



## MEDICATION DISPENSED IN COMPLIANCE AIDS

### Interpretation Statement

In our current Regulations, Section 17.15 states: *Medications dispensed to clients to improve compliance shall conform to the practice directive approved by Council with regard to packaging, labelling and storage requirements.*

Until such time as the practice directive is circulated, members must continue to be compliant with direction as provided in this interpretation statement that was based on former regulations. Members must *ensure that the containers are marked with the lot number and the expiration date. The expiration date to be used is determined by the Standards set by the United States Pharmacopoeia as may be amended from time to time.\**

When the original regulation was written, most monitored dosage systems contained one drug per blistered card; lot and expiry date of the single drug were recorded on the package. With the widespread use of monitored dosage systems containing multiple drugs, there has been misunderstanding in how to apply the regulation.

Compliance with legislation may be achieved by using either the first or second procedure for single-drug monitored dosage systems, or choosing between the third or fourth option below for multiple-drug monitored dosage systems.

#### Single-drug compliance aid/monitored dosage systems

1. Record the lot number from the stock bottle on each package, and apply an expiry date of one year from the date the drug is packaged or the expiration date on the manufacturer's container, whichever is earlier, on each package, **or**
2. Using a log, record or filling chart, record the lot and expiry date from the stock bottle used during the preparation of the package. Next, create your own unique "lot number" assigned to that particular log, record or filling chart, and record only your newly-created unique "lot number" on the packages associated with that chart. Apply an expiry date of one year (365 days) from the date the drug is repackaged or use the expiration date on the manufacturer's container, whichever is earlier, on each package.

#### Multiple-drug compliance aid/monitored dosage systems

3. On the package(s), record the lot number from each stock bottle used during the preparation of the package(s), and apply one expiry date, in accordance with the standards set by the USP\*, or



4. Using a log, record or filling chart, record the lot numbers and expiry dates for each stock bottle used during the preparation of the package(s). Next, create your own unique “lot number” assigned to that particular log, record or filling chart, and record only your newly-created “lot number” on the package(s) associated with that chart. Apply one expiry date on the package(s), in accordance with the standards set by the USP\*.

If the second or fourth options are used, the paper copy of the log, record or filling chart, with the lot number and expiry dates noted, must be retained for fifteen years. If the paper copy is scanned electronically to the patient’s profile, the paper copy must be retained for 2 years, and the electronic copy for fifteen years, as outlined in current Regulation 17.22(1).

*\* USP standard for monitored dosage systems containing more than one medication per blister: “...such beyond-use date or period of time shall not be longer than the shortest recommended beyond-use date for any dosage form included therein **or not longer than 60 days** from the date of preparation of the patient medpak and shall not exceed the shortest expiration date on the original manufacturer’s bulk containers for the dosage forms included therein...” Alternatively, a more stringent expiry date may be applied, as per site policy.*