



Economic and Technical Aspects of Small-Scale Institutional Pharmaceutical Production in Developing Countries

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Pharmaceutical compounding is an integral part of the practice of pharmacy in both the developing and developed nations of the world. However, in areas that are limited in professional staff and/or access to robust pharmaceutical distribution systems, local institutions have escalated the compounding concept and have established processes that are essentially “local pharmaceutical production.” Although this practice is widespread, the rationale and basis for this production varies depending on several access issues including quality and economic issues.

Because pharmaceutical compounding is conducted either by professional pharmacists or under their immediate supervision, on a small scale using modest compounding tools, the control requirements are generally less stringent than those required for the large-scale manufacture of pharmaceutical products in compliance with Good Manufacturing Practices (GMP). The extension of the compounding concept to “local pharmaceutical production” can be considered in a similar light. Because of the expectation that these products will be used over a short period of time, stability studies are generally not required, although some limited stability studies should be conducted on the products if they are retained more than a month.

The production of sterile and terminally sterilized products is especially challenging in this environment because of the validation and sterility testing requirements necessary to support these types of operations. However, for modest-scale production and/or selected products with very short expiry periods, the added expense of establishing and maintaining this type of facility may be justified or even the only option available. Local production can aid in keeping the inventory of more labile preparations such as suspensions, ointments, drops, etc., at a minimum by producing them from the more stable solids such as the active pharmaceutical ingredient (API) or solid dosage forms containing the desired API. In areas where there are few professional pharmacists and/or distribution outlets, it is reasonable to prepare formulations to be maintained in a short-term inventory to assure reasonable access to these products in these poorly served areas. However, in all cases, the needs of the patients to have access to appropriate, reliable, quality therapeutic products suitable for their needs is paramount. This poster highlights some of the technical challenges related to the establishment of compounding operations for the production of different classes of pharmaceuticals; non-sterile and sterile products such as ophthalmics; and terminally sterilized large-volume parenterals (LVPs). It also examines the financial implications of setting up and establishing these operations for the different classes of products in developing countries or limited access areas.