lose their effectiveness? Did consumption of those drug formulations prove to be harmful for the patients?

The information that drug products remain active after their expiry date first came to public domain after the SLEP (Shelf Life Extension Programme) study conducted by US FDA on request of U S Defence Authority in 1986⁴. The study found that most of the tested drug products retained their potencies even after 15 years of expiry dates printed on the labels. The federal SLEP extends the expiration dates on qualifying drugs and other materials in federal stockpiles. The program is an acknowledgement of the fact that the actual shelf life of drugs and other medical products may be longer than their stated expiration date,

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depending on their useful life. Stockpiling of drugs for emergency use and heavy economic loss due to expiry date led the developed countries to study and revalidate the expiry date of drug formulations⁵. Unfortunately the law in underdeveloped or poor countries does not allow stockpiling and the expired drugs are destroyed. Lesson needs to be taken to create appropriate facilities to ascertain the potency of drugs after expiry date.

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