

Chempack 2.0: A Policy Roadmap

The Emergency Services Coalition for Medical Preparedness is dedicated to raising the nation's level of disaster response and medical preparedness. The ESCMP aims to ensure that the protective health of emergency services for various public health disaster threats is considered as part of a national strategy for responder health and safety. Protected responders can protect the communities they serve. This discussion paper is among a series that examine current policy and practices, and includes practical steps for improvement.

The Chempack Program was developed by the Centers for Disease Control and Prevention (CDC) ten years ago to “forward place” caches of nerve agent antidote and symptomatic treatments at the local level “to provide a sustainable resource to respond quickly to a nerve agent incident.”

Historically, the management of the Program has depended on federal staffs remotely monitoring caches and travelling nationwide to and from localities to replenish expiring drug product. This is an unduly costly process. To achieve the stated goal of a sustainable strategy we recommend a significant shift of management responsibility to localities and private sector partners, along with sustained funding for expanding the formulary of drug products in the Program. Critical to this is a harmonized alignment and integration of the Department of Defense/FDA Shelf Life Extension Program (SLEP), and the FDA Emergency Use Authorization process which provides a genuine sustainment option.

Local pharmacists (with the support of CDC Chempack staff and product manufacturers/distributors) are capable of managing rotation of “soon-to-expire” stock, as needed. Vendor management of pharmaceuticals has proven to provide superior timeliness, cost and efficiency, given this is a core competency of these firms. Local pharmacists are able to make determinations of needs specific to their own communities. The rationale for in-person federal inspection has been overcome by Internet-based remote monitoring capacity. Further, by encouraging a regional approach through local collaboration all caches can be managed by fewer staff with more consistency and control.

Recommendation 1, Local Management:

- *Transfer select routine Chempack sustainment activities to local pharmacists and use resultant cost savings (via reduced federal staff administrative overhead) to further develop a Chempack quality assurance program; enhance exercises; and expand the Chempack formulary to address additional threats.*
- *Allow localities to determine the appropriate formulary for local conditions and add products to a defined core Chempack cache (e.g. cyanide antidotes and potassium iodide).*
- *Update current Chempack monitoring systems with cost effective online systems.*

Chemical agent antidote and treatment development has not kept up with initial projections. This has also been true of the larger countermeasure development enterprise. Among reasons cited are lack of incentives for private sector research and manufacture, changing threat analysis and the time since previous intentional events. Nonetheless, there are important new products awaiting introduction into the Chempack.

Recommendation 2, Renew and Replenish the Formulary:

- *Use administrative savings to update the protections provided by the Chempack.*
- *Use advanced purchase commitments and other modern financing options to provide incentives for enhanced and new product lines.*

The core Chempack products are stable aqueous salts. If stored under proper conditions, these products will remain safe and effective significantly beyond the initial shelf lives set by the manufacturers. The CDC currently applies the FDA Shelf-life Extension Program (SLEP) to select Chempack products. The Program can be made more efficient by managing agreements with manufacturers for longer initial shelf-life dating under certain conditions.

The expansion of SLEP beyond DoD to include state/local membership has been delayed by repackaging concerns. The current SLEP process requires that extended product be turned over to a “state licensed drug repackaging firm” to have product relabeled with new expiration dates. This is a costly process; as there are few “repackagers” and service and shipping rates are high. If repackaging (and associated shipping) costs can be avoided, Chempack annual maintenance costs would be greatly reduced.

Recommendation 3, Simplify Shelf-Life Management:

- *Work with manufacturers to identify a “Chempack Only” version of products. Such versions will have longer initial shelf-life dates and accommodate simplified labeling for SLEP administration.*
- *Propose to FDA that “Chempack Only” products do not include expiration date data on their immediate containers and packaging. Instead, data would be contained in a pouch affixed to the outside of each Chempack container. At the time of activation, expiration date adhesive labels would be affixed to products before being released by pharmacies. When new product expiration dates occur due to SLEP, new sets of labels would be provided. This approach would greatly reduce repackaging overhead costs.*

The Chempack Program has not been reimagined in the ten years since it was developed. In the meantime the nation has added 30 million residents, 70% of them in the South and West. Locally maintained Chempack caches must include periodic threat and hazard assessments taking into account shifts in population and chemical industry expansion; Chemical antidotes need to be available in less than 45 minutes. To be the sustainable local asset close enough to population centers, Chempack must be continuously improved and extended.

Recommendation 4, Pilot Change Process:

- *Fund two or more pilot projects to identify innovative practices for the development of the next generation of locally managed Chempack.*
- *Establish a practitioner-led Board to oversee a continuous quality improvement process.*

The Chempack Program is an essential part of the National Preparedness Goal required across the whole community to protect not only emergency responders but the residents they serve. It is time to build the Program out as a second-generation program via local management, engagement of the private sector, implementation of SLEP efficiencies and improved use of technology to ensure the efficacy and security of the installations. The recommendations above are a starting point.

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