

Integration of temperature-controlled requirements into pharmacy practice

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Abstract

Objectives: To describe (a) Food and Drug Administration (FDA) regulations and guidelines issued by several professional organizations to ensure appropriate storage, handling, and distribution of temperature-controlled prescription drugs from manufacturer to wholesaler to pharmacy to patients; (b) pharmacy business practices that ensure the dispensing of high-quality temperature-controlled drug products; and (c) education that facilitates patients' important role in maintaining product quality.

Data sources: PubMed from 1950 to 2007 using the search terms *drug stability in transit*, *drug stability storage tablet*, *drug stability testing*, *drug stability transportation*, *drug stability relative humidity*, and *drug storage high temperature*. Nonprimary sources included the FDA website (www.fda.gov), presentations from meetings or workshops, and websites of professional organizations. Additional resources were identified from bibliographies collected by the authors.

Data extraction: Relevant data were extracted independently by the authors.

Data synthesis: The important role of pharmacists in ensuring the quality of drugs dispensed to and handled/stored by patients is supported by business practices that (a) promote purchase of quality temperature-controlled drugs (including quality agreements with providers), (b) ensure appropriate handling and storage upon receipt, (c) ensure proper packaging for receipt by patients, (d) provide relevant information to patients, and (e) evaluate issues associated with possible compromised transit, handling, and storage of temperature-controlled drug products.

Conclusion: The transit, handling, and storage of temperature-controlled drug products within complex supply chains provide opportunities for exposure of such drugs to temperatures above or below those recommended by the manufacturer. Pharmacists have opportunities to integrate business practices that facilitate the proper receipt, handling, and storage of temperature-controlled drug products. These practices will enhance the dispensing of high-quality, efficacious drug products to patients

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Learning objectives

- List two requirements of the Food and Drug Administration good manufacturing practice regulations that are intended to maintain the stability of temperature-controlled drug products and dietary supplements within the cold chain.
- State two requirements of the National Association of Boards of Pharmacy Model Rules for Licensure of Wholesale Distributors that support distribution of stable and efficacious drugs within supply chains.
- Describe five actions that pharmacists can take to maintain the stability and efficacy of temperature-controlled drug products dispensed from a pharmacy.
- List three actions that a pharmacist can take upon learning that a temperature-controlled drug product has encountered an undesirable temperature excursion.
- State four education topics that can enhance the proper handling and storage of temperature-controlled drug products by patients.

ACPE Activity Type: Knowledge-Based



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and proper handling and storage by patients.

Keywords: Drug products, stability, cold chain, pharmacy practice, patient education.

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A pharmacist's traditional medication dispensing role has shifted to include a clinical focus on prescribing and monitoring patient care. Automated programs, including mail order pharmacy, allow the time for these additional clinical responsibilities. Given the shift in dispensing trends, quality programs used throughout the pharmaceutical industry to transport medications must be implemented at a local pharmacy level.

At a Glance

Synopsis: To maintain the stability and efficacy of temperature-controlled drug products, their exposure to the recommended temperature range derived from stability tests conducted by the manufacturer must be maintained. However, after shipment from the manufacturer, these drug products may be exposed to excessive hot or cold temperatures as they are transported, handled, and stored by one or more wholesalers before being received by a pharmacy and used by the patient. Pharmacists have an important role in integrating business practices that (a) reduce their risk of purchasing compromised temperature-controlled drugs and (b) enhance the proper receipt, handling, storing, and dispensing of quality temperature-controlled pharmaceuticals to patients.

Analysis: Standardized business practices imposed by Food and Drug Administration (FDA) regulations require manufacturers to conduct stability tests that determine the recommended maximum temperature (or temperature range) that will maintain the stability of temperature-controlled drug products during shipment, handling, and storage in supply chains. The supply chains may be quite complex and involve multiple modes of transportation and one or more wholesale distributor before being purchased by a pharmacy and used by patients. Despite wholesaler business practices required by FDA and guidelines issued by several professional organizations, temperature-controlled pharmaceuticals may encounter excessive temperatures within supply chains. Several business practices can be integrated by pharmacists to reduce possible purchase of compromised temperature-controlled drug products and ensure proper handling, storage, and dispensing or delivery of quality pharmaceuticals to patients. Pharmacists also can provide information to patients that will enhance their ability to properly transport and store temperature-controlled drug products.

Although the stability and quality of temperature-controlled prescription and over-the-counter (OTC) drug products is typically assumed during transit, the supply chain is quite complex. Diverse modes of sea, air, and land transport are used in the handoff among manufacturers, distributors, wholesalers, pharmacies, and final dispensation to the patient. Pharmacists must ensure that product integrity is not compromised by exposure to undesirable temperature or humidity. Several organizations offer guidance to integrate good cold chain business practices in the handling of temperature-controlled drug products.

Guidance on the stability of temperature-controlled drug products

Food and Drug Administration

The good manufacturing practice (GMP) regulations of the Food and Drug Administration (FDA) require drug product labels to specify storage conditions and contain an expiration date as determined by results of appropriate stability testing.¹ Drug products are to be tested in the same container-closure system in which the drug is marketed and, if full shelf life data are not available, accelerated studies combined with stability information of the components, including finished drug product and container-closure system, may be used to support tentative expiration dates.² Before shipping, the manufacturer must store the product under appropriate temperature, humidity, and light conditions.³ In addition to drugs, FDA has established minimum manufacturing, packaging, labeling, and storage practices to ensure the quality of dietary supplements. The final rule requires the manufacturer to verify the identity of each dietary ingredient prior to its use in the manufacturing process with implementation dates of June 25, 2008, for companies with 500 or more full-time equivalent employees; June 25, 2009, for those with fewer than 500 but 20 or more full-time equivalent employees; and May 25, 2010, for those with fewer than 20 full-time equivalent employees.⁴

Prescription Drug Marketing Act of 1987

The Prescription Drug Marketing Act of 1987 requires licensed wholesale distributors of prescription drugs to document detailed storage and handling procedures and employee training programs that address temperature and humidity control.⁵ FDA guidelines for state licensure of prescription drug wholesalers ensure that the identity, strength, quality, and product purity are not adversely affected during handling and storage. As mandated by FDA, state licensing laws require adequate storage and quarantine areas within a wholesaler facility.⁶ Each facility must include regulated temperature, ventilation, humidity, and lighting that meet requirements of the product labeling or official compendium such as the *United States Pharmacopeia–National Formulary (USP-NF)*. Wholesalers are required to have written procedures on meeting storage



Table 1. Good cold chain pharmacy practices

(1) Verify wholesalers/distributors and pharmacies you purchase from use a tool such as a quality agreement.

- Do they use an appropriate storage environment for temperature-controlled products?
- Do procedures exist to prevent exposure of received products to temperature extremes in the interval from receipt to placement in facility storage sites?
- Do they store products in accordance with good pharmacy practice?
- Are written procedures and employee training available to ensure proper receipt and storage of drug products?
- Is documented written information provided about ordered products that were exposed to an undesirable temperature excursion?

(2) Implement SOPs for pharmacy storage.

Procedures for monitoring temperature ranges of products in pharmacies include electronic temperature devices in both storage and refrigeration units. Commercially available monitoring devices can alert staff of changes in pharmacy storage temperatures and provide data in the event of an extreme weather event or power failure. Another resource is FDA. During normal business hours, questions may be directed to FDA at 301-796-3400 (for drug products) and 800-835-4709 (for biologic products). After-hours calls to the FDA emergency operation line at 301-443-1240 will be forwarded to the appropriate center or office for advice. Last, pharmaceutical manufacturers can provide lot-specific information for their products exposed to an extreme weather event. SOP for response to inadvertent storage at room temperature, notifications, alarms, or in the event of refrigeration or air conditioning unit maintenance or failure should include an assessment of medication in need of relocation to a functioning refrigeration unit or disposal.

(a) Follow internal SOPs for good cold chain receiving.

- Ensure that temperature-controlled drug products received by or distributed from the pharmacy are suitably packaged in containers that maintain an appropriate environment during extreme weather conditions.
- Examine delivery documents to ensure that the product was not subjected to an inappropriate distribution delay.
- Identify products that should not be stored at room temperature upon receipt via mail or ground carrier.
- Track the status of drug products that encountered a documented unacceptable temperature excursion before being received by the pharmacy.
- Establish written procedures and train staff on proper refrigerated and nonrefrigerated receiving practices.

(b) Follow internal SOPs for good cold chain storage.

- Identify products to be stored in a frozen state and those requiring storage within a specific temperature range.
- Check freezer section(s) for drugs that should not be frozen.
- Check refrigerator and other locations for to-be-refrigerated or to-be-frozen drugs.
- Monitor the accuracy of refrigerator and freezer thermometers.
- Store drugs in a manner that does not block air flow within a refrigerator.
- Ensure that drug storage refrigerators are dedicated to drugs (no food or other nondrug items).
- Establish a schedule to check expiration date and rotation of temperature-controlled products.
- Establish written procedures and train staff on proper refrigerated and nonrefrigerated storage practices.

(3) Qualify pharmaceutical packaging for home delivery.

While business-to-business distribution may have quality agreements between manufacturer and wholesalers or pharmacies, packaging for home delivery must ensure proper storage until the patient returns the product to a refrigerator. Seasonal and regional weather, carrier logistics including delivery time and charges, warehouse storage space, and product mass will affect the specifications needed in a thermal container. Passive thermal containers use phase-change materials such as frozen gel packs for refrigerants, and the container's insulation will affect the required packout with refrigerants and thermal barriers.

- Expanded polystyrene is the most common and inexpensive molded container, qualifies for overnight shipment at certain thickness and density, and is recyclable. Polyurethane can last for 2 to 5 days and has lower refrigerant requirements.
- Panel systems can be collapsible, and vacuum-insulated panels have the advantage of better insulation and thinner walls, thereby reducing dimension and refrigerant and providing superior performance.
- Flexible insulated pouches offer savings on storage and weight-based shipping.



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- Refrigerants include rigid bricks or bottles for reusability or low-cost flexible bags with water-based gels as the phase-change material. Testing or validating the packout against temperature profiles associated with various shipping lanes and seasons is a component of quality programs.
- Carrier logistics affecting performance of a shipping container include minimizing transport hours and decreasing the time that packages are left outside or on the back of a carrier truck.
- When appropriate, both chemical and mechanical indicators offer a low-cost option for temperature assurance to the customer, while digital models are a more accurate means of monitoring with data download options (refer to USP <1118> Monitoring Devices—Time, Temperature, and Humidity).
- Patient notification of delivery date via labeling or phone calls and pharmacy recovery procedures for packages returned to the carrier can also limit failed shipments.
- Prequalified packouts may not require an additional temperature monitor; however, the number of performance hours or thermal stress in the delivery chain increase costs to manufacture such containers.
- Universal packouts do not require seasonal or regional adjustments, maximizing operational efficiency.

(4) Evaluate and report drug product stability issues.

In the event of an unexpected temperature excursion, pharmacists are encouraged to contact the manufacturer and access published literature to obtain drug product stability information. For example, recent literature describes the stability of several insulin products exposed to simulated summer and winter ground delivery conditions²² and Cohen et al.²³ identified 79 injectable, oral, and ophthalmic products that are labeled for refrigerated storage but may be stored at room temperature for an acceptable duration. The following examples obtained from peer-reviewed journals have been reported to occur after exposure to excessive temperature: misshapen or split capsules^{24–26} and reduced content of an active ingredient in tablets and ampoules.²⁷ Pharmacists are also encouraged to report product stability concerns to the manufacturer and/or FDA and, by doing so, may provide the following new and important information to both entities:

- Product problems involving drug products may be reported to FDA by using the MedWatch form (available in the Physicians' Desk Reference) or by phone (800-332-1088), fax (800-332-0178), or the Internet (www.fda.gov/med-watch).²⁸
- Product problems involving vaccines may be reported to FDA by using the VAERS form (available in the Physicians' Desk Reference) or by phone (800-822-7967), fax (877-721-0366), e-mail (info@vaers.org), or the Internet (www.vaers.hhs.gov).²⁹

(5) Educate customers and patients.

- Identify temperature-controlled drugs and methods for proper handling and storage in the home, workplace, and while traveling.
- Provide written instructions if necessary.
- Instruct patients to avoid unintended exposure of drugs to abnormal temperatures (e.g., leaving drugs in a parked vehicle in a hot or cold environment).
- Instruct patients to avoid exposure of drugs to high humidity within the home (e.g., storing a drug container with removed lid in a bathroom).
- Encourage patients to contact a pharmacist to discuss any concern about a drug product that may have been exposed to abnormal temperatures.

Abbreviations used: FDA, Food and Drug Administration; SOP, standard operating procedure; USP, U.S. Pharmacopeia; VAERS, Vaccine Adverse Event Reporting System.

requirements; if not defined, a drug product may be held at a "controlled" room temperature as defined in an official compendium. FDA also specifies specific temperatures that must be maintained during the shipment of several vaccines, as well as whole blood, red blood cells, plasma, and platelets.⁷

Current anticounterfeiting initiatives by FDA and other stakeholders support using radiofrequency identification (RFID) tags to track the distribution of a prescription drug product from a manufacturer to wholesaler(s) and pharmacy.

Although RFID tags enabled to monitor temperature, humidity, and vibration data may provide a useful technology to facilitate proper cold chain practices, RFID and other electronic technologies used to track movement of products within the U.S. pharmaceutical supply chain are not in widespread use.^{8,9}

International Conference on Harmonization

FDA requirements closely follow guidelines issued by the International Conference on Harmonization (ICH). Partners of the



ICH tripartite include FDA and the regulatory authorities of the European Union and Japan. A key objective of ICH is to enhance mutual acceptance of research and development data among the partners. In addition to GMPs for active pharmaceutical ingredients, ICH guidelines address stability testing of new drug substances, products, and dosage forms.¹⁰

National Association of Boards of Pharmacy

The Model Rules for the Licensure of Wholesale Distributors of the National Association of Boards of Pharmacy (NABP) address requirements of the physical facilities, environmental monitoring equipment, inspection of outgoing prescription drugs, and procedures to process returned drug products.¹¹ The physical facility must be of suitable construction to ensure that drug products are maintained in accordance with the product labeling or compendia such as *USP-NF*. Storage areas must provide adequate temperature, humidity, ventilation, lighting, and security. In addition, the facility must contain a quarantine area for storage of damaged or deteriorated products until their return to the manufacturer. Proper storage of prescription drug products must be documented by appropriate temperature and humidity recording equipment and/or logs, and each outgoing shipment is to be inspected to prevent the distribution of prescription drugs that have been damaged in storage or held under improper conditions. If the conditions under which a prescription drug has been returned cast doubt on its safety, identity, strength, quality, or purity, the wholesale distributor must return it to the supplier. NABP inspects the physical facility and business operations of a wholesale distributor before initial licensure and not less than once every 3 years thereafter. The model rules also mandate that a wholesale distributor distributing or acquiring prescription drugs to or from another wholesaler inspect the latter at least once every 3 years.

United States Pharmacopoeia

United States Pharmacopoeia (USP) is an independent science-based public health organization that sets quality standards for prescription and OTC drugs and dietary supplements manufactured and sold in the United States.¹² USP General Chapter <1079> Good Storage and Shipping Practices provides information to ensure product stability within the supply chain. This information includes but is not limited to

- Proper handling and storage of drug products in warehouses, trucks, shipping docks, and pharmacies.
- Receipt of drugs by a pharmacy and distribution from a pharmacy to patients or customers.
- Returns of drug products from patients or customers.
- Training of personnel to monitor and respond to adverse temperatures.
- Storage of physician samples handled by sales representatives in automobiles.

USP Chapter <1150> Pharmaceutical Stability accounts for the nonlinear effect of higher temperatures on product degradation during shipping excursions by calculating the mean kinetic temperature (MKT), using the natural logarithm to weight temperature fluctuations, resulting in a higher value than a simple arithmetic mean. Refer to USP <1160> Pharmaceutical Calculations in Prescription Compounding for sample MKT calculations. Several additional USP chapters pertain to good pharmacy practice.

USP Chapter <1191> Stability Considerations in Dispensing Practice discusses drug stability factors relevant to the dispensing of medication by a pharmacist. In addition to factors that can affect the stability of compounded prescriptions negatively, this chapter discusses the responsibility of pharmacists to rotate stock; store products in the recommended environment; detect unstable stored products; be aware of possible stability problems associated with repackaging, diluting, or mixing of products; and inform patients about the proper storage of medications. USP Chapter <1160> Pharmaceutical Calculations in Prescription Compounding also notes the need for pharmacists to consider the effects of humidity on stability of compounded products that may be subject to intermittent opening during prolonged storage in the pharmacy. USP Chapter <1118> Monitoring Devices—Time, Temperature, and Humidity describes devices that measure temperature and humidity either at a point in time or during a specific interval within the supply chain. These include mercury thermometers and chemical, infrared, thermocouple, and thermomechanical devices. The humidity measuring devices vary from dew point and infrared hygrometers to more complex devices that measure humidity-induced variation of electrical current. Validation of these devices is also discussed. In addition, USP Chapter <1150> Pharmaceutical Stability defines four international climate zones (I through IV) that may affect design of stability studies for packaging and storage of drug products.

Parenteral Drug Association

Technical Report no. 39., revised 2007, *Guidance for Temperature-Controlled Medicinal Products: Maintaining the Quality of Temperature-Sensitive Medicinal Products Through the Transportation Environment*, by the Parenteral Drug Association provides guidance on essential principles and practices to transport temperature-sensitive medicinal products through the supply chain.¹³ The guidance applies to manufacturers, wholesalers, repackagers, and transport providers that handle and store temperature-sensitive products for which quality may be adversely affected by temperature extremes. Prescription drug products, investigational drugs, intermediates, excipients, active pharmaceutical ingredients, and diagnostic products that require a limited storage range to maintain quality are included.

The report describes principles of validation to verify that the equipment and systems can perform effectively and reproduc-



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ibly throughout the anticipated cold chain ranges and describes a process flow based on the following actions:

- Select packaging based on product temperature sensitivity and modes of transportation.
- Conduct transport tests in a temperature-controlled chamber or other simulated environment.
- Conduct tests of actual or representative product that are actually transported within the intended supply chain.
- Develop and implement training of all participants.
- Develop and implement quality systems to audit the supply chain.
- Implement and monitor the distribution system.
- Comply with regulatory requirements and guidelines.

Pharmaceutical wholesaler organizations

Healthcare Distribution Management Association. The Healthcare Distribution Management Association (HDMA), whose members handle, store, and deliver approximately 80% of prescription drugs sold in the United States,¹⁴ has issued wholesale distributor best practice guidelines to promote the integrity of the drug supply chain. The guidelines include handling and storage of prescription drugs shipped from another wholesaler. HDMA recommends that purchasing wholesalers document the seller's pharmaceutical storage practices, including temperature monitoring program. Follow-up biannual inspections of the physical site are also recommended.¹⁵ HDMA also has conducted supply chain conferences to discuss cold chain issues.

Health Industry Group Purchasing Association. The Pharmacy Working Group of the Health Industry Group Purchasing Association (HIGPA) recently addressed possible product integrity issues associated with the purchase of drug products in short supply. If such products are obtained from unfamiliar alternative wholesalers that are outside the routine source(s), the risk of purchasing an adulterated drug (i.e., one exposed to a temperature that is not within the recommended range) may be increased. To reduce this risk, HIGPA recommends that pharmacists should have access to technology that tracks storage conditions and validates conformance to USP standards for temperature-sensitive drug products within a supply chain.¹⁶ Verifying that supply chains for imported or reimported drug products meet USP standards is not possible currently; therefore, HIGPA has indicated that FDA should develop regulations that ensure the integrity of imported drug products.

Good cold chain pharmacy practices

Pharmaceuticals in the United States may travel through a complex supply chain that includes 3 large primary and approximately 6,000 smaller wholesalers before being received by a pharmacy.¹⁷ In the case of shortages, primary wholesalers may purchase drugs from smaller wholesalers; in pursuit of price discounts, smaller wholesalers may purchase drugs from each

other.¹⁸ As indicated by USP, manufacturers and distributors should work together to establish proper handling, transit, and storage within a complex pharmaceutical supply chain involving multiple handoffs prior to receipt by the patient or customer.¹² Specifically for cold chain products requiring refrigeration, USP Chapter <1079> requires storage at 2°C to 8°C (36°F–46°F) or as otherwise labeled. Drug products labeled for 2°C to 8°C storage may vary widely in their tolerance of short-term exposure to heat and cold during shipping. In accordance with USP Chapter <1079>, products to be stored at 20°C to 25°C (68°F–77°F) may have excursions to 15°C and 30°C (59°F and 86°F) if the MKT is no greater than 25°C (77°F).

Several easily implemented quality programs that enhance delivery of high-quality cold chain (temperature-controlled) drug products to customers and patients are described in Table 1.^{19–21}

Conclusion

As a result of job-related frequent handling and storage of drug products, pharmacists and associated staff are well positioned to detect and prevent drug stability issues. As patient advocates, pharmacists are invested in the effectiveness of prescribed medications and supporting quality programs. Actions taken at the time of receipt and storage of cold chain drug products within the pharmacy ensure the effective packaging and external delivery of these drug products to customers and patients. As with many diverse operations, the consistent application of cold chain procedures is enhanced by writing and implementing standard operating procedures that include training all relevant pharmacy staff. Integration of temperature-controlled requirements into pharmacy practice will ensure quality, integrity, and efficacy.

Glossary

Cold chain: A supply chain that includes the handling, transportation, and storage of a temperature-controlled drug substance or finished drug product.

Drug stability: Capacity of a drug substance or finished drug product to remain within specifications established to ensure its identity, strength, quality, and purity from the date of manufacture and packaging until labeled expiration.

Integrity: An indication that a drug substance, finished drug product, or its packaging has maintained the physical and chemical specifications that existed at the time of final manufacturing or packaging.

Quality: An indication that drug substance, drug product, or its packaging meets and maintains predetermined standards.

Quality agreement: A written acknowledgment that the seller of a drug substance or drug product will comply with agreed handling, distribution and storage criteria prior to receipt by the purchaser.



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1. **The Food and Drug Administration (FDA) good manufacturing practice (GMP) regulations include which of the following provisions?**
 - a. Accelerated shelf-life studies may be used to determine tentative expiration dates of a drug product.
 - b. GMP requirements apply to manufacturers, wholesalers, and pharmacists.
 - c. GMP requirements do not apply to dietary supplements.
 - d. Alternatives a and b are correct.
2. **The National Association of Boards of Pharmacy model rules require which of the following actions by drug wholesalers?**
 - a. Inspect manufacturers from whom they purchase drugs
 - b. Conduct stability tests of random samples of temperature-controlled drug products
 - c. Provide documentation that prescription drugs were stored at appropriate temperature and humidity
 - d. Alternatives a and c are correct.
3. **Parenteral Drug Association Technical Report no. 39., revised 2007, addresses which of the following procedures for businesses that handle and transport drug products?**
 - a. Implementation of quality systems to audit the supply chain
 - b. Storage facilities in pharmacies
 - c. Calibration of various types of thermometers and hygrometers
 - d. Alternatives a and c are correct.
4. **USP Chapter <1079> refers to which procedures that promote good pharmacy practice?**
 - a. Validating all temperature-measuring instruments
 - b. Establishing quality agreements between a pharmacy and wholesaler
 - c. Proper handling and storage of prescription drug products
 - d. Alternatives b and c are correct.
5. **Qualified pharmaceutical packaging includes**
 - a. Knowledge of the shipping lanes and season.
 - b. Testing or validating the packout against temperature profiles as part of a quality program.
 - c. When appropriate, use of a chemical or mechanical indicator for temperature assurance to the customer.
 - d. All of the above alternatives are correct.

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- 6. Which of the following topics typically would be included in a quality agreement between a pharmacy and wholesaler?**
- Inspection of a manufacturer storage facility
 - Written training procedures for handling, storage, and shipping of drug products, including communication on exposure to undesirable temperature fluctuations
 - Verification that the manufacturer packaged all temperature-controlled drug products with polystyrene
 - Alternatives b and c are correct.
- 7. Which of the following is the most appropriate action a pharmacist can take after becoming aware that a drug product has been exposed to an undesirable temperature excursion?**
- Gather information on the length and type of excursion, including similar excursions.
 - Retrieve the national drug code and lot number(s) and report the incident to the manufacturer to request product stability information.
 - For questions to FDA, call during normal business hours or the after-hours line or report an incident via the Internet, MedWatch (for reports involving drugs), or the Vaccine Adverse Event Reporting System (for reports involving vaccines) form.
 - All of the above alternatives are correct.
- 8. Which of the following actions would be included in pharmacy procedures to enhance appropriate receipt and storage of temperature-controlled drug products?**
- Ensure that all temperature-controlled drug products are packed in containers with polyurethane.
 - Store drugs labeled to be frozen and to be refrigerated in the walk-in cooler after receipt.
 - Establish written procedures and train staff on proper practices after identifying drug products exposed to undesirable temperature fluctuations.
 - Alternatives a and c are correct.
- 9. Which of the following procedures likely would be good pharmacy practice to handle, store, and dispense temperature-controlled drug products?**
- Use electronic temperature devices to alert staff on changes in pharmacy storage temperatures.
 - Establish standard operating procedures for response to inadvertent storage temperatures, including contacting the manufacturer or FDA as appropriate.
 - Refer patients to the wholesaler for information on handling temperature excursions.
 - Alternatives a and b are correct.
- 10. Pharmacists can provide the following information to patients to maintain the efficacy of temperature-controlled drug products.**
- Upon arrival at place of residence, place temperature-controlled drug products in a refrigerator at your convenience.
 - Instruct to avoid leaving drug products in vehicles during hot or cold external temperatures.
 - Inform customers that drugs to be stored in the refrigerator can also be stored in a freezer.
 - Instruct to contact a pharmacist in the event of concern about a temperature-controlled drug product.
 - Alternatives b and d are correct.

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Managing oneself: An essential skill for managing others

David A. Holdford

Abstract

Objectives: To discuss the importance of self-management for student pharmacists, pharmacists, and pharmacy managers and present a series of steps that students and new pharmacists can use in managing themselves.

Data sources: An English language-only literature search was conducted of the PubMed and International Pharmaceutical Abstracts databases from 1980 to 2007 using the keywords *managing and career*, *managing oneself*, and *career management*. Information from the search was supplemented with selected articles and books from the management and self-improvement literature.

Study selection: Cited sources were chosen based on their relevance to the article's objectives.

Data extraction: By the author.

Data synthesis: Common steps associated with managing oneself and one's career consist of taking responsibility for your life, knowing yourself, deciding what you want to do and be, establishing goals to achieve the life you want to live, and taking action. A major goal of any self-management plan for managers is to develop soft interpersonal skills that help individuals manage themselves and influence the world around them.

Conclusion: Effective self-management is necessary for success in managing others. The steps are relatively simple but take a lifetime to master.

Keywords: Careers, management, job satisfaction, Tools for Advancing Pharmacy Practice.

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Learning objectives

- Describe why successfully managing oneself is essential for effectively managing others.
- Explain the role of a personal mission statement.
- List the five basic steps of managing oneself.
- Describe the role of emotional intelligence in managing oneself.
- Identify strategies for increasing one's ability to manage oneself.

ACPE Activity Type: Knowledge-Based



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"All my life, I always knew I wanted to be somebody. I see now that I should've been more specific."

Lily Tomlin

An idea that has surfaced in the general management literature is that managers must effectively manage themselves before they can ever hope to effectively manage others.¹ This idea, however, appears to be missing in pharmacy literature. A search of the PubMed and International Pharmaceutical Abstracts databases from 1980 to 2007 using keywords *managing and career*, *managing oneself*, and *career management* did not reveal any report on effective self-management explicitly as it pertains to student pharmacists and practicing pharmacists. Examination of pharmacy textbooks provided similar results. Although guidance on advancing up the career ladder or on distinct career topics such as time and stress management has been provided in articles and book chapters, no report specifically discussing pharmacists' roles and responsibilities in managing themselves has appeared in the literature. Consequently, this article was created for use as a tool for students and pharmacists interested in the topic. The purpose is to provide an introduction to managing oneself to be used in leadership development, personnel management, and other managerial training and education.

Importance of managing oneself

Managing pharmacy personnel is a difficult task to do well. It may appear to be easy—or simply common sense—from the comfortable viewpoint of individuals who have never managed

people. However, in high-pressure pharmacy practice conditions, where pharmacy personnel can be tired, emotional, and overworked, managing is a lot harder than it looks.

Managing is difficult, in part, because it requires pharmacist managers to balance their own desires with the demands of the people they manage and the people to whom they report.² The needs of pharmacist managers often take a back seat to others in order to maintain a smooth running pharmacy. Pharmacists who accept responsibility over others are no longer free to do or say whatever they want, because doing so can hurt the operation of the pharmacy and the productivity of the people they manage. A misplaced comment or a poorly articulated criticism of coworkers can trigger an unproductive conflict or communicate an unintended message, thereby hurting team morale.³ Opposition to or open criticism of upper management by pharmacist managers can damage perceptions of leaders and undercut the pharmacy's initiatives. In fact, after pharmacist managers accept responsibility over others, they can no longer freely engage in many behaviors, including those listed in Table 1.

Clearly, many behaviors shown in Table 1 can communicate negative messages to coworkers and hurt a manager's credibility. Credibility is essential to developing commitment in colleagues and maintaining good professional relationships.^{4,5} Therefore, managers who cannot control their behavior hurt the success of the team and damage relationships with team members.^{6,7}

Consider the negative effect on coworkers of managers who do not control their emotions. If stressed, they can pass on that stress to others. If angry, they can lash out at and hurt peoples' feelings. If doubtful, that uncertainty can spread among everyone. Indeed, the whole health care team can suffer whenever pharmacist managers express frustration by snapping at people, demonstrate jealousy of the accomplishments of coworkers, or think that no one can do the work as well as they can. Pharmacist managers who show disrespect for those around them, become defensive when questioned, lack self-confidence, or value their own interests over that of the organization can seriously compromise their ability to manage.

Controlling one's emotions does not mean bottling them up without release, which can be stressful on the body and result in physical symptoms such as ulcers, headaches, and other ailments. Bottling emotions also can result in hidden emotions eventually bubbling up into a cathartic outburst at an inappropriate moment. Instead, controlling one's emotions means coping with emotions productively. One way is to develop better ways of communicating one's feelings to others (Example: "Your behavior makes me feel like you don't care about our patients."). Another way to cope is to reframe how one views a situation (Example: "That person's behavior does not mean that he does not care about our patients. He just hasn't developed good patient-centered habits.").

At a Glance

Synopsis: By effectively managing themselves, pharmacists can realize success in managing others. This article describes a systematic process for self-management and provides advice to help student pharmacists and pharmacists start the journey toward striking acceptable worklife balances and, ultimately, achieving true professional and personal fulfillment. Essential steps for managing oneself and others are provided.

Analysis: *Pharmacists who manage themselves effectively stand in stark contrast with those who do not. Many talented pharmacists fail to control their negative behaviors, thereby damaging professional relationships and effecting bad personal career choices. Developing emotional intelligence—self-awareness, self-regulation, motivation, empathy, and social skills—is a goal of self management. Emotional intelligence can be improved by taking self-assessment tests, seeking mentorship and advice on personal development from trusted colleagues, and reflecting on life and work.*



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Table 1. Unacceptable attitudes/behaviors of people in managerial positions

- Pushing one's problems off onto others
- Being inconsistent in words and actions
- Failing to keep promises
- Showing favoritism to individuals
- Getting even with people who make one angry
- Goofing off
- Being moody
- Being unclear when communicating to others
- Failing to take responsibility for one's decisions
- Bringing personal problems to work
- Talking freely about fears and insecurities
- Saying whatever comes to mind
- Failing to support upper management
- Being disorganized
- Avoiding conflicts
- Putting off important decisions
- Expecting everyone to like him/her
- Being a buddy to the people he/she supervises
- Asking people to do things that he/she refuses to do

Effective managers exercise control over their immediate impulses and tendencies.^{8,9} Although some pharmacist managers may want to scream at a technician for sloppy work or blame someone else for a problem, they must weigh the consequences of doing so on workplace productivity. In most cases, losing control is counterproductive to the goal of a smooth running, effective pharmacy. Capable managers understand this. They manage their personal emotions so that they can effectively influence the work of others. In short, good managers successfully manage themselves.

Pharmacists who effectively manage themselves stand in stark contrast with those who do not manage themselves successfully.^{10,11} Many smart and talented pharmacists fail to control their negative behaviors. Consequently, they repeatedly make errors in their professional relationships and personal career choices.

For some pharmacists, the path to failure starts in pharmacy school, where they never develop the necessary skills for managing themselves and their careers as professionals.^{1,12} As students, they put off identifying the life they want or developing a path to get there. Instead, they go to class, study for tests, and get into a rhythm of school life that excludes any thoughtful career planning. Typically, their career destination is some vague notion of personal success, such as "get a job" or "make some money."

After graduation they may take on managerial responsibilities.

However, many accept the new responsibility based on a misunderstanding of what a managerial role entails or how it might meet their own personal needs. Many will find that the job does not generate the feeling of accomplishment or enjoyment for which they hoped. This dissatisfaction may lead them to seek new jobs and pursue promotions in an effort to find some success, without clearly defining what success means to them. Before they know it, 10 years have passed, and they are unhappy with their career in pharmacy.

Like Lily Tomlin said in the above quote, they "wanted to be somebody." However, they did not establish a clear embodiment of that somebody or develop an effective plan for becoming that somebody. Rather, they let fate and luck determine their professional path and were surprised when things did not end up as well as they hoped.

Objectives

This article discusses how students and pharmacists can manage themselves in order to manage others. It focuses on the role of self-management for managers but can benefit anyone who wants to achieve professional success. A systematic process for self-management is described, and advice on getting students and pharmacists started is provided.

Truths about managing one's professional life

Before a student pharmacist or pharmacist begins the process of self-management, understanding and accepting certain truths is essential. Although these truths appear obvious to many, they are not universally accepted.

A pharmacy degree and license do not guarantee success

Some individuals in the profession feel that a pharmacy license entitles them to a great job. They believe that completing a pharmacy degree and passing the pharmacist licensing exam will automatically trigger a rewarding career. However, they fail to realize that a pharmacy degree and pharmacy license only gives them an *opportunity to compete* for a successful career. Each fledgling pharmacist has the responsibility of seizing one of the numerous opportunities available to them.

Hard work does not guarantee success

Working hard on unimportant tasks wastes time and prevents a person from doing what really needs to be accomplished. Regardless of how hard a person works, if that work is spent on trivial tasks or those that should be delegated to others, the effort will be wasted or inefficient. To differentiate important tasks from the unimportant, pharmacists must have a clear vision of their roles and responsibilities. Without that understanding, hard work can just as easily lead to failure.



Table 2. The five components of emotional intelligence at work

Self-awareness	The ability to recognize and understand one's personal moods, emotions, and drives and their effect on others. Without this capability, improvement in the other components of emotional intelligence is impeded.
Self-regulation	The ability to control or adjust to disruptive impulses and moods. Includes the ability to think before acting. Necessary for developing a reputation for trust and integrity.
Motivation	Internal motivation to achieve a goal with energy and persistence.
Empathy	Ability to understand and respond to the emotional needs of others. Essential in building personal relationships and customer service.
Social skills	Proficiency in managing relationships, building networks, and political shrewdness. Essential for leading change and persuading others.

Source: Reference 6.

Good grades in pharmacy school have little effect on long-term career success

Good grades may help new graduates get their first jobs; however, this is often because most new pharmacy graduates have generic resumes that make it hard for employers to distinguish among job applicants. Faced with little information about students, employers try to use grades to gain insight about new pharmacy graduates' intellectual abilities and work habits. However, employers really want to know whether a person will succeed in a future job, and school grades are not necessarily good indicators of an individual's ability to make it in the real world.

Therefore, employers also use resumes and personal references to assess prospective employees' potential for future success.¹³ They look for a record of accomplishments in school and work under the assumption that past behavior will help predict behavior in the future. The essential term to consider is "accomplishments." Rather than knowing that individuals *joined* organizations, employers want to know what they *accomplished* in those organizations (e.g., whether they held a leadership position, organized a major volunteer event, received any awards for their accomplishments). Employers also want to know what others have to say about prospective employees. They want specific recommendations from others that express the applicants' capabilities in various dimensions of performance, such as productivity, leadership, communication, teamwork, and service excellence. A good record of accomplishments on a resume and excellent recommendations from employers, coworkers, and professors can often overcome mediocre grades.

Although good grades may not be a good long-term predictor of success, they still have some value in judging graduating students. Good grades can indicate some mastery of professional skills, and excellent students are often the same ones who establish a record of leadership and accomplishments

at school. Nevertheless, good grades alone are not sufficient because the behaviors that make students excel in school may not be the same as behaviors that result in success after graduation. Success is based on other factors, including how much new graduates know, what they can do, the relationships they develop, and a certain amount of luck.

Steps for managing oneself

Many books presenting methods for better managing one's career and life are available in any bookstore. These books use a variety of approaches to appeal to different audiences, but all essentially make the following general recommendations to each reader: take responsibility for your life, know yourself, decide what you want, establish goals and objectives, and take action.

Step 1: Take responsibility for your life

Many people in this world suffer from *victimitis*, a disease in which sufferers choose to be victims of the world and refuse to take control of their careers and lives.¹⁴ They drift through life with little direction and blame others when things do not turn out well for them. They are the ones who say, "Look what you made me do," or "My boss keeps holding me back." They remain victims rather than take control.

Managers are prone to victimitis. They might feel that accepting blame would diminish them in the eyes of their followers. Their egos also may make it difficult to accept personal flaws. Therefore, they find ways to shift the blame. However, failure to take responsibility hurts the credibility of managers.^{4,5} It sends a bad message that can be interpreted in various undesirable ways, including, "I care more about my image than the organization" or "Do as I say, not as I do." Managers who fail to take responsibility are less effective.

Sufferers of victimitis are not able to learn from their failures or prevent future ones because failures are never their



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fault. Someone else is always the cause of their problems. Sufferers have a “powerless” view of the world and see themselves as victims of their parents, teachers, bosses, spouses, family, and fate. Indeed, some victims appear to get perverse pleasure in describing how the world is out to get them. Worst of all, the habit of playing the victim can spread to other people in an organization like a virus and turn a healthy pharmacy into a “whinery.” Unless these individuals take charge of their lives, they will always struggle to find personal success.

Sufferers of victimitis can change, but only if they recognize that they have the condition and are willing to change. Sufferers can start to turn things around by first banning excuse-laden or blame-oriented language from their vocabulary.¹⁵ Instead of saying, “My boss makes me so angry,” say, “I choose to let my boss’s behavior get to me.” Rather than saying, “There is too much work to do. It’s killing me!”, say, “I need to do a better job of prioritizing tasks and delegating work to technicians.” The word “me” in a complaint instead of “I” confirms a person’s passivity and helplessness, and it encourages continual negative behaviors.¹⁵ Using “I” indicates a person’s active role in a situation and suggests actions that a person can take to improve things.

Step 2: Know yourself

Self-awareness is an important part of leading and managing.^{6,7,16} Self-awareness is a person’s ability to have a deep understanding of one’s emotions, strengths, weaknesses, needs, and drives. People who have a high degree of self-awareness can identify how their individual nature and behaviors can affect their lives. Thus, they are able to develop strategies and habits to adjust to their personal weaknesses and strengths. For instance, managers who are aware of their tendency to interrupt others who are speaking might consciously develop the substitute habit of waiting until others are finished speaking their mind before talking. Alternatively, managers who recognize how their response to stress aggravates confrontational situations can use stress-control techniques (e.g., breathing exercises) that help control their response to that stress.

Self-awareness includes an understanding of personal characteristics and priorities.¹⁷ People who are highly self-aware clearly understand what is important to them and why. This helps in making difficult decisions such as deciding to pursue a lucrative job offer that conflicts with personal principles. People who are self-aware are better able to make decisions without worrying or second guessing themselves.⁷ Individuals with low self-awareness have more difficulty choosing what path to take and worry afterward whether they did the right thing.

One can improve self-awareness through self-assessment.^{18,19} Self-assessment consists primarily of answering the following questions: (1) What are my strengths? (2) What are my weaknesses? (3) What are my tendencies and habits?

What are my strengths? Many pharmacists believe they know their strengths but are probably wrong. More likely, they have never encountered situations that identify their true capabilities. The reason is that many pharmacists work in jobs that, although busy and stressful, do not effectively test their capabilities. Hence, they can go through their professional lives never putting their creativity, communication skills, sense of humor, or non–job-related capabilities to the test. To truly discover their strengths, they need to systematically challenge themselves with difficult goals and assess their success in achieving those goals.¹ When individuals continually challenge themselves in their professional and personal lives and assess their success, they discover where their strengths lie. In a similar vein, if they never place any real demands on their capabilities, they will never know what they can achieve.

The idea behind identifying one’s strengths is that strengths are what help people to succeed.^{20,21} One’s strengths increase a person’s visibility and positively differentiate individuals from others. Therefore, authors of self-improvement books often argue that people should focus on developing those strengths. Thus, pharmacists who excel at developing personal relationships might seek new situations that develop those capabilities even more (e.g., volunteering, leadership roles). Identifying strengths can also help people find careers that play to these strengths and allow them to stand out. This, in turn, gives them more opportunities for future success.

What are my weaknesses? If strengths help pharmacists succeed, weaknesses can cause them to fail. Therefore, some self-improvement gurus argue that individuals should identify how personal weaknesses, such as poor time management or the inability to delegate, hold them back in their professional life. For example, pharmacists may realize that their writing skills are not good enough for them to advance in a corporate environment, so they employ a personal writing coach to help develop their writing capabilities. The objective is to improve sufficiently upon one’s weaknesses to prevent them from inhibiting progress toward career goals.

What are my habits and tendencies? Our personal habits and tendencies are unconscious behaviors affecting how we work and live. They can help, hurt, or simply define us. Thus, they are important to understand and control.^{22,23} The majority of each person’s day is spent in habitual, unconscious routines that communicate both desirable and undesirable messages to others. Often, habitual behaviors say more to people than any words. Good habits save time by letting one complete tasks with little conscious thought. Bad habits can reduce a person’s effectiveness and even destroy a career.

Understanding and changing bad habits is an important part of self-management.¹ Bad habits can be unlearned if they are identified and consciously altered. Coworkers, friends, and family are important sources for identifying and helping change



bad habits. They can provide direct and indirect feedback about annoying behaviors.

Well-established steps exist for breaking bad habits.^{24,25} The first is to identify a habit to change and then tell others (e.g., coworkers or family members) about intentions to change. This both reinforces the intention to change and allows others to provide reminders whenever any backsliding to old habits occurs. The next step is to identify an alternative action to substitute for the undesired habitual behavior (e.g., chewing gum instead of smoking). This alternative fills the void left by stopping the behavior. Finally, progress in changing the habit needs to be monitored, preferably by recording success or failure on a daily calendar. At the end of each day, individuals can ask themselves if they were successful in changing the habitual behavior. If they succeed in stringing together a period of days (e.g., 21) without engaging in the behavior, they are likely to have broken the bad habit. Then the process of conquering another bad habit can begin.

Personal tendencies are more difficult to change than habits because they deal with an individual's nature. Unlike habits, they are not learned. They are part of who we are. Rather than changing personal tendencies, understanding their impact and how to adapt to them is important.

Many standardized tests are available for helping people understand the tendencies associated with their psychological makeup and how they approach and solve problems. One of the best known is the Myers-Briggs test. It assesses a person's preferences for communication, work, personal relationships, and leadership. It identifies the degree to which an individual is introverted or extroverted, intuitive or sensing, thinking or feeling, and judging or perceiving. From these preferences, people can be classified into 16 different personality types with unique tendencies of behaviors. Although some limits exist regarding what can be validly learned from the Myers-Briggs test,²⁶ it can provide insight about how we make decisions and allow us to adjust for these tendencies when necessary. Self-assessments using tests like the Myers-Briggs can help us understand how we behave and suggest ways to be more effective in our lives.

Step 3: Decide what you want to do

An important step in knowing oneself is to establish personal priorities. This consists of discovering what kind of life one wants to lead and what values one considers important. This process is often complicated by a broad range of personal, situational, and environmental factors that obscure one's true feelings. For instance, our understanding of our personal priorities is influenced by our parents, family, friends, coworkers, religious organizations, and others. Often their priorities can become jumbled up in ours, making it difficult to screen our personal wants from theirs. Developing a personal mission statement is one way of establishing priorities.

A personal mission statement is a broad and specific state-

ment of direction that is meant to guide one's future actions.²⁷ It is a verbal declaration of why a person was put on earth and what that person wants to achieve while there. A personal mission might be as simple as "to leave the world in better condition than when I came into it" or as complex as a person wants.

Knowing what is important to one's personal mission is useful in decision making and aligning personal values with those of others (e.g., one's employer).^{27,28} This is key for leaders and managers who may face difficult choices when dealing with coworkers, upper management, and patients. Knowledge about one's personal mission can help when choosing what leadership positions to take and professional roles to assume. It can also help in setting personal guidelines for behaviors, approaches to problems, and personal values. If these things are not explicit in the mind of a leader, setting a consistent vision for the organization and behaving in a steady, dependable manner will be more difficult. In other words, if leaders do not know what they stand for, it will be hard to set a vision for followers and act in a way consistent with that vision.

A single way of writing a mission statement does not exist because it is personal, although many people have preferences. Some have suggested that it be as short as a single sentence in length. Others have argued that a good mission statement should be simple enough to be easily understood by a 12-year-old child or memorable enough to be able to cite from memory at gunpoint.²⁹ Nevertheless, there are no wrong or right mission statements. The only requirement is that the mission statement have personal significance. The individual writing a mission statement is the only one who can judge its appropriateness. Several examples of mission statements are listed below.²⁹

- To live in the highest state of consciousness, the state of enlightenment.
- To raise a family and to give to others.
- To be the kind of person my dog thinks I am.

Some people may think that a mission statement is too confining, but a clearly defined mission can help simplify a person's life and reduce stress. In life, everyone will face difficult decisions. Knowing one's personal mission can help prioritize the tradeoffs associated in making these decisions. Understanding what is most important in our lives will help in choosing the best paths with a minimum of anxiety and doubt. Understanding one's mission is essential in balancing the worklife strains faced by pharmacists. Success in meeting the sometimes conflicting goals of employers and our own personal needs requires that we articulate our priorities and negotiate boundaries in a manner that strikes acceptable worklife balances.² Most employers are willing to work with pharmacists to achieve this equilibrium if it means that pharmacists will be less stressed and distracted and more committed at work.³⁰ It is also essential for true professional and personal fulfillment.³¹ However, negotiation is difficult if pharmacists do not have a clear understanding of their goals.



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Step 4: Establish goals and objectives to achieve your mission

After pharmacists have started the first steps in the lifelong process of self-assessment, they should be able to form a better plan for personal success. They may never have a perfect picture of their future but will be further along than before. Now, they can begin working toward achieving the life they envision.

Achieving one's life mission is accomplished by identifying personal and career goals consistent with that mission and working to achieve them. Limiting one's goals to a manageable number is important, because too many goals can be overwhelming. Often, focusing on just three or four goals that are important and meaningful is preferable. For student pharmacists, these goals may include identifying a future employer, being elected to a student office, and enriching a personal relationship. For practicing pharmacists, the goals might consist of making a career change, establishing financial independence, and spending more time with family.

After major goals have been identified, separate objectives should be developed, in writing, for achieving each goal. Objectives are more specific declarations than goals of what an individual wants to achieve. Objectives establish precise, measurable outcomes to be achieved in a defined time period. For example, a goal of achieving financial independence might be set into action by establishing an objective to save 15% of gross salary by the end of the year. At the end of the year, whether this specific objective has been accomplished will be obvious.

Writing down objectives makes them seem more real and urgent than objectives that are left to float around vaguely in one's head.³² The process of writing one's objectives also increases commitment toward achieving them. Identifying both short-term (weekly or monthly) and long-term (yearly) objectives is important. Short-term objectives drive immediate action, while long-term ones encourage a strategic direction toward one's final goals.

When developing objectives, asking what skills, knowledge, and experience are needed to achieve one's final goals is important.²⁰ One way of doing this is to talk to people who have success in achieving similar objectives. Schedule an informational interview to identify how these individuals achieved their success, their path to achieving it, the capabilities they needed to succeed, and their recommendations to people seeking similar opportunities. Then, prepare a list of objectives toward gaining any missing skills, knowledge, and experiences identified. For example, pharmacists seeking a switch from community pharmacy practice to long-term care may set the following objectives: speak to three people about jobs in long-term care facilities, take a course in gerontology to help increase their skills, and plan to attend a meeting of the American Society of Consultant Pharmacists within the next year. Periodic checks will help the pharmacists monitor progress toward achieving

their stated goals.

Goal-directed behavior is useful because it continually moves individuals toward their final destination. Working toward a goal can also reduce stress because individuals feel greater control and movement toward success.³³ As long as they can see some progress toward their goals, everyday problems and aggravations are easier to overlook.

Step 5: Take action

Students and pharmacists must begin working on their strategies for success immediately. They should not wait until next week or next year to start getting serious about their careers and work life. Today, they should ask themselves, "Where do I want to go?" "What skills and knowledge do I need to develop?" "What personal habits are holding me back?"

If this is overwhelming, take small steps. One strategy that may work for some pharmacists is to take 5 minutes to work on one thing that moves them toward achieving their personal mission. If, after 5 minutes, they do not feel like doing more, they should give themselves permission to stop. Nevertheless, they may find that after they start, they continue for much longer.

Every student and new pharmacist should look at their resume and ask what listed accomplishments and skills stand out. When an employer sees their resume, what items clearly indicate that their potential value and success to an employer? Have friends or coworkers provide feedback about the resume. Make it clear to friend or coworkers that they should provide an honest assessment of what they see. If gaps exist, take actions to fill them.

Finally, buy a book or attend a class. An entire industry exists for helping individuals manage their lives and careers. Go to a bookstore and walk the shelves of the self-help section. Find a book that looks useful and read it. Attend a career- or skill-development class. Many employers will pay for and even provide them.

Managing oneself and others

A major goal of self-management for managers is to develop interpersonal skills necessary to lead others. These interpersonal skills have been labeled emotional intelligence in the management literature, and they have been recently promoted as a critical set of capabilities necessary for people to successfully manage others.^{6,7,16} Developing these interpersonal skills is vital in leading others and getting their commitment in the workplace. Unlike the intellectual intelligence measured by IQ tests, emotional intelligence describes the set of soft skills necessary for dealing with people.

Emotional intelligence is made up of the following capabilities: self-awareness, self-regulation, motivation, empathy, and social skills (Table 2). The five components of emotional intelligence give managers and leaders the ability to successfully adapt to different situations.⁶ Identifying deficiencies in emo-



tional intelligence and developing them is crucial for pharmacy managers.⁹ Suggestions for pharmacists who wish to increase their emotional intelligence are as follows:

- (1) Take self-assessment tests. They can help pharmacists better understand themselves and identify deficiencies that need improvement.
- (2) Ask for formal feedback as part of any annual evaluation from an employer. Communicate a desire for honest feedback that can be used in personal development.
- (3) Identify and cultivate people who will provide mentorship and advice on personal development. Senior coworkers, professional acquaintances, and even experienced friends can offer valuable information about how to improve and succeed.
- (4) Read self-improvement books. They can offer insightful examples and advice to supplement what is learned from mentors and advisors.
- (5) Take time out to reflect on life and work. Reflection is the key to learning from personal experience and readings. Develop the habit of replaying and analyzing personal and professional situations that occur. Ask, "What can I learn from this situation? What would I do differently? What would happen if I did so?"

Conclusion

The subject of managing oneself is not new. The problem for student pharmacists and new practitioners is that little has been written for them specifically. Although some articles and book chapters have discussed time management,³⁴ stress management,³⁰ supervisory training,³⁵ and career planning,^{36,37} no source covers the broader domain of managing oneself. This is a problem given its role in developing strong leaders,^{28,38} establishing trust in coworkers,^{39–41} building good relationships with patients,⁴² and effectively working with one's boss.⁴³

Pharmacists who wish to avoid complacency in their careers may find it useful to heed the following advice: "It is never too early to start preparing for one's next job." This may sound especially strange for individuals who are happy in their current positions. However, few of us will find a single job in which we will work all of our lives. Most people have multiple jobs and careers over a lifetime. Pharmacists who see their current job as preparation for their next position are more likely to be proactive about self-development. They will be more likely to seek opportunities in their current position that challenge them and provide useful experience.

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Assessment Questions

Instructions: The assessment test for this activity must be taken online; please see “CPE Processing” below for further instructions. There is only one correct answer to each question. This CPE will be available online at www.pharmacist.com no later than April 30, 2009.

1. **Lily Tomlin, a famous actor and comedienne, once declared, “All my life, I always knew I wanted to be somebody. I see now that I should’ve been more specific.” What was she saying?**
 - a. She was blaming others for her difficulties in life.
 - b. She was saying that she never really took responsibility for her life.
 - c. She was stating that had a poorly defined personal mission.
 - d. She was saying that she never really was aware of her problems.
2. **Which of the following is true about “managing yourself”?**
 - a. To take control of your life, you must stop blaming others for your personal failures.
 - b. Good grades achieved in school have a long-lasting effect on an individual’s success after graduation.
 - c. The Meyers-Briggs test is designed to test the five dimensions of emotional intelligence.
 - d. Knowing *what you don’t want in life* is more important than *knowing what you want in life*.
3. **The statement, “I want to graduate from pharmacy school in spring 2011 with a minimum 3.5 grade point average,” is an example of which of the following?**
 - a. Objective
 - b. Mission
 - c. Goal
 - d. Vision
4. **Which of the following describes a condition in which individuals hold a “powerless” view of themselves within the world?**
 - a. Blameosis
 - b. Victimitis
 - c. Helpless-tosis
 - d. Whinery
5. **Which of the following is a productive managerial behavior?**
 - a. Asking people to do things that one refuses to do him/herself
 - b. Getting even with people one does not like
 - c. Saying whatever comes to mind
 - d. Critically assessing employees’ performance
6. **Which of the following is the hardest thing to change in managing oneself?**
 - a. Goals
 - b. Habits
 - c. Objectives
 - d. Personal tendencies
7. **A.H. is a pharmacist who takes on extra responsibilities at work. When asked why he worked much harder than the boss expected him to, A.H. replied, “One never knows what the future will bring. I am learning now to prepare for my next job.” The purpose of using one’s current job to train for future jobs is a good strategy in managing oneself because it helps pharmacists to do which of the following?**
 - a. Hop from job to job to maximize salary
 - b. Make one’s employer happy
 - c. Avoid being complacent about one’s professional development
 - d. Gain the upper hand in negotiations with employers
8. **D.P. asked a mentor to review her resume for ways to improve it in the eyes of potential employers. After looking over the resume, her mentor said that D.P.’s resume showed her to be very busy but did not show her ability to succeed in the future. What should D.P. do to appeal to employers?**
 - a. Show what she has accomplished
 - b. Provide her grade point average to demonstrate her intelligence
 - c. List the organizations in which she has been a member
 - d. Add more items to the resume of the activities in which she has participated
9. **Several years ago, a research study in the *Journal of Personality and Social Psychology* showed that incompetent people are often supremely confident in their abilities. In fact, they are often more confident than people who do things well. This finding shows that overconfidence is associated with a deficiency in which of the following?**
 - a. Self-regulation
 - b. Social skills
 - c. Self-awareness
 - d. Empathy
10. **Which of the following components of emotional intelligence is associated with the ability to persuade others to your point of view?**
 - a. Self-regulation
 - b. Social skills
 - c. Self-awareness
 - d. Empathy



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08-506

Hidden costs of free samples

With the downturn in the economy, expect more patients to seek free medication samples from their ambulatory care clinics and physicians. Sample medications often are dispensed to patients in physician offices, but patients usually do not realize the potential for harm. Frequently, samples are dispensed without computer screening for drug interactions, duplicate therapies, allergies, or contraindications. Sometimes sample medication is outdated or deteriorated. Pharmacy oversight of the dispensing process is often lacking. Patient education and drug recalls may be overlooked, and unsecured storage can allow easy access to prescription drugs.

Lotion or eye drop?

Lack of patient administration instructions and warnings on the labels and packages of samples also can be problematic. Recently, a patient experienced severe burning in her eyes and blurred vision when she instilled what she thought were eye drops. A coworker noticed the



Figure 1. Does this package contain 200 mg or 600 mg Celebrex? The patient's allergist had given her the product for topical application after allergy shots. Unfortunately, it was in a small plastic container very similar to ophthalmic containers. The woman inadvertently placed it next to the eye

drops she kept at work and grabbed the wrong bottle. She saw her ophthalmologist and her eye was flushed, but the woman reported blurred vision for several hours.

Ink for eczema

In a second case, a dermatologist gave what he thought was a sample 30-g tube of tacrolimus (Protopic—Astellas) 0.1% ointment to a 17-year-old female patient, telling her to apply it for treatment of facial contact dermatitis/eczema. The patient applied it as directed over her facial rash. Imagine her surprise when the contents turned out to be nothing more than ink from a promotional felt tip marker manufactured to look like the drug product (Figure 2)! The patient scrubbed her face and

was seen in an emergency room to treat a local reaction to the ink. A topical steroid was prescribed with rapid resolution of symptoms, and no permanent sequelae. Reportedly, the manufacturer has ceased distributing these promotional markers dressed up to look like their product.

Dosage confusion

In another case, a nurse who works in patient safety reported an issue with packages of sample celecoxib (Celebrex—Pfizer) that she received recently from her rheumatologist along with a prescription for Celebrex 200 mg twice daily. The outside carton of each sample pack stated "Celebrex 200 mg," which made her think that each package contained a 200-mg capsule. She found, however, that the box contained three capsules on a blister card that also stated "200 mg" (Figure 1).

The nurse felt she needed more information to know whether she should take three capsules for a 200-mg dose or just

one capsule. She called the physician's office and was told that this question is asked frequently. Many of this physician's patients are senior citizens, who, even if unsure, may not call to clarify the dose. A drug information professional at Pfizer confirmed that the company has received reports of overdoses when all three capsules (600 mg) were taken by patients who thought this was a 200-mg dose.

Counseling needed

When pharmacists are made aware that a patient has been supplied with drug samples, they should ensure that the patient understands how to use the medication properly. Sample medications should be treated like new prescriptions with respect to screening for drug inter-



Figure 2. Which one contains medication and which one is merely a pen?

actions, duplicate therapies, allergies, and contraindications. When obtaining and entering patient demographic and health information, ask if any sample medications have been provided. If they have been, ask to view them and provide any necessary missing information. Be sure to check the expiration date. In addition, you can enlist the help of your patients by telling them to notify you whenever sample medications have been provided so that you can add the medication to their prescription history in your pharmacy computer system.

The case of the lotion packaged in a container resembling an ophthalmic product should serve as a reminder to community pharmacists who dispense any nonophthalmic topical in a container that looks like an eye drop. Counsel patients on proper use and apply an auxiliary sticker that describes the proper route of administration.

—**Institute for Safe Medication Practices**

The reports described in this column were received through the ISMP Medication Errors Reporting Program (MERP). Errors, close calls, or hazardous conditions may be reported on the Institute for Safe Medication Practices (www.ismp.org) website or communicated directly to ISMP by calling 800-FAIL-SAF (800-324-5723) or e-mailing ismpinfo@ismp.org. The topics in this column are covered in greater detail in *Medication Errors, 2nd edition*, written by ISMP President Michael R. Cohen, BPharm, MS, ScD. The book may be purchased from APhA at www.pharmacist.com or by calling 800-878-0729.

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CREON® 20 MINIMICROSPHERES® (Pancrelipase Delayed-release Capsules, USP)

500199 Rev Feb 2006

PRESCRIBING INFORMATION

DESCRIPTION

CREON® 20 Capsules are orally administered and contain pancrelipase (lipase 20,000 USP Units, protease 75,000 USP Units and amylase 66,400 USP Units per capsule) which is of porcine pancreatic origin. Each CREON 20 Capsule is filled with 497 mg of delayed-release MINIMICROSPHERES®.

Inactive ingredients include dibutyl phthalate, dimethicone, hydroxypropylmethylcellulose phthalate, light mineral oil and polyethylene glycol. The capsule shells contain gelatin, red iron oxide, titanium dioxide and yellow iron oxide. The capsule imprinting ink contains dimethicone, 2-ethoxyethanol, shellac, soya lecithin, and titanium dioxide.

CLINICAL PHARMACOLOGY

The pancreatic enzymes in CREON 20 Capsules are enteric-coated to resist gastric destruction or inactivation. The pancreatic enzymes catalyze the hydrolysis of fats to glycerol and fatty acids, protein into proteoses and derived substances and starch into dextrins and short chain sugars.

INDICATIONS

CREON 20 Capsules are indicated for patients with pancreatic exocrine insufficiency as is often associated with:

- cystic fibrosis
- chronic pancreatitis
- post-pancreatectomy
- post-gastrointestinal bypass surgery (e.g., Billroth II gastroenterostomy)
- ductal obstruction from neoplasm (e.g., of the pancreas or common bile duct)

CONTRAINDICATIONS

CREON 20 Capsules are contraindicated in the early stages of acute pancreatitis or in patients who are known to be hypersensitive to pork protein.

WARNINGS

Should symptoms of hypersensitivity appear, discontinue medication and initiate symptomatic and supportive therapy if necessary.

Strictures in the ileo-cecal region and/or ascending colon have been reported in cystic fibrosis patients treated with high doses of high-potency pancreatic enzyme supplements containing 20,000 or greater USP units of lipase per capsule. The underlying mechanism is unknown, but caution should be exercised when doses in excess of 6,000 USP units lipase per kg per meal fail to resolve symptoms, especially in patients with a history of intestinal complications such as meconium ileus equivalent, short bowel syndrome, surgery or Crohn's disease. If symptoms suggestive of gastrointestinal obstruction occur, the possibility of bowel stricture should be investigated including evaluation of pancreatic enzyme therapy.

PRECAUTIONS

CREON 20 Capsules MINIMICROSPHERES SHOULD NOT BE CRUSHED OR CHEWED or placed on foods having a pH greater than 5.5. These can dissolve the protective enteric coating resulting in early release of enzymes, irritation of oral mucosa, and/or loss of enzyme activity.

Information for Patients

CREON 20 Capsules are a pancreatic enzyme product prescribed to promote improved digestion of foods, especially fat. The prescribed dosage should be taken with each meal and snack or as directed by the physician. The capsules can be swallowed whole, or the contents poured on soft, bland food. Care should be taken to avoid chewing or crushing of the capsule contents, which can result in early release of enzymes, irritation of oral mucosa, and/or loss of enzyme activity. Patients should maintain adequate fluid intake. The prescribed dose range should not be exceeded without calling your doctor.

The most common adverse reactions involve the stomach and intestine including diarrhea, nausea, vomiting, bloating, constipation, stomach cramps or pain. If these symptoms are persistent, contact your doctor.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies in animals have not been performed to evaluate carcinogenic potential.

Pregnancy, Category C

Animal reproduction studies have not been conducted with pancrelipase. It is also not known whether pancrelipase can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. CREON 20 Capsules should be given to a pregnant woman only if clearly needed.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when CREON 20 Capsules are administered to a nursing mother.

ADVERSE REACTIONS

The most frequently reported adverse reactions to pancreatic enzyme-containing products are gastrointestinal in nature which may include nausea, vomiting, bloating, cramping, constipation or diarrhea. Less frequently, allergic-type reactions have also been observed. Very high doses of pancreatin have been associated with hyperuricosuria and hyperuricemia.

DOSAGE AND ADMINISTRATION

Clinical experience should dictate initial starting dose. Doses should be taken during meals or snacks, not before or after. Do not take without food.

Adults and Children Over 6 Years Old

Usual initial starting dosage is one CREON 20 Capsule per meal or snack.

Children Under 6 Years Old

The exact dosage of CREON 20 Capsules should be selected based on clinical experience for this age group.

For cystic fibrosis patients, typical doses are 1,500 - 3,000 USP lipase units/kg/meal. Dosage should be adjusted according to the severity of the disease, control of steatorrhea and maintenance of good nutritional status. Doses in excess of 6,000 USP lipase units/kg/meal are not recommended.

Dose increases, if required, should occur with careful monitoring of body weight and stool fat content. When changing strengths of pancreatic enzyme products, care should be taken to maintain equivalent lipase units for each divided dosage.

It is important to ensure adequate hydration of patients at all times while taking pancreatic enzymes.

Where swallowing of capsules is difficult, the capsules may be carefully opened and the MINIMICROSPHERES added to a small amount of soft food, with a pH less than 5.5. The soft food should be swallowed immediately without chewing and followed with a glass of water or juice to insure swallowing.

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PRESCRIBING INFORMATION

DESCRIPTION

CREON® 5 Capsules are orally administered and contain pancrelipase (lipase 5,000 USP Units, protease 18,750 USP Units and amylase 16,600 USP Units per capsule) which is of porcine pancreatic origin. Each CREON 5 Capsule is filled with 124 mg of delayed-release MINIMICROSPHERES®.

Inactive ingredients include dibutyl phthalate, dimethicone, hydroxypropylmethylcellulose phthalate, light mineral oil and polyethylene glycol. The capsule shells contain gelatin, red iron oxide, titanium dioxide, yellow iron oxide and FD & C blue No. 2. The capsule imprinting ink contains dimethicone, 2-ethoxyethanol, shellac, soya lecithin, and titanium dioxide.

CLINICAL PHARMACOLOGY

The pancreatic enzymes in CREON 5 Capsules are enteric-coated to resist gastric destruction or inactivation. The pancreatic enzymes catalyze the hydrolysis of fats to glycerol and fatty acids, protein into proteoses and derived substances and starch into dextrins and short chain sugars.

INDICATIONS

CREON 5 Capsules are indicated for patients with pancreatic exocrine insufficiency as is often associated with:

- cystic fibrosis
- chronic pancreatitis
- post-pancreatectomy
- post-gastrointestinal bypass surgery (e.g., Billroth II gastroenterostomy)
- ductal obstruction from neoplasm (e.g., of the pancreas or common bile duct)

CONTRAINDICATIONS

CREON 5 Capsules are contraindicated in the early stages of acute pancreatitis or in patients who are known to be hypersensitive to pork protein.

WARNINGS

Should symptoms of hypersensitivity appear, discontinue medication and initiate symptomatic and supportive therapy if necessary.

Strictures in the ileo-cecal region and/or ascending colon have been reported in cystic fibrosis patients treated with high doses of high-potency pancreatic enzyme supplements containing 20,000 or greater USP units of lipase per capsule. The underlying mechanism is unknown, but caution should be exercised when doses in excess of 6,000 USP units lipase per kg per meal fail to resolve symptoms, especially in patients with a history of intestinal complications such as meconium ileus equivalent, short bowel syndrome, surgery or Crohn's disease. If symptoms suggestive of gastrointestinal obstruction occur, the possibility of bowel stricture should be investigated including evaluation of pancreatic enzyme therapy.

PRECAUTIONS

CREON 5 Capsules MINIMICROSPHERES SHOULD NOT BE CRUSHED OR CHEWED or placed on foods having a pH greater than 5.5. These can dissolve the protective enteric coating resulting in early release of enzymes, irritation of oral mucosa, and/or loss of enzyme activity.

Information for Patients

CREON 5 Capsules are a pancreatic enzyme product prescribed to promote improved digestion of foods, especially fat. The prescribed dosage should be taken with each meal and snack or as directed by the physician. The capsules can be swallowed whole, or the contents poured on soft, bland food. Care should be taken to avoid chewing or crushing of the capsule contents, which can result in early release of enzymes, irritation of oral mucosa, and/or loss of enzyme activity. Patients should maintain adequate fluid intake. The prescribed dose range should not be exceeded without calling your doctor.

The most common adverse reactions involve the stomach and intestine including diarrhea, nausea, vomiting, bloating, constipation, stomach cramps or pain. If these symptoms are persistent, contact your doctor.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies in animals have not been performed to evaluate carcinogenic potential.

Pregnancy, Category C

Animal reproduction studies have not been conducted with pancrelipase. It is also not known whether pancrelipase can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. CREON 5 Capsules should be given to a pregnant woman only if clearly needed.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when CREON 5 Capsules are administered to a nursing mother.

ADVERSE REACTIONS

The most frequently reported adverse reactions to pancreatic enzyme-containing products are gastrointestinal in nature which may include nausea, vomiting, bloating, cramping, constipation or diarrhea. Less frequently, allergic-type reactions have also been observed. Very high doses of pancreatin have been associated with hyperuricosuria and hyperuricemia.

DOSAGE AND ADMINISTRATION

Clinical experience should dictate initial starting dose. Doses should be taken during meals or snacks, not before or after. Do not take without food.

Adults and Children Over 6 Years Old

Usual initial starting dosage is two to four CREON 5 Capsules per meal or snack.

Children Under 6 Years Old

The exact dosage of CREON 5 Capsules should be selected based on clinical experience for this age group. Patients can be started on one to two capsules per meal or snack.

For cystic fibrosis patients, typical doses are 1,500 - 3,000 USP lipase units/kg/meal. Dosage should be adjusted according to the severity of the disease, control of steatorrhea and maintenance of good nutritional status. Doses in excess of 6,000 USP lipase units/kg/meal are not recommended.

Dose increases, if required, should occur with careful monitoring of body weight and stool fat content. When changing strengths of pancreatic enzyme products, care should be taken to maintain equivalent lipase units for each divided dosage. It is important to ensure adequate hydration of patients at all times while taking pancreatic enzymes.

Where swallowing of capsules is difficult, the capsules may be carefully opened and the MINIMICROSPHERES added to a small amount of soft food, with a pH less than 5.5. The soft food should be swallowed immediately without chewing and followed with a glass of water or juice to insure swallowing.

HOW SUPPLIED

CREON 5 MINIMICROSPHERES (Pancrelipase Delayed-release Capsules, USP) are available in a two-piece gelatin capsule (orange opaque top half, blue opaque bottom half) imprinted in white with "SOLVAY" and "1205". Each capsule contains tan-colored delayed-release MINIMICROSPHERES of pancrelipase supplied in bottles of:

100.....NDC 0032-1205-01

250.....NDC 0032-1205-07

CREON 5 Capsules must be stored at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F).

[See USP Controlled Room Temperature.] PROTECT FROM MOISTURE. DO NOT REFRIGERATE. Dispense in tight, light-resistant containers. For human consumption only.

Rx only

Manufactured By:
Solvay Pharmaceuticals GmbH,
Hannover, Germany

Marketed by:

Solvay Pharmaceuticals, Inc.
Marietta, GA 30062

500197 Rev Feb 2006

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R_x only

CREON® 10
MINIMICROSPHERES® (Pancrelipase Delayed-release Capsules, USP)

500198 Rev Feb 2006

PRESCRIBING INFORMATION

DESCRIPTION

CREON® 10 Capsules are orally administered and contain pancrelipase (lipase 10,000 USP Units, protease 37,500 USP Units, and amylase 33,200 USP Units per capsule) which is of porcine pancreatic origin. Each CREON 10 Capsule is filled with 249 mg of delayed-release MINIMICROSPHERES®.

Inactive ingredients include dibutyl phthalate, dimethicone, hydroxypropylmethylcellulose phthalate, light mineral oil and polyethylene glycol. The capsule shells contain black iron oxide, gelatin, red iron oxide, titanium dioxide, and yellow iron oxide. The capsule imprinting ink contains dimethicone, 2-ethoxyethanol, shellac, soya lecithin, and titanium dioxide.

CLINICAL PHARMACOLOGY

The pancreatic enzymes in CREON 10 Capsules are enteric-coated to resist gastric destruction or inactivation. The pancreatic enzymes catalyze the hydrolysis of fats to glycerol and fatty acids, protein into proteoses and derived substances and starch into dextrins and short chain sugars.

INDICATIONS

CREON 10 Capsules are indicated for patients with pancreatic exocrine insufficiency as is often associated with:

- cystic fibrosis
- chronic pancreatitis
- post-pancreatectomy
- post-gastrointestinal bypass surgery (e.g., Billroth II gastroenterostomy)
- ductal obstruction from neoplasm (e.g., of the pancreas or common bile duct)

CONTRAINDICATIONS

CREON 10 Capsules are contraindicated in the early stages of acute pancreatitis or in patients who are known to be hypersensitive to pork protein.

WARNINGS

Should symptoms of hypersensitivity appear, discontinue medication and initiate symptomatic and supportive therapy if necessary.

Strictures in the ileo-cecal region and/or ascending colon have been reported in cystic fibrosis patients treated with high doses of high-potency pancreatic enzyme supplements containing 20,000 or greater USP units of lipase per capsule. The underlying mechanism is unknown, but caution should be exercised when doses in excess of 6,000 USP units lipase per kg per meal fail to resolve symptoms, especially in patients with a history of intestinal complications such as meconium ileus equivalent, short bowel syndrome, surgery or Crohn's disease. If symptoms suggestive of gastrointestinal obstruction occur, the possibility of bowel stricture should be investigated including evaluation of pancreatic enzyme therapy.

PRECAUTIONS

CREON 10 Capsules MINIMICROSPHERES SHOULD NOT BE CRUSHED OR CHEWED or placed on foods having a pH greater than 5.5. These can dissolve the protective enteric coating resulting in early release of enzymes, irritation of oral mucosa, and/or loss of enzyme activity.

Information for Patients

CREON 10 Capsules are a pancreatic enzyme product prescribed to promote improved digestion of foods, especially fat. The prescribed dosage should be taken with each meal and snack or as directed by the physician. The capsules can be swallowed whole, or the contents poured on soft, bland food. Care should be taken to avoid chewing or crushing of the capsule contents, which can result in early release of enzymes, irritation of oral mucosa, and/or loss of enzyme activity. Patients should maintain adequate fluid intake. The prescribed dose range should not be exceeded without calling your doctor.

The most common adverse reactions involve the stomach and intestine including diarrhea, nausea, vomiting, bloating, constipation, stomach cramps or pain. If these symptoms are persistent, contact your doctor.

Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies in animals have not been performed to evaluate carcinogenic potential.

Pregnancy, Category C

Animal reproduction studies have not been conducted with pancrelipase. It is also not known whether pancrelipase can cause fetal harm when administered to a pregnant woman or can affect reproduction capacity. CREON 10 Capsules should be given to a pregnant woman only if clearly needed.

Nursing Mothers

It is not known whether this drug is excreted in human milk. Because many drugs are excreted in human milk, caution should be exercised when CREON 10 Capsules are administered to a nursing mother.

ADVERSE REACTIONS

The most frequently reported adverse reactions to pancreatic enzyme-containing products are gastrointestinal in nature which may include nausea, vomiting, bloating, cramping, constipation or diarrhea. Less frequently, allergic-type reactions have also been observed. Very high doses of pancreatin have been associated with hyperuricosuria and hyperuricemia.

DOSAGE AND ADMINISTRATION

Clinical experience should dictate initial starting dose. Doses should be taken during meals or snacks, not before or after. Do not take without food.

Adults and Children Over 6 Years Old

Usual initial starting dosage is one to two CREON 10 Capsules per meal or snack.

Children Under 6 Years Old

Usual initial starting dosage is up to one CREON 10 Capsule per meal or snack.

For cystic fibrosis patients, typical doses are 1,500 - 3,000 USP lipase units/kg/meal. Dosage should be adjusted according to the severity of the disease, control of steatorrhea and maintenance of good nutritional status. Doses in excess of 6,000 USP lipase units/kg/meal are not recommended.

Dose increases, if required, should occur with careful monitoring of body weight and stool fat content. When changing strengths of pancreatic enzyme products, care should be taken to maintain equivalent lipase units for each divided dosage. It is important to ensure adequate hydration of patients at all times while taking pancreatic enzymes.

Where swallowing of capsules is difficult, the capsules may be carefully opened and the MINIMICROSPHERES added to a small amount of soft food, with a pH less than 5.5. The soft food should be swallowed immediately without chewing and followed with a glass of water or juice to insure swallowing.

HOW SUPPLIED

CREON 10 MINIMICROSPHERES (Pancrelipase Delayed-release Capsules, USP) are available in a two-piece gelatin capsule (brown opaque top half, natural transparent bottom half) imprinted in white with "SOLVAY" and "1210". Each capsule contains tan-colored delayed-release MINIMICROSPHERES of pancrelipase supplied in bottles of:

100.....NDC 0032-1210-01

250.....NDC 0032-1210-07

CREON 10 Capsules must be stored at 25°C (77°F); excursions permitted to 15°-30°C (59°-86°F).

[See USP Controlled Room Temperature.] PROTECT FROM MOISTURE. DO NOT REFRIGERATE. Dispense in tight, light-resistant containers. For human consumption only.

Manufactured By:

Solvay Pharmaceuticals GmbH
Hannover, Germany

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500198 Rev Feb 2006

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PANGESTYME™ IS UNAVAILABLE, BUT...

**YOU'LL BE HAPPY TO KNOW
CREON® IS STILL THERE FOR YOU.**

CREON® didn't become the #1-prescribed pancreatic enzyme brand overnight.¹
We've had over 20 years of success helping patients lead healthier lives.

INDICATION

CREON® is indicated for patients with pancreatic exocrine insufficiency as is often associated with cystic fibrosis, chronic pancreatitis, post-pancreatectomy, post-gastrointestinal bypass surgery, and ductal obstruction from neoplasm.

IMPORTANT SAFETY INFORMATION

- Contraindications: CREON® is contraindicated in the early stages of acute pancreatitis or in patients who are known to be hypersensitive to pork protein.
- Warnings: Should symptoms of hypersensitivity appear, discontinue medication and initiate symptomatic and supportive therapy if necessary.
- Adverse Reactions: The most frequently reported adverse reactions to pancreatic enzyme-containing products are gastrointestinal in nature which may include nausea, vomiting, bloating, cramping, constipation or diarrhea. Less frequently, allergic-type reactions have also been observed. Very high doses of pancreatin have been associated with hyperuricosuria and hyperuricemia.

REFERENCE: 1. IMS Health® IMS National Prescription Audit™, December 2008.

CREON is a registered trademark of Solvay Pharmaceuticals, Inc.

Please see full Prescribing Information on the previous pages.

Pangestyme (Pancrelipase Delayed-Release Capsules) is a trademark of ETHEX Corporation.

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Solvay
Pharmaceuticals



CREON®
(Pancrelipase Delayed-Release Capsules, USP)

CREON®: a tradition of trust

#1-prescribed pancreatic enzyme¹

for more information call 1-888-410-2806