



DEPARTMENT OF THE AIR FORCE
HEADQUARTERS UNITED STATES AIR FORCE
WASHINGTON DC

JUN 24 2003

MEMORANDUM FOR SEE DISTRIBUTION

FROM: HQ USAF/SG
110 Luke Avenue, Room 400
Bolling AFB, DC 20032-7050

SUBJECT: Air Force Medical Service Policy on Force Health Protection Prescription Products

The Assistant Secretary of Defense for Health Affairs (ASD(HA)) Memorandum, Policy for Use of Force Health Protection Prescription Products FHPPP, dated 24 Apr 03, (attachment 1) and the Under Secretary of Defense for Personnel and Readiness (USD(P&R)) Memorandum, Requirements Associated with the Food and Drug Administration of Pyridostigmine Bromide Tablets as Nerve Agent Pretreatment, dated 27 Mar 03 (attachment 2), direct procedures for managing FHPPP. IAW these policy memorandums, all Medical Treatment Facilities (MTFs) are directed to implement these policies as written and to utilize the following additional guidance.

FHPPP include, but are not limited to, atropine/2-PAM chloride/CANA auto-injectors, certain antimicrobials including antimalarials, and pyridostigmine bromide (PB) tablets. These items may not be issued without a prescription. When the Combatant Command issues instructions to dispense FHPPP to service members, the Combatant Command SG or other authorized physician may issue a blanket prescription (see attachment 1). If a blanket prescription is not issued, a credentialed health care provider may write individual prescriptions for FHPPP when appropriate. The individual prescriptions must address the same requirements as described in the blanket prescription policy. The health care provider will ensure necessary medical screening is accomplished prior to dispensing the FHPPP. The administration of all FHPPP shall be preceded and/or accompanied by appropriate education to ensure that recipients are aware of the exclusion criteria, dosing information, potential side effects and recommended responses, sources for additional information, and any other information appropriate for the proper use of the product.

Medical Logistics Activities will bulk issue FHPPP to troop commanders or individually issue them to deploying members (the troop commander/individual acts only as a courier to deliver the FHPPP to the medical logistics function at the deployed location). Once directed by the Combatant Commander to actually dispense FHPPP to service members, the products will be issued by qualified medical personnel IAW criteria and guidance in attachment 1. MTF and deployed medical commanders should use the implementation instructions outlined in attachment 3 to issue PB tablets.

The issuance of FHPPP shall be documented on an SF 600 and filed in the member's deployed medical record (DD Form 2766) and in AFCITA Plus, if available. In addition, if the member actually uses the FHPPP, this will be documented in the "Medications" block of the DD

Form 2766 (block 3) and on the DD Form 2796 and electronically in PIMRG2 during post-deployment processing.

The Food and Drug Administration licensing of PB tablets requires that all service members be properly trained in the history, use, drug action and side effects associated with the product. Training tools (video, briefing, etc.) will be developed in the future to assist with this training and incorporated into annual chemical warfare training. MTF personnel must be available to assist with this training, and in the interim should use the patient package insert in attachment 2 to provide this training. The briefing that is in development will be available on the AFMS website (<https://www.afms.mil/sgx/sgxw>). Deploying health care providers will be given a copy of the package insert prior to deployment.

My POC for this issue is Major Jacqueline Mudd, AF/SGXW, 110 Luke Avenue, Room 408, Bolling AFB, DC 20032-7050, DSN 297-5574, email jacqueline.mudd@pentagon.af.mil.



JAMES G. ROUDEBUSH
Major General, USAF, MC, CFS
Deputy Surgeon General

Attachments:

1. ASD(HA) Memo, Policy for Use of FHPPP, 24 Apr 03
2. USD(P&R) Memo, Requirements Associated with the FDA Approval of PB Tablets as Nerve Agent Pretreatment
3. AFMLO PB Tabs Instruction Paper

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THE ASSISTANT SECRETARY OF DEFENSE

1200 DEFENSE PENTAGON
WASHINGTON, DC 20301-1200

HEALTH AFFAIRS

APR 24 2003

MEMORANDUM FOR ASSISTANT SECRETARY OF THE ARMY (M&RA)
ASSISTANT SECRETARY OF THE NAVY (M&RA)
ASSISTANT SECRETARY OF THE AIR FORCE (M&RA)
DIRECTOR, JOINT STAFF

SUBJECT: Policy for Use of Force Health Protection Prescription Products

A requirement of the Federal Food, Drug and Cosmetic Act (21 USC 353(b)(1)) is that certain drugs, vaccines and other medical products, because of the need for medical involvement to assure safe and effective use, may only be used under a physician's prescription. This memorandum establishes policy to comply with this statutory requirement in the context of prescription products used for force health protection. This policy establishes three primary requirements: prescription, issuance in accordance with established medical criteria, and record keeping.

Prescription Requirement

All Force Health Protection Prescription Products (FHPPP) shall be issued under a prescription. A blanket prescription may be issued by a physician serving as the Assistant Secretary of Defense (Health Affairs) (applicable to any or all components of the Department of Defense (DoD)), the Surgeon General of the Army, Navy, or Air Force (applicable to personnel in or under the command or authority of the Army, Navy, or Air Force, respectively), or the Command Surgeon of a Combatant Command (applicable to persons within a Combatant Commander's area of responsibility). A blanket prescription shall describe:

- The categories of military personnel and other individuals who are required and/or eligible to receive an FHPPP;
- The exclusion criteria for identifying individuals who for medical reasons are not required and/or eligible to receive an FHPPP;
- Appropriate dosing information, including start and stop dates or events;
- Any applicable storage, shipment, and maintenance requirements; and
- Any other appropriate requirements or guidance pertaining to proper medical use of the product.

Issuance of Prescription Product

All FHPPP shall be provided or issued by qualified personnel who have been instructed on the exclusion criteria and other medical guidance applicable to the product. These personnel

HA POLICY: 03-007

shall conduct necessary medical screening and issue FHPPP consistent with such criteria and guidance.

The administration or issuance for self-administration of all FHPPP shall be preceded and/or accompanied by appropriate education to ensure that recipients are aware of the exclusion criteria, dosing information, potential side effects and recommended responses, sources for additional information, and any other information appropriate for the proper use of the product.

Although the inclusive list of FHPPP may vary between areas of responsibility based on differing threats, examples of such products include atropine/2-Pam chloride auto-injectors, certain antimicrobials including antimalarials, and pyridostigmine bromide.

Record Keeping

The provision or issuance of FHPPP shall be documented in medical records of the personnel or individuals receiving the FHPPP.

Additional Requirements

Health care providers shall record serious adverse events in medical records and shall report serious adverse reactions to the Adverse Events Reporting System of the Department of Health and Human Services using the Food and Drug Administration MEDWATCH or Vaccine Adverse Event Reporting System procedures and forms.

DoD Directive 6200.2, "Use of Investigational New Drugs for Force Health Protection," August 1, 2000, applies to the use of investigational new drugs for force health protection.

Definition

In this memorandum, the term "force health protection" means an organized program of healthcare preventive or therapeutic treatment, or preparations for such treatment, designed to meet the actual, anticipated, or potential needs of a group of military personnel in relation to military missions.



William Winkenwerder, Jr., MD

cc:

Surgeon General of the Army

Surgeon General of the Navy

Surgeon General of the Air Force

Deputy Director for Medical Readiness, Joint Staff

HA POLICY: 03-007



UNDER SECRETARY OF DEFENSE
4000 DEFENSE PENTAGON
WASHINGTON, D.C. 20301-4000

MAR 27 2003

PERSONNEL AND
READINESS

MEMORANDUM FOR SECRETARY OF THE ARMY
SECRETARY OF THE NAVY
SECRETARY OF THE AIR FORCE
CHAIRMAN, JOINT CHIEFS OF STAFF
DIRECTOR, DEFENSE LOGISTICS AGENCY

SUBJECT: Requirements Associated with the Food and Drug Administration Approval of
Pyridostigmine Bromide Tablets as a Nerve Agent Pretreatment

On February 5, 2003, the Food and Drug Administration (FDA) approved the use of pyridostigmine bromide (PB) tablets for nerve agent pretreatment against Soman. The approval provides the Department of Defense (DoD) with a product that will enhance force health protection against chemical threats. However, as part of the approval process, certain logistical and medical record keeping requirements were identified. This memorandum addresses clinical requirements applicable to use of PB. Nothing in this memorandum affects conditions of employment of civilian employees.

First, use of PB must be recorded in servicemembers' personal medical records and the automated information data system (e.g., MEDPROS, SAMS, AFCITA, CHCS, PDTS, if archived). I recommend recording individual issue of PB tablets in a manner that will facilitate these record-keeping requirements.

Second, due to the product's temperature-stability profile, PB tablets must be issued to personnel within 3 months if removed from refrigeration and stored at controlled room temperature (59 - 86 degrees F, or 15 - 30 degrees C). PB tablets must be discarded/destroyed 90 days after they are issued to individuals, whether they were previously stored in a refrigerator or at controlled room temperature. Services must establish plans to issue replacement stocks of PB tablets to servicemembers every 90 days, if there is a continuing threat of exposure to Soman. Because of the need to dispose of PB tablets issued to personnel after 90 days, Services should consider the availability of replacement stocks when establishing a basis of initial issue (i.e. some units may want to issue only one packet/sleeve of PB instead of two to each servicemember to reduce potential wastage).

Third, an interim patient package insert must be provided with each packet of PB tablets. Services will comply with the instructions at attachment 1 with regard to the distribution and dispensing of the interim patient package insert. This plan also calls for the replacement of all retained pre-approval stocks of PB tablets within five years.

Fourth, the approval of the product resulted in the creation of approved labeling by the Food and Drug Administration (package insert for health care providers). The requirements for

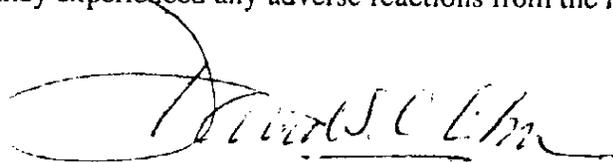


distribution of this approved labeling to physicians, physician assistants, pharmacists, nurses, and medics are provided at attachment 2.

Fifth, the approval of PB was accompanied by the need to ensure all servicemembers and other affected personnel are properly trained in the history, use, drug action and side effects associated with this product. Long term, this training should be incorporated into each Service's training activities. More urgent, however, is the requirement to provide adequate training and information to deployed servicemembers. A new revised interim patient package insert is being quickly fielded and distributed with PB, providing new information (attached). In addition, a briefing package is available (attached).

Sixth, Services will maintain electronic/hard copy medical records of personnel to whom PB is distributed or offered. These records may be required for surveys or studies to determine safety and medical benefit of PB. Services will make available to representatives of the US Army Medical Research and Materiel Command, or their contractors when requested, non-classified electronic rosters of such personnel — and hard copy/electronic medical records generated as part of the military operation — for FDA-required post-marketing studies to determine safety and medical benefit of PB. Additionally, incorporation of data obtained on PB use should be made part of ongoing longitudinal health studies (e.g., Millennium Cohort Study).

Finally, post-deployment questionnaires should include a new line documenting whether the individual did or did not take these medical countermeasures during the deployment and whether they perceived that they experienced any adverse reactions from the medication.



David S. C. Chu

Attachments:
As stated

Department of Defense

Pyridostigmine Bromide Tablets, 30 mg

Licensure Transition Logistics Plan

Issue The licensure/New Drug Application (NDA) approval for Pyridostigmine Bromide (PB) tablets under the "Animal Rule" by the Food and Drug Administration (FDA) created a unique opportunity for the Department of Defense (DoD). Normally, products labeled as Investigational New Drugs (INDs) must be withdrawn from the field once NDA approval is achieved. Unlike most investigational products, PB tablets are distributed to worldwide locations for contingency use rather than for "research" purposes. For this reason, removal of IND-labeled material from the field immediately after NDA approval would be detrimental to force health protection and national defense. In order to meet requirements for ready access to PB tablets, a Transition Logistics Plan was developed to cover the interim between current status with pre-approval PB in the field and conversion to new product manufactured post FDA approval. The DoD must now execute that plan. Key aspects of this plan are described below.

Background The DoD, through the Services, must communicate and issue the new, approved, detailed labeling for PB tablets (the package insert) to all health care providers. The DoD must provide all personnel receiving PB tablets with new patient information. The FDA is permitting the DoD to use an interim product information sheet (the patient package insert) to replace the current patient package insert enclosed in the IND-labeled PB inventory. The Services must ensure personnel receive these new patient package inserts. The DoD must replace all retained IND-labeled PB inventory with newly licensed product over a maximum period of five years from the NDA approval date (February 5, 2008).

DoD Transition Logistics Plan There are three key aspects of the Transition Logistics Plan.

1. The Services must distribute the approved package insert to all physicians and health care providers, down to the medic-level. The approved package insert provides detailed clinical information needed for the safe, appropriate prescribing of PB tablets and monitoring of personnel for safety and effectiveness. Due to the short time frame between approval of the NDA and potential use of PB tablets, a multi-pronged approach, employing numerous methods such as e-mail, official DoD messages, website pages, and hardcopy will be performed by the Services. More information about the provision of the approved package insert can be found in the Annex titled "Distribution Plan for Approved Labeling of Pyridostigmine Bromide (Package Insert for Health Care Providers)."
2. The Services must execute a comprehensive plan to ensure all servicemembers receiving the current IND-labeled PB tablets also receive an interim patient package insert regarding the approval of this drug by the FDA under the Animal Rule. To fulfill that requirement, the Services will remove the old patient package insert from sleeves of IND-labeled PB tablets

and issue replacement interim patient package inserts at the time these tablets are dispensed (the interim plan).

3. The Services will execute the phased replacement of IND-labeled product with appropriately labeled, licensed PB tablets over a maximum of 5 years from NDA approval (the replacement plan). More specific details of both the interim plan and the replacement plan are provided below.

Interim Plan - Provision of interim patient package insert The Services will ensure servicemembers and other personnel receive the appropriate interim patient package insert. These inserts replace the current patient package inserts enclosed with the IND-labeled inventory. The following language will be added to the interim patient package inserts:

- **Please remove and discard previous information provided in the PB packet and replace it with this information sheet.**
- **This Information Sheet also updates the information on the cardboard sleeve and foil pack containing your PB.**
- **The US Food and Drug Administration (FDA) has approved 30 mg PB tablets as a pretreatment against a Soman nerve gas attack. Therefore, PB is no longer considered investigational when used as a nerve agent pretreatment against Soman.**
- **Discard your PB tablets 3 months after issue.**
- **You must read the following information about PB to find out more about its risks and benefits and how to use it.**

The Services will instruct personnel to remove the old, IND patient package inserts from sleeves of IND-labeled PB tablets at time of dispensing and replace those with new, interim patient package inserts. These new patient package inserts must be issued with the IND product after licensure, because removal of the current IND-labeled inventory from the field and replenishment of this materiel with licensed product would be detrimental to military readiness and potential contingency operations.

The Services' Medical Logistics Agencies and the Defense Logistics Agency will distribute these *interim patient package inserts*. *Ten sheets will be distributed with each pouch containing ten sleeves of PB tablets.* These required interim patient package inserts will be attached or banded to each Mylar pouch/bag containing ten sleeves of PB tablets while in storage and distribution, and must accompany the materiel throughout the supply chain to point of dispensing.

DoD will issue a Medical Materiel Quality Control Message through medical logistics channels directing the Services to distribute the interim patient package inserts to all sites possessing PB tablets. Additionally, the message will direct sites to dispense/issue these interim patient package inserts, one insert with each sleeve of PB tablets.

Services will confirm receipt of the interim patient package inserts at each receiving location and will provide detailed directions for issue/dispensing of these with each sleeve of PB tablets throughout the chain of custody and issue.

Replacement Plan The DoD must replace current IND-labeled product with licensed product within a reasonable period. DoD proposed a phased approach for the replacement of IND-labeled product over a maximum of five years from the NDA approval date. The Services will continue to use retained IND-labeled PB inventory, dispensed with the interim patient package insert during this transition period. All retained IND-labeled stocks of PB tablets will be replaced with newly manufactured material over a maximum of five years (approximately 20% of stocks each year). All IND-labeled stocks of PB tablets will be replaced with newly produced PB tablets not later than February 5, 2008.

Conclusion Careful execution of the DoD PB Transition Logistics Plan supports DoD's needs for force health protection and a reasonable transition to replace IND-labeled product with licensed PB tablets.

Distribution Plan for Approved Labeling of Pyridostigmine Bromide

(Package Insert for Health Care Providers)

Background. The Department of Defense (DoD) has pre-positioned large amounts of pyridostigmine bromide (PB) tablets labeled as investigational drugs for force health protection purposes. The recent Food and Drug Administration approval of the New Drug Application (NDA) now requires communication of the approved labeling to health care providers. This paper describes the DoD plan to provide health care providers the approved labeling of pyridostigmine bromide.

Plan. Due to the short time frames between the approval of the NDA and a potential need for use of the product, a multi-pronged approach is proposed.

- a. Services to utilize e-mail notifications (attachment of the .pdf version of the approved package insert) through major subordinate commands to all physicians and other health care providers (down to medic level). U.S. Army to include notification to those health care personnel assigned outside of the U.S. Army Medical Command (e.g., Forces Command, 8th Army, U.S. Army Reserve Command). For those organizations with an e-mail system that has return receipt, utilize the return receipt option to document receipt of the message by the health care providers. Notification of services to include National Guard/Reserve units in addition to active duty forces. Electronic mail routes to also include health care information system (composite health care system mail messaging).
- b. Joint Staff to notify combatant commanders and command surgeons of the approved labeling and the requirement to distribute the labeling to health care providers of their respective component services. Emphasis to be placed on distribution of information to deployed and deploying medical personnel, particularly Reserves, who are deployed and may not be able to access their normal e-mail.
- c. Services to provide information to health care providers in hard copy at mobilization stations for reserve and active forces.
- d. DoD and Services will prominently post a message to web sites used by health care providers in the course of their routine business. Include link with pdf down-load and html viewed versions of approved label. Potential sites may include (not exhaustive list):

Department of Defense:

Assistant Secretary of Defense for Health Affairs
Deployment Link (Deployment Health Support)
Deployment Health Clinical Center

TRICARE
The Military Vaccines Web Site
Anthrax Vaccine Program
Pharmacoeconomic Center
Uniformed Services University of Health Sciences
Armed Forces Epidemiological Board
DoD GulfLINK

U.S. Air Force:

Surgeon General of the Air Force
Air Force Medical Treatment Facilities
Air Force Link
Air National Guard
Air Force Wing Commands
Air Force Institute for Environment, Safety and Occupational Health Risk Analysis

U.S. Army:

Surgeon General of the Army (Army Medicine)
Army Medical Department Center and School
Army Regional Medical Commands and Medical Treatment Facilities
Army Link
Army Reserve On-line (U.S. Army Reserve Command)
The Army National Guard (National Guard Bureau)
U.S. Army Medical Research and Materiel Command
U.S. Army Medical Materiel Development Activity
U.S. Army Medical Materiel Activity
U.S. Army Medical Research Institute of Chemical Defense
U.S. Army Center for Health Promotion and Preventive Medicine
U.S. Army Pharmacy
U.S. Army Soldier and Biological Chemical Command
U.S. Army Knowledge On-line
U.S. Army PERSCOM

U.S. Navy:

Surgeon General of the Navy
Bureau of Medicine and Surgery
Navy Medical Treatment Facilities
Navy On-line Link
Naval Reserve Force
Naval Medical Information Management Center
Navy Pharmacy
Naval Health Research Center
Navy Environmental Health Center

Virtual Naval Hospital
U.S. Marines
Marines Life Line
Marine Corps Manpower and Reserve Affairs
Marine Corps Anthrax Vaccine Program

e. DoD to inform other Federal departments that may have direct or indirect roles in support of DoD, e.g., Department of Transportation (U.S. Coast Guard), Central Intelligence Agency, Homeland Defense, Department of Justice, Department of State, Department of Veterans Affairs, Department of Health and Human Services, Department of Energy.

f. Defense Logistics Agency to include approved package insert with any newly procured PB.

g. DoD to coordinate with publisher of Military Medicine to include story of PB approval and package insert in next possible edition. Services to coordinate with Public Affairs Officers to use other forums to make announcement (e.g., Army's MEDCOM Mercury).

Important Information

Rx Only

February, 2003

Pyridostigmine Bromide (PB) 30 mg

- Please remove and discard previous information provided in the PB packet and replace it with this information sheet.
- This information sheet also updates the information on the cardboard sleeve and foil pack containing your PB.
- The US Food and Drug Administration (FDA) has approved 30 mg PB tablets as a pretreatment against a Soman nerve gas attack.
- Therefore, PB is no longer considered investigational when used as a nerve agent pretreatment against Soman.
- Discard your PB tablets 3 months after issue.
- You must read the following information about PB to find out more about its risks and benefits and how to use it.

Protection against Chemical Warfare Agents

Pyridostigmine bromide is approved for protection against the chemical nerve agent Soman (GD). Other chemical nerve agents include Sarin (GB), Tabun (GA) and VX. Nerve agents work by making your muscles weak. They can make you lose control of your muscles. You can die if your breathing muscles are paralyzed.

Your main protection against chemical weapons is your chemical protective mask and battle dress overgarment. You also have other items to help you if you are exposed to chemical warfare agents. These items are:

Two antidotes (atropine and 2-PAM) —that are part of the MARK I Nerve Agent Antidote Kit or ATNAA (Antidote Treatment - Nerve Agent Autoinjector).

Pyridostigmine Bromide (PB) — PB is approved as a pretreatment against a Soman nerve agent attack. The approval is based on safety studies in humans and effectiveness (how well it works) studies conducted in animals. The FDA has approved PB based only on animal studies of effectiveness because it is not ethical to do these studies in humans. Human studies would require exposing people to the deadly effects of nerve agents, risking poisoning them or even killing them. Studies in monkeys and guinea pigs show

that pretreatment with PB makes the antidotes (atropine and 2-PAM) work better against Soman (GD). PB pretreatment in animals has not been shown to make the antidotes work better against other nerve agents. Based on the animal studies of whether PB works against Soman, it is thought that any potential benefits from use of PB occur only if:

(1) PB is taken within 8 hours before, but not right before, exposure to the nerve agent Soman. (If PB is taken right before (when the nerve gas attack alarm is given) or during nerve agent exposure, it may not work and may make the effects of Soman worse).

(2) Atropine and 2-PAM are used when symptoms of nerve agent poisoning occur.

How To Take Your PB

(1) Your chain of command will tell you when it is time to take PB. This decision will be based on the threat of exposure to Soman nerve agents.

(2) You must take 1 tablet of PB every 8 hours until your chain of command tells you to stop taking PB.

(3) Do not take PB more often than you are told. **Do not double up on your dose if you miss taking it.**

(4) There is no known advantage to taking extra PB right before Soman exposure.

(5) No further PB should be taken after nerve agent exposure has occurred.

(6) Instead of taking more PB after nerve agent exposure has occurred, if you experience most of the **MILD** symptoms of nerve agent poisoning, you should **IMMEDIATELY** hold your breath (**DO NOT INHALE**) AND PUT ON YOUR PROTECTIVE MASK. Then administer atropine and 2-PAM (*one* MARK I kit or *one* ATNAA).

(7) Contact your unit medical officer if side effects from PB continue and limit duty performance.

Who should not take PB

Do not take PB if you:

- Have a history of bowel or bladder blockage (obstruction);
- Are overly sensitive to anticholinesterase medicines (certain drugs used during surgery like physostigmine, edrophonium, neostigmine, and ambenonium);

Tell your doctor or medic before taking PB if you:

- Are pregnant;
- Have asthma;
- Are allergic to bromide;
- Take blood pressure medicine;
- Have high eye pressure (glaucoma).

Also, tell your doctor about all your other medical conditions you may have including heart problems, or reflux esophagitis (GERD).

Side Effects

Side effects include stomach cramps, watery eyes, gas, blurred vision, diarrhea, runny nose, nausea, difficulty or tightness in breathing, frequent urination, acid stomach (including heartburn or reflux), increased salivation, tingling of fingers, toes, arms, and legs, sweating, muscle twitching or weakness, headaches, muscle cramps, and dizziness. Most side effects are mild and will go away without treatment. If your side effects do not go away, see your unit doctor or medic. This is not a complete list of symptoms that may occur. See your unit doctor right away if your side effects are very bad or for any symptoms that concern you.

PB has been safely used and has been FDA approved for over 40 years in the U.S. to treat a disease called myasthenia gravis (MG). Human studies of PB at doses intended for military use have found PB to be generally safe.

About your rights and welfare:

DOD may collect information on the use of PB to help decide how best to protect deployed forces in the future. Information that identifies you will remain private (confidential). However, the FDA may review any data collected by DoD for the purpose of evaluating PB. Direct questions about your rights and welfare to your unit medical officer, or e-mail questions to hsrrb@det.amedd.army.mil.

For more information about PB:

Talk to your unit medical officer or medic. You can also e-mail questions about PB directly to the U.S. Army Medical Research and Materiel Command at address hsrrb@det.amedd.army.mil.

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Medical Directorate
700 Robbins Ave
Philadelphia, PA19111

For: Office of The Surgeon General
U.S. Army Medical Research
and Materiel Command (MCMR-RCQ-RA)
504 Scott Street
Fort Detrick, MD 21702-5012

USAMMDA 30206450

AFMS Instructions for Pyridostigmine Bromide Tablet (PB Tabs) Shipment and Distribution During Deployment

Background: Recent FDA guidance (MMQC-03-1061) changed PB tabs from an investigational to a therapeutic drug. In order to accommodate this change, new rules were enacted by FDA and agreed upon by DoD. These rules state once PB tabs are removed from refrigeration and stored at room temperature they only have a 6 month shelf life. Once the PB tabs are dispensed to individual troops they only have a 90 day shelf life and must be replaced after that time.

Bottom Line: The AFMS' position is the 90-day clock starts when troops are dispensed PB Tabs in theater under the orders of the theater commander or delegate. Medical Logistics Activities (MLA) will dispense the new patient protection inserts (PPIs) at that time. The AFMS will continue to issue PB Tabs to troop commanders who will act as couriers for transporting into theater, IAW AFMAN 23-110/Vol 5, where they will turn in all items to an MLA.

Procedure:

- At the time of troop deployment, MLA will remove PB tabs from refrigerated storage and issue to the troop commander at the deployment line
- Individuals deploying by themselves are considered a "troop commander" and will be issued the PB tabs for transport and turn-in
- Troop commander will transport the PB tabs into theater acting as a courier for these items (The troop commander acts as a trusted agent who is transporting the items from one MLA to another)
- Immediately upon arriving in theater, the troop commander will turn over the PB tabs to a representative of the MLA at the in-processing line or at the medical treatment facility
 - During this transport time the PB tabs are still considered to be within the control of medical logistics and the 6 month/ 90 day potency period has not begun
 - PB tabs are not shipped refrigerated by the manufacturer; they are placed in refrigeration once received by the MLA
 - If the receiving MLA does not have refrigerated storage capability, the 6 month potency timeframe begins upon receipt in theater
- Upon direction of the theater commander or designated subordinate that PB tabs should be dispensed to individual troops; the 90 day potency period begins
- MLA must advise AFMLOC when refrigerated storage is not available or when PB tabs are dispensed to ensure replacement stock is identified, ordered and received within the prescribed time limitations
- New PPIs were shipped directly from the printer to specified MLAs in Feb '03
 - If not yet received, MLA should continue to issue PB Tabs to troop commanders
- PPI will be inserted to PB tab packaging at time it is dispensed to individual troops