

PDREP

Product Data Reporting and Evaluation Program Automated Information System (PDREP AIS) is the computer program used by DLA-TS Medical for recording, investigating and reporting findings of product quality deficiencies.

How Are Product Quality Deficiency Reports (PQDR) Received?

At DMM On-line, <https://www.medical.dla.mil/Portal/Customer/ProductQualityDeficiency.aspx>, is a form (SF368) which is used by all DLA commodities in reporting deficiencies. The reporting activity may fill out the form, save it to their computer and attach it to the pre-addressed e-mail provided at DMM On-line. The provided e-mail is convenient because it notifies all concerned at the same time.

If the PQDR is not sent from the e-mail on DMM On-line, DLA-TS is required to forward the report to the Services' Logistic Offices, the DHA, and the FDA. This can be done prior to entering the PQDR into PDREP or within PDREP as part of the record. The latter is preferred if time restraints are met.

In addition the reporting activity may attach any information, pictures, or existing reports such as risk management reports to the e-mail.

Basically we will accept the information in any manner convenient to the medical facility. The report may also be transmitted by fax (215-737-5555), by telephone (usually for Category 1) to our Customer Interaction Center (CIC) at 1-877-DLA-CALL (352-2255), e-mail is dlacontactcenter@dla.mil, or by mail, 700 Robbins Avenue, ATTN: DLA T-S Medical FSSB, Philadelphia, PA 19111.

Who May Submit a PQDR?

ANYONE! Anyone who has creditable knowledge of an unsafe medical product or event may submit a report. A Category 1 complaint must be authorized by a medical officer. A Category 1 complaint is used to report drugs or devices which may have caused or contributed to a death or serious injury.

How To Apply For Access To PDREP?

Access to PDREP is available on Internet at <https://pdrep.csd.disa.mil/pdrep/pdrephome.do>. Click on "Request Account" and fill in form. Mandatory fields are denoted by (M). DLA-TS Medical DODDAAC is SC0200. Apply for access as "Originator Point" and "Action Point" and if you are reviewing and closing reports as "Screening Point" and Submit Request.

How Is The Report Entered Into PDREP?

Normally, as with other commodities, the report is entered directly into PDREP by the reporting facility. However, most medical facilities do not have access to PDREP neither as an originator nor as a screening point. Therefore the reports are entered by the medical product specialists. Instructions will be issued separately.

Briefly the report is entered as if by the reporting activity (ORIGINATOR). It is then forwarded to the SC0200 screening point, which may or may not assign it to an action point.

What To Do If You Receive a PQDR in PDREP?

DLA-TS Medical Product Specialist will investigate and resolve the concerns of our customer. In the past we had significant vested interest in maintaining safe products in the depots. Today it is still important to be aware of the problems incurred by our customers so that we may procure safe products and reduce the risk to patients and caregivers.

General Considerations.

1. Risk Assessment: Risk assessments are normally done by the medical officer at the reporting facility but DHA has the authority to evaluate and over-ride the assessment.
2. Past History: Both DLA and the FDA have files on past complaints.
3. Impact of Supply:

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GENERAL GUIDANCE FOR PQDRS

There are two categories of complaints:

CATEGORY 1: Category 1 complaints shall be authorized by a medical officer at the reporting facility or at Defense Health Agency (DHA).

CATEGORY 2: Any product quality deficiency not designated as a category 1.

Category 1 complaints are initially investigated by the medical advisors at DHA. As medical officers they have the authority to substantiate or reclassify the complaint.

After the complaint has been adjudicated it and all category 2 complaints are investigated and resolved by DLA T-S Product Specialist (PS).

HOW TO PROCESS PQDRs.

1. Review the report for accuracy and familiarize yourself with the suspect product and the reported event.
2. Review past complaints and recalls.
 - a. FDA files at <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/cfrsearch.cfm>;
Click on Adverse Events and/or Recalls
 - b. DLA T-S Complaint List & Status, R:\QADData\COMPLAINTS\Complaints (filed by year).
 - c. PDREP search for similar complaints and products.
 - d. DLA T-S Recalls, R:\QADData\RECALLS\Recalls 2014\ RECALLS 2014.xlsx.
 - e. MMQC recalls,
http://www.usamma.amedd.army.mil/assets/apps/nala_qaweb/nala_query_type.cfm.
3. Enter the PQDR into PDREP. You must have Originator access. SC0200 is the PDREP code for DLA T-S Medical.
IMPORTANT! You must change this code to the DoDDAC of the reporting activity.
See below for more information on PDREP.
4. In PDREP send a formal acknowledgement to the originator (and others at the facility) and notify the appropriate service logistic office, the DHA and the FDA. Include any significant information from your review and ask any questions you may have.

Points of contact are:

Army: Charlene.l.warrendavis.mil@mail.mil
randy.j.harris.civ@mail.mil
teresa.e.bess.civ@mail.mil
steven.l.johnson36.civ@mail.mil
cheryl.d.bailey.ctr@mail.mil
jessica.l.keister.civ@mail.mil

Navy: etta.ingram@med.navy.mil
mmqc2@med.navy.mil

AF Jan.Mitchell@us.af.mil
afmoa.sgalc.alerts@us.af.mil
afmoa.sgalx.pd@us.af.mil

DHA Brenda.l.miller.civ@mail.mil
Jeannette.allison.civ@mail.mil

FDA angela.davis@fda.hhs.gov
Jeffrey.eaton@fda.hhs.gov

5. Notify the manufacturer/distributor of the deficiency even if the reporting activity has already done so. If a reply is required, specify a reply by date. This notification can be done in any of the following ways:

- By Action Point Letter. In PDREP
Click on "Action Point Letters," select "Action Point Cover Letter" and click "Generate." The Action Point Cover Letter is automatically addressed to the firm based on the CAGE code. Enter an e-mail address if known and cc others as appropriate. If no e-mail is available the letter may be printed and sent by post. The letter has a set template which can and should be modified to suit the particular PQDR.

- By e-mail. Up-load into PDREP as .pdf file.
- By postal letter. Up-load into PDREP as .pdf file.

6. The complaint is to be completed within 45 days (30 days for a Category 1). If more time is required an interim reply must be sent every 30 days.

7. Maintain a record of all the actions taken during the process for formalizing on a closing letter. In addition to the six mandatory paragraphs, give a brief summary of the original problem.

8. Once the customer's concerns have been resolved the PQDR may be closed. A closing letter is required and a notification of closure sent to the Originator. The closing letter must be reviewed and signed by a supervisor.

PRODUCT DATA REPORTING AND EVALUATION PROGRAM (PDREP).

PDREP is a repository for all significant information for entering, processing and closing PQDRs. It is not however geared to medical complaints. Many of the dropdown menus do not apply particularly as to drug products.

Most of the PQDRs we receive today are local purchase items and/or do not have an NSN. If the product does have an NSN and it is entered into PDREP it will produce a QN in EBS. We should consult with a supervisor to determine if the NSN is to be used in PDREP.

PDREP has developed into a comprehensive reporting system for GIDEPs and SDRs as well as PQDRs.

