

UN/EDIFACT

DRAFT DOCUMENT

Medical adverse drug reaction message

This message has undergone only an initial technical assessment which may have found certain technical and presentation problems. These will be solved before the message is submitted as a request for Status 1. Anything shown under Section 5 (or, in some cases, which should have been shown in Section 5 - directory variations) is NOT approved at this stage. Further information on the development of this message can be obtained from the Rapporteur's EDIFACT Board Secretariat. This document is issued for information and comments and is not intended for implementation.

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0. INTRODUCTION

This specification provides the definition of the Medical adverse drug reaction message (MEDADR) to be used in Electronic Data Interchange (EDI) between trading partners involved in administration, commerce and transport.

1. SCOPE

1.1 Functional Definition

The medical adverse drug reaction message allows a party to send an adverse drug reaction report concerning a single case to national and international regulatory authorities.

1.2 Field of Application

The Medical adverse drug reaction message may be applied for both national and international trade. It is based on universal commercial practice and is not dependent on the type of business or industry.

1.3 Principles

This message may be transmitted:
- from health professionals to regulatory administrations and pharmaceutical industry.
- between regulatory administrations.
- between pharmaceutical companies and regulatory administrations.
- within administrations or pharmaceutical companies.

- from administrations to the collaborative drug surveillance centre (WHO Uppsala).

One message permits to send a single case report of adverse drug reactions. That means:

- one patient.
- one or more suspected reaction(s).
- one or more suspect drug(s).

If several reactions are included in one message they should be related. Thus if a drug causes a first reaction for which a second drug is given causing a second reaction two messages (reports) should be submitted.

The message could also accommodate reporting for pre registration events (clinical trials).

2. REFERENCES

See UNTDID, Part 4, Chapter 2.6 UN/ECE UNSM - General Introduction, Section 1.

3. TERMS AND DEFINITIONS

See UNTDID, Part 4, Chapter 2.6 UN/ECE UNSM - General Introduction, Section 2.

4. MESSAGE DEFINITION

4.1 Data Segment Clarification

This section should be read in conjunction with the Branching Diagram and the Segment Table which indicate mandatory, conditional and repeating requirements.

0010 UNH, Message header

A service segment starting and uniquely identifying a message.

The message type identifier for the Medical Adverse Drug Reaction message is MEDADR.

Note: The MEDADR message conforming to this document must contain the following data in segment UNH composite S009:

Data element	0065 MEDADR
	0052 0
	0054 2
	0051 RT

0020 BGM, Beginning of message

A segment for unique identification of the message and specification of its function.

0030 DTM, Date/time/period

A segment identifying the date and/or time of message generation and/or other dates and/or times relevant to the entire report.

0040 RFF, Reference

A segment for specifying a reference related to the entire report, including the identification of the study involved.

0050 LOC, Place/location identification

A segment for specifying the place (country) where the reaction

- occurred or the reaction was reported.
- 0060 ATT, Attribute
A segment for specifying the nature, type, seriousness and the outcome of the adverse drug reaction episode.
- 0070 DOC, Document/message details
A segment identifying the type of report (i.e. pre-authorisation clinical trial, post-authorisation study, etc.).
- 0080 FTX, Free text
A segment with free text information, in coded or clear form, for giving further clarification, where required, to the entire report. The segment should be used for any relevant information or literature references for the adverse drug reaction episode.
- 0090 Segment group 1:
PNA-ADR-RFF-DTM-PDI-SPR-EMP-QUA-CCI-MEA-FTX-SG2
A group of segments giving information about the patient or other parties relevant to the adverse drug reaction episode.
- 0100 PNA, Party name
A segment for specifying the identification and/or name of the patient or an associated party such as the reporter, the message sender, etc.
- 0110 ADR, Address
A segment for specifying the address of the actual party.
- 0120 RFF, Reference
A segment for specifying alternative identification numbers of the actual party such as patient record number.
- 0130 DTM, Date/time/period
A segment for specifying relevant dates and/or times such as the date of birth of the patient as well as the age of the patient at time of reaction.
- 0140 PDI, Person demographic information
A segment for specifying demographic information such as sex.
- 0150 SPR, Organisation classification details
A segment for specifying the type and medical specialty of a healthcare organisation.
- 0160 EMP, Employment details
A segment for specifying the type and medical specialty of a healthcare professional.
- 0170 QUA, Qualification
A segment for specifying the professional qualifications of a person.

- 0180 CCI, Characteristic/class id
such a segment for specifying the age group of the patient
as child, adult or elderly.
- 0190 MEA, Measurements
A segment for specifying the weight and height of the
patient.
- 0200 FTX, Free text
A segment with free text information, in coded or clear
as form, for specifying additional patient information such
information. medical history, past drug history and autopsy
- 0210 Segment group 2: CTA-COM
communication A group of segments identifying a contact and
numbers for the actual party.
- 0220 CTA, Contact information
A segment for specifying contact information for the
actual party such as the sender of the message.
- 0230 COM, Communication contact
other A segment providing the phone number, fax number or
the telecommunication number of the contact specified for
actual party.
- 0240 Segment group 3: CIN-DTM-DAM-STS-FTX
reaction(s) A group of segments for specifying the adverse drug
of a patient.
- 0250 CIN, Clinical information
A segment for specifying the type of the adverse drug
reaction.
- 0260 DTM, Date/time/period
the A segment for specifying dates and/or times relevant to
the adverse drug reaction such as the start and end date of
adverse reaction.
- 0270 DAM, Damage
adverse A segment for specifying the severity of the actual
drug reaction.
- 0280 STS, Status
adverse A segment for specifying the outcome of the actual
drug reaction.
- 0290 FTX, Free text
A segment with free text information, in coded or clear
form, to give further description of the adverse drug
reaction.
- 0300 Segment group 4: LIN-CCI-RSL-DTM-STA-FTX
A group of segments specifying the relevant test performed
concerning the adverse drug reaction.

0310 LIN, Line item
A segment specifying the number of this investigation.

0320 CCI, Characteristic/class id
A segment for specifying the characteristics of the investigation.

0330 RSL, Result
A segment for specifying the result of the investigation.

0340 DTM, Date/time/period
A segment for specifying dates and/or times relevant to the investigation and/or result such as date of investigation performed.

0350 STA, Statistics
A segment for specifying statistical information about a specific investigation such as number of times with normal results and number of times with un-normal results.

0360 FTX, Free text
A segment specifying free text information, in coded or clear form, to give additional information about the investigation and/or the result.

0370 Segment group 5: IMD-DSG-INP-CIN-DTM-RFF-QTY-STS-FTX
A group of segments identifying each drug and giving related information such as dosage.

0380 IMD, Item description
A segment for identifying a drug.

0390 DSG, Dosage administration
A segment for specifying the dosage and administration specifications of a drug.

0400 INP, Parties to instruction
A segment for specifying the dosage regime.

0410 CIN, Clinical information
A segment for specifying the indication for usage of the drug.

0420 DTM, Date/time/period
A segment for specifying dates and/or times relevant to the administration of the drug such as start and stop of a drug treatment.

0430 RFF, Reference
A segment for specifying additional drug identification such as the batch number or the marketing authorisation number of a drug.

0440 QTY, Quantity
A segment for specifying the amount of substance administered in each dose.

0450 STS, Status
A segment for specifying the status of the drug in relation to the adverse drug reaction episode, the action taken concerning the actual drug as well as the effect of drug

re-

challenge.

0460 FTX, Free text
 A segment specifying free text information, in coded or clear form, to give additional information about the

drug.

0470 CNT, Control total
 A segment to provide message control totals as required.

0480 UNT, Message trailer
 A service segment ending a message, giving the total number of segments in the message and the control reference number of the message.

4.2 Data segment index (Alphabetical sequence by tag)

- ADR Address
- ATT Attribute
- BGM Beginning of message
- CCI Characteristic/class id
- CIN Clinical information
- CNT Control total
- COM Communication contact
- CTA Contact information
- DAM Damage
- DOC Document/message details
- DSG Dosage administration
- DTM Date/time/period
- EMP Employment details
- FTX Free text
- IMD Item description
- INP Parties to instruction
- LIN Line item
- LOC Place/location identification
- MEA Measurements
- PDI Person demographic information
- PNA Party name
- QTY Quantity
- QUA Qualification
- RFF Reference
- RSL Result
- SPR Organisation classification details
- STA Statistics
- STS Status
- UNH Message header
- UNT Message trailer

4.3 Message structure

4.3.1 Segment table

Pos	Tag Name	S	R
0010	UNH Message header	M	1
0020	BGM Beginning of message	M	1
0030	DTM Date/time/period	M	9
0040	RFF Reference	C	99
0050	LOC Place/location identification	C	9
0060	ATT Attribute	C	9
0070	DOC Document/message details	C	9
0080	FTX Free text	C	99
0090	ÄÄÄÄÄ Segment group 1 ÄÄÄÄÄÄÄÄÄÄÄÄÄÄÄÄÄÄ C		

3				
0420	DTM Date/time/period	C	9	
3				
0430	RFF Reference	C	9	
3				
0440	QTY Quantity	C	9	
3				
0450	STS Status	C	9	
3				
0460	FTX Free text	C		
9ÄÄÄÄÄÄÄÄÄÄÄÄÜ				
0470	CNT Control total	C	9	
0480	UNT Message trailer	M	1	

5. DIRECTORIES

5.1 Base Directory

Draft directory D.96B.

5.2 Explanation of directory variations

No directory variation.