Guidelines to Regulate SF Medical Product

In the "Drug Act, 1940" the following provision is present for post marketing surveillance:

22. (c) take samples of any drug which is being manufactured, or being sold or is stocked or exhibited for sale or is being distributed;

23. (3) Where an Inspector takes a sample of a drug for the purpose of test or analysis, he shall intimate such purpose in writing in the prescribed form to the person from whom he takes it and, in the presence of such person unless he willfully absents himself, shall divide the sample into four portions and effectively seal and suitably mark the same and permit such person to add his own seal and mark to all or any of the portions so sealed and marked.
Provided that where the sample is taken from premises whereon the drug is being manufactured, it shall be necessary to divide the sample into three portions only.

23. (4) The Inspector shall restore one portion of a sample so divided or one container, as the case may be, to the person from whom he takes it, and shall retain the remainder and dispose of the same as follows:-
(i) one portion or container he shall forthwith send to the Government Analyst for test or analysis;
(ii) the second he shall produce to the Court before which proceedings, if any, are instituted in respect of the drug; and
(iii) the third, where taken, he shall send to the warrant or, if any, named under the proviso to sub section (3) of section 19.

To effectively perform the regulation of SF medical product activity a guideline is needed. In this purpose the following WHO guideline has been adopted:

- GUIDANCE ON TESTING OF "SUSPECT" FALSIFIED MEDICINES: Working document QAS/15.634/Rev.3 August 2017

As this is a draft guideline, the final guideline also will be adopted after finalized by WHO.

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