

Date: July 30, 2014

To: San Mateo County EMS Providers and Personnel

From: Gregory H. Gilbert, MD, FAAEM 
EMS Medical Director

RE: Expired DuoDote and Atropen Auto-injectors

The following is a current EMS Agency policy on the use of expired medications:

Expired medications may not be used, with the exception of DuoDote and Atropen. When auto-injectors are unavailable for replacement, DuoDote and Atropen auto-injectors may be used up to five years past their expiration dates. Auto-injectors must be intact, sealed and have been stored under reasonable conditions.

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This is a good opportunity to present information regarding expired medications in general. However, please keep in mind **only DuoDote and Atropen auto-injectors may be used past their expiration dates.**

Safety. There are no published reports of human toxicity due to ingestion, injection or topical application of current drug formulations after their expiration date. The only reported exception to date was renal tubular damage occurring after the use of degraded tetracycline in a formulation that is no longer available.²

Expiration Date. The expiration date on the manufacturer's package is based on the stability of the drug in its original sealed container. The date does not necessarily mean that the drug was found to be unstable after a longer period; it means only that real-time data or extrapolations from accelerated degradation studies indicate that the drug in the closed container will still be stable at that date. Most drug products have a labeled shelf-life of one to five years, but once the original container is opened for use or dispensing, the expiration date on the container no longer applies.

Stability. Data from the Department of Defense/FDA Shelf Life Extension Program, which tests the stability of drug products past their expiration date, has shown that 2650 (88%) of 3005 lots of 122 different drug products stored in their unopened original containers remained stable for an average of 66 months after their original expiration date.³

Liquid Drugs. Solutions and suspensions are generally not as stable as solid dosage forms. In one report, however, four outdated atropine samples (three from solutions up to 12 years past expiration



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and one from a World War II-era auto-injector) were all found to contain significant amounts of the drug.⁸ Suspensions are especially susceptible to freezing.

Conclusion. When no suitable alternative is available, and there is no indication that they are unsafe, outdated drugs may be effective. How much of their potency they retain varies with the drug, the lot and the storage conditions, especially humidity, but many drugs stored under reasonable conditions in their original unopened containers retain 90% of their potency for at least 5 years after the expiration date on the label, and sometimes much longer. Given the safety of the medications, there is no downside to auto-injecting if the need arises.

I hope this helps to answer any confusion regarding expired DuoDote and Atropen auto-injectors specifically, and why it is acceptable to use them. For further information, I have included a list of references below.

References

1. Drugs past their expiration date. Med Lett Drugs Ther 2002; 44:93.
2. GW Frimpter et al. Reversible “Fanconi Syndrome” caused by degraded tetracycline. JAMA 1963; 184:111.
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4. US Department of Health and Human Services. Guidance for federal agencies and state and local governments: potassium iodide tablets shelf life extension. Available at: www.fda.gov. Accessed December 15, 2009.
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6. C Scholtissek and RG Webster. Long-term stability of the antiinfluenza A compounds amantadine and rimantadine. Antiviral Res 1998; 38:213.
7. R Regenthal et al. The pharmacologic stability of 35-year old theophylline. Hum Exp Toxicol 2002; 21:343.
8. JG Schier et al. Preparing for chemical terrorism: stability of injectable atropine sulfate. Acad Emerg Med 2004; 11:329.
9. FER Simons et al. Outdated EpiPen and EpiPen Jr autoinjectors: past their prime? J Allergy Clin Immunol 2000; 105:1025.