PharmaNet Adverse Drug Event (ADE)

Cheat Sheet

Created with information provided by the PharmaNet ADE Project Team

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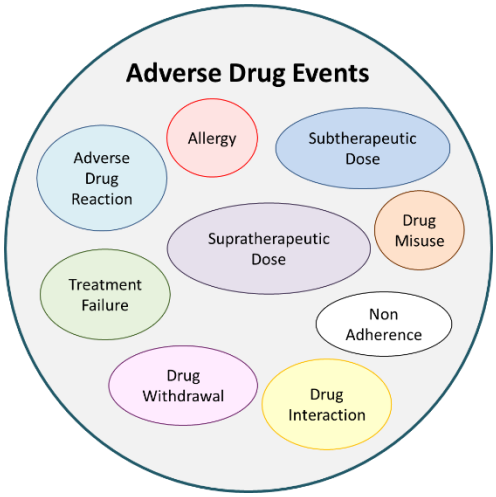
Introduction

An Adverse Drug Event (ADE) is 'Harm caused by appropriate or inappropriate use of a drug whereas adverse drug reactions are a **subset** of these events, where harm is directly caused by a drug under appropriate use (i.e. at normal doses). Adverse drug events may include cases of provider error, non-adherence, or incorrect dosages. (Nebeker, Barach, & Samore, 2004).



Information recorded by acute care providers in PharmaNet will include a broad range of ADEs, including as a subset ADRs. As the PharmaNet system will flag these ADEs for review upon subsequent dispensations of the medication, it is important for community pharmacists to review the information contain in the comments of recorded ADE/ADRs to determine the most appropriate action.

The ActionADE research team have completed significant research into what details of an ADE should be recorded to accurately, but succinctly inform other care providers of the event. As ActionADE is a research project there will be limited patients with ADE records, Pharmacists will still record ADRs as per the usual process in PharmaNet. For more information on ActionADE you can visit their web page.

Display of ADE information in a Patient's PharmaNet Profile in Kroll Service Pack 20

Look for the ***ADE** in the Clinical Conditions tab of the patient profile, it denotes an "ADE" record. When you see *ADE you must look for additional ADE details under the culprit drug in the Adverse Reaction tab of the patient's profile.

Example:

CLINICAL CONDITION (ZPB1)	*ADE_1450_Deep vein thrombosis
Clinical Condition Comment: INR=1	

ADVERSE REACTION (ZPB2)	Warfarin - DIN 2240205
Adverse Reaction Comment: *ADE_1450_Subtherapeutic Dose_Certain_Hospital extended_3mg_daily	

NOTE: Kroll Service Pack 21 introduces new functionality to improve the users experience of ADE information and brings this information together in a new ADE tab.

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The following ADE information will be recorded in the PharmaNet record:

CLINICAL CONDITIONS TAB		
Data element	What it contains & allowed values	Comments
ADE Identifier	*ADE	Flags that this condition is associated with an ADE and its impact to therapy should be considered in the context of the ADE. The pharmacist must look for further details of the ADE in the 'Adverse Reaction' tab. This can be done by matching the *ADE identifier.
Time Stamp	hh=hour (00 - 23) / mm=minutes (00 - 60)	Where a patient has multiple ADEs recorded, permits the matching of symptoms experienced in clinical conditions tab to the correct ADE information recorded in the adverse reaction tab.
Clinical Condition	Name of condition or symptom	Primary symptom/condition experienced as part of the ADE.
Comment Detail	Up to two further conditions/symptoms or lab value	Provides further details of symptoms experienced as part of the ADE, may also include a relevant lab value (eg. INR)

ADVERSE REACTION TAB		
Data Element	**What it contains**	**Comments**
Drug Name and DIN	Drug name and DIN of the drug associated with the ADE.	This is often referred to as the culprit drug. PharmaNet will check any future dispenses against this DIN and flag as a prior ADR where a potential cross sensitivity exists. The pharmacist must review the ADE record to determine the appropriate action.
ADE Identifier	*ADE	Flags that this record should be treated as an ADE versus ADR.
Time Stamp	hh=hour (00 - 23) / mm=minutes (00 - 60)	Where a patient has multiple ADE recorded, permits the matching of symptoms experienced in clinical conditions to the ADE information recorded in the ADR section
Adverse Drug Event Type	Adverse Drug Reaction Allergy Subtherapeutic dose Supratherapeutic dose Treatment failure Drug Withdrawal Drug Interaction Non-Adherence Drug Misuse	Defines the type of Adverse Drug Event. This informs a pharmacist of the most appropriate clinical intervention. For example, a patient arrives in the ER experiencing seizures due to not taking their phenytoin. This would be documented as an ADE due to non-compliance, the expectation is that the pharmacist will encourage the patient to take their medication as prescribed to prevent a repeat of the non-adherence ADE.
Certainty	Certain Likely Possible Unlikely Refuted	The level of certainty the acute care provider has that the culprit drug caused the associated symptoms/diagnosis. 'Refuted' indicates that the providers has determined that the drug did not cause this ADE. For example, for ‘Refuted’, allergy testing reveals that a rash subsequent to amoxicillin was likely attributed to use during a viral infection not a true allergy.

<table>
<tr><td rowspan="8">ADE Outcome</td><td>Death</td><td rowspan="8">The outcome of the ADE event, it provides some insight to the severity of the ADE.</td></tr>
<tr><td>Permanent Disability</td></tr>
<tr><td>Worsen Preexist Cond</td></tr>
<tr><td>Fetal Defect</td></tr>
<tr><td>Hospitalization</td></tr>
<tr><td>Hospital Extended</td></tr>
<tr><td>Emergency Visit</td></tr>
<tr><td>Life Threatening</td></tr>
<tr><td>Dose with Units</td><td>free text</td><td rowspan="2">Included where applicable, eg. Subtherapeutic and Supratherapeutic dose.</td></tr>
<tr><td>Frequency</td><td>free text</td></tr>
<tr><td colspan="3">The information in the ADR comment is in the above order with each data element separated by an underscore.

Comment: *ADE_hhmm_Adverse Drug Event Type_Certainty_ADE Outcome_Dose_Frequency</td></tr>
</table>

Recording your Clinical Decisions

The ActionADE research is dependent upon pharmacists recording in PharmaNet their clinical decisions based upon the ADE information presented to them.

The PharmaNet Drug Use Evaluation (DUE) will alert on an ADE as part of the claim process. As these are ADEs versus ADRs, **do not** assume the medication should be discontinued or replaced. In some cases, it is appropriate to ensure the patient takes their medication as in the case of an ADE due to non-adherence. Depending on your Kroll software version this ADE information will be presented differently.

In Kroll SP 20, the user must review the comment details of the ADR and match to the associated Clinical Condition, via *ADE_hhmm identifier, to assess how the ADE alert should be managed clinically. To record the clinical decision in response to ADE information subsequent to the DUE alert, a pharmacist must manually reverse and resubmit any further claim with the appropriate reversal and rational codes

In Kroll 10 SP 21 the software will merge the information together in a unified alert and provide appropriate option buttons to the user which will pre-populate the reversal and rationale intervention codes for you.

If an issue is noted prior to submission of a claim via review of the patient's PharmaNet profile, the pharmacist can enter the rationale intervention code on the initial claim submission.

PharmaNet Intervention Codes for Reversals due to ADE

Code	Description
RA	Due to ADE alert.
RD	Defer clinical decision.
RO	Override alert.

PharmaNet Intervention Codes to indicate a decision to proceed with the dispense despite the ADE information

Code	Description
AA	Fill despite prior substance use.
AB	Benefit outweighs risk.
AE	ADE report erroneous.
AI	ADE alert inappropriate.
AK	ADE acknowledged and prescription changed.
AR	ADE refuted.
AT	ADE resolved/treated.

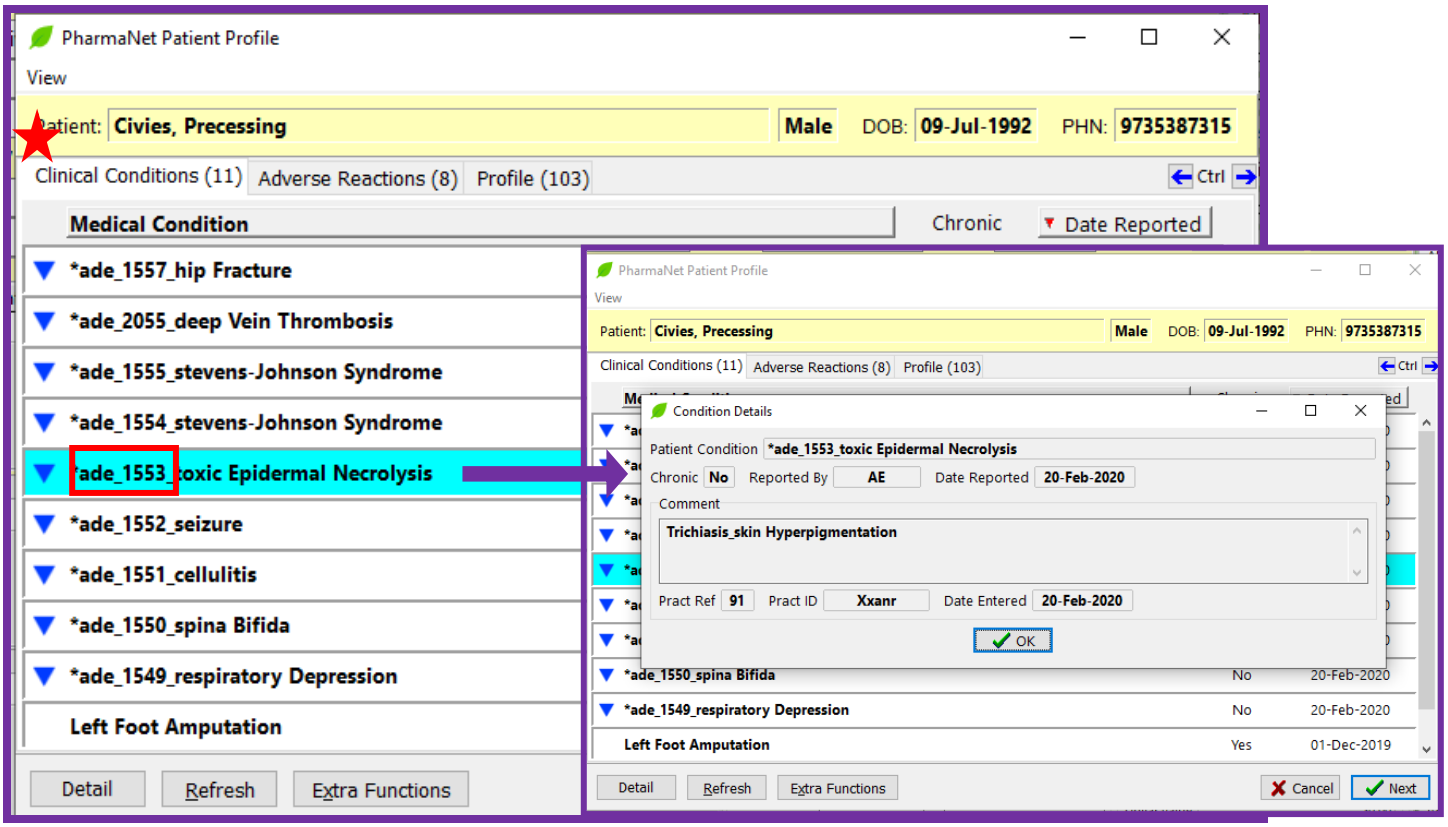
PharmaNet Intervention Codes to indicate a therapeutic change as a result of ADE information.

Code	Description
AK	ADE acknowledged and prescription changed.

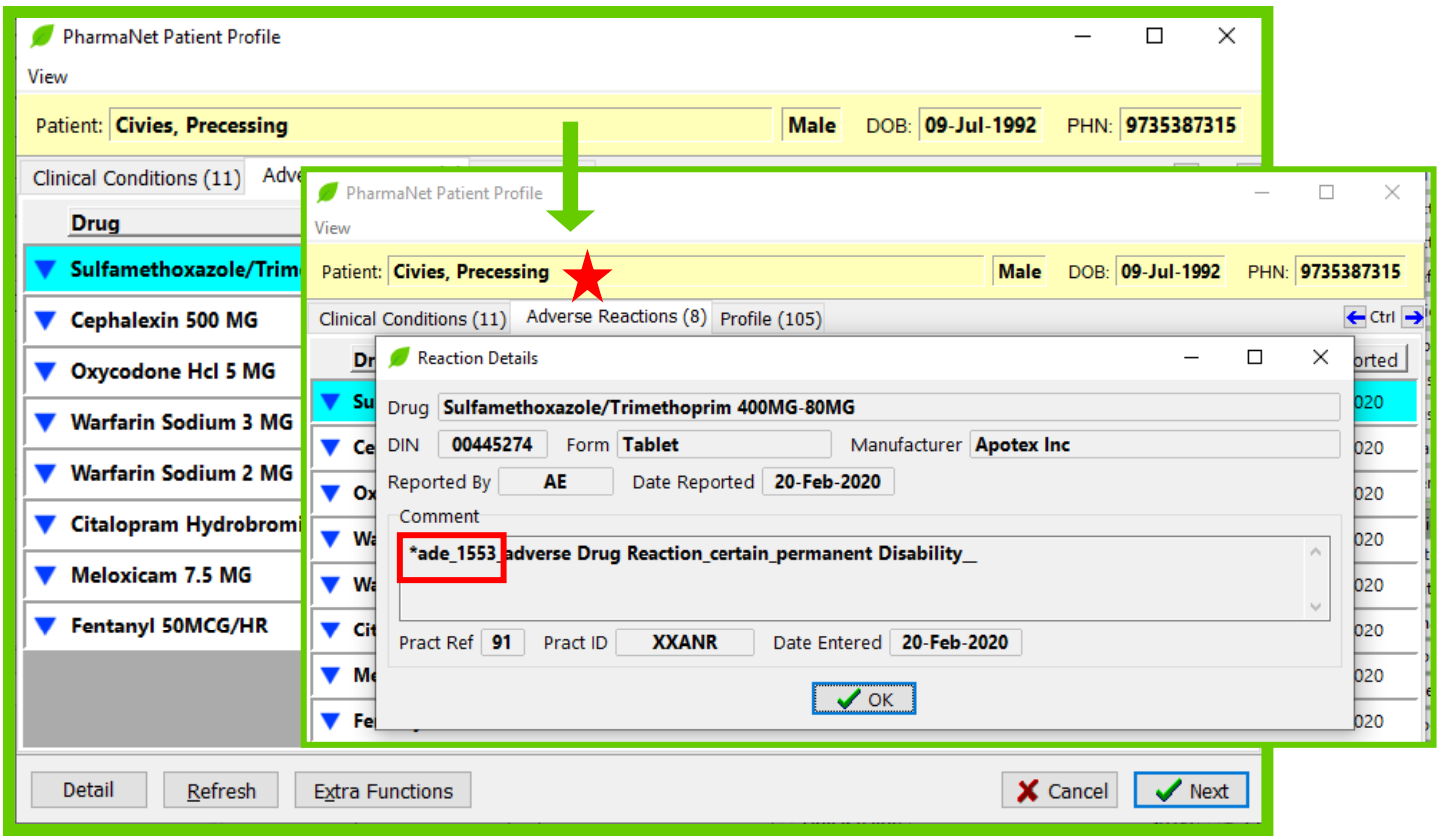
** See Appendix 1 – Workflow to record pharmacist clinical decisions in PharmaNet

Display of ADE information in Kroll version 10.20 and prior

Clinical Conditions Tab



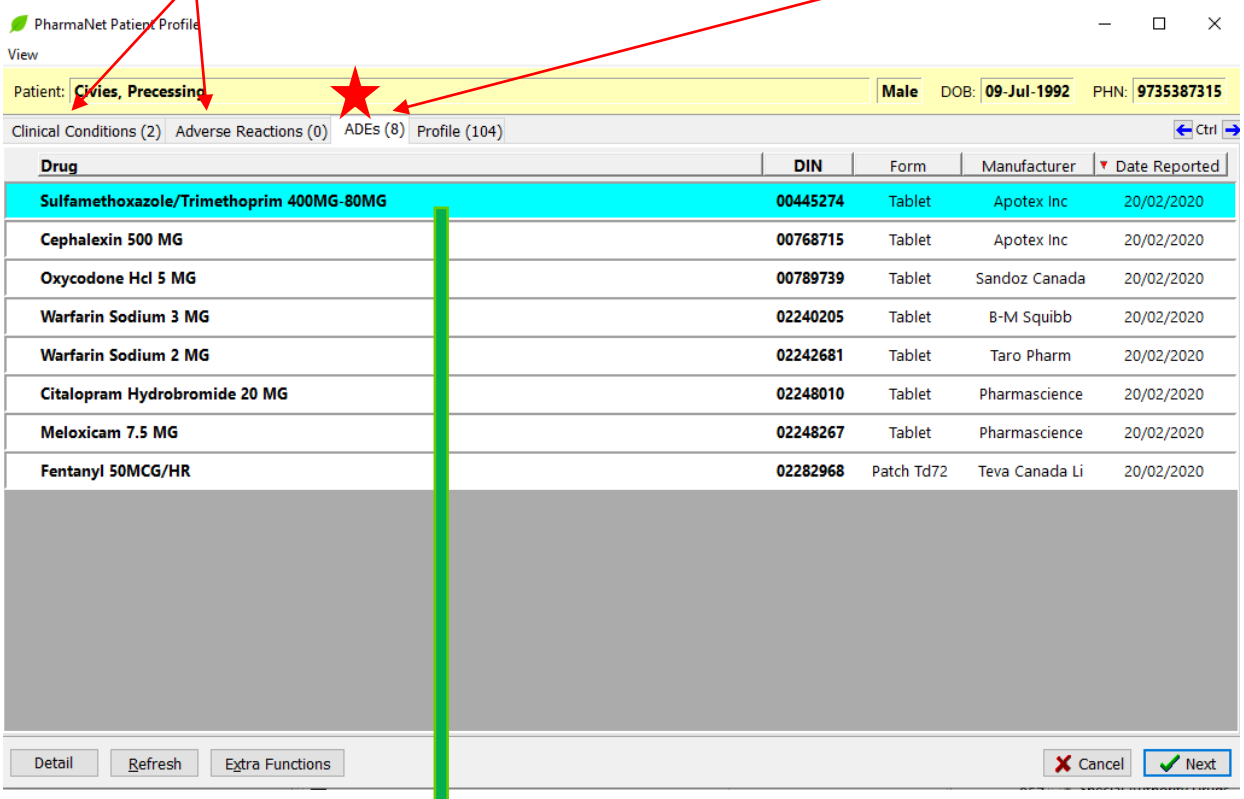
Adverse Reactions Tab

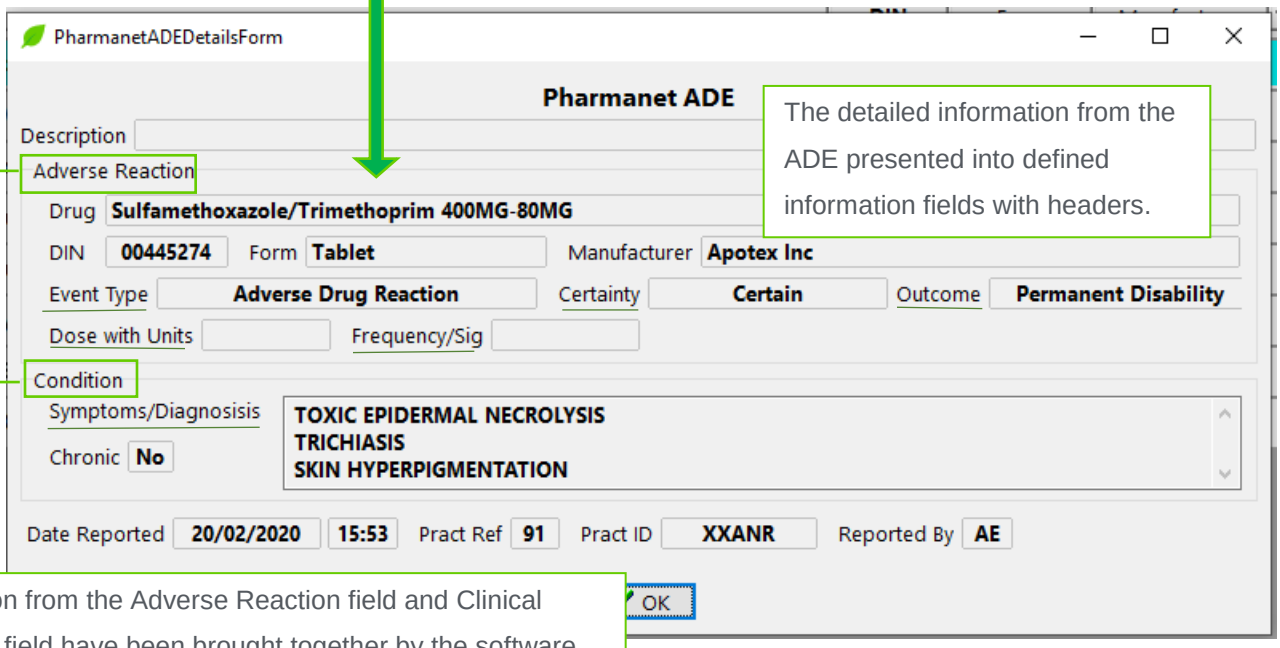


Display of ADE information in Kroll version 10.21

Clinical Conditions and Adverse Reactions tab contain information from pharmacies only.

A new “ADE” tab displays adverse drug event information recorded by acute care sites via ActionADE.





The detailed information from the ADE presented into defined information fields with headers.

Information from the Adverse Reaction field and Clinical Condition field have been brought together by the software by matching the *ADE_hhmm identifier

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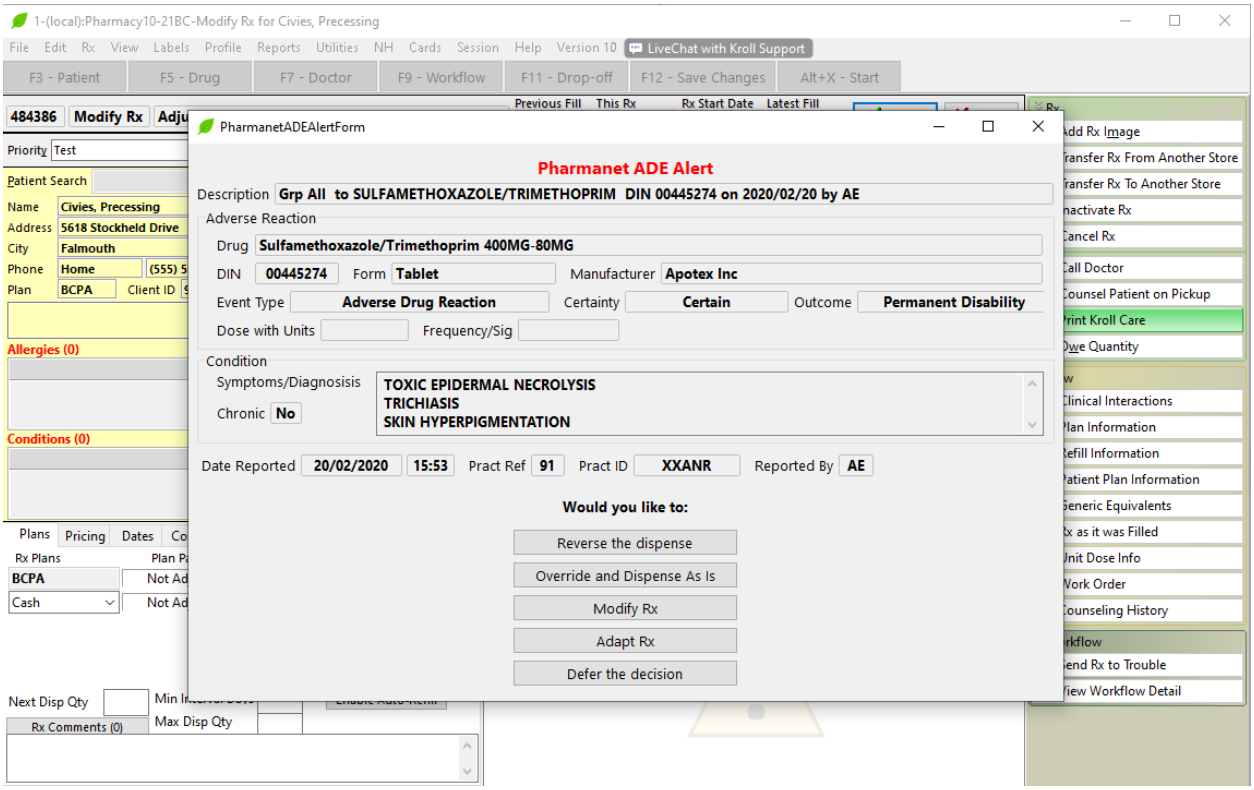
Display of ADE information in Kroll version 10.21 continued.

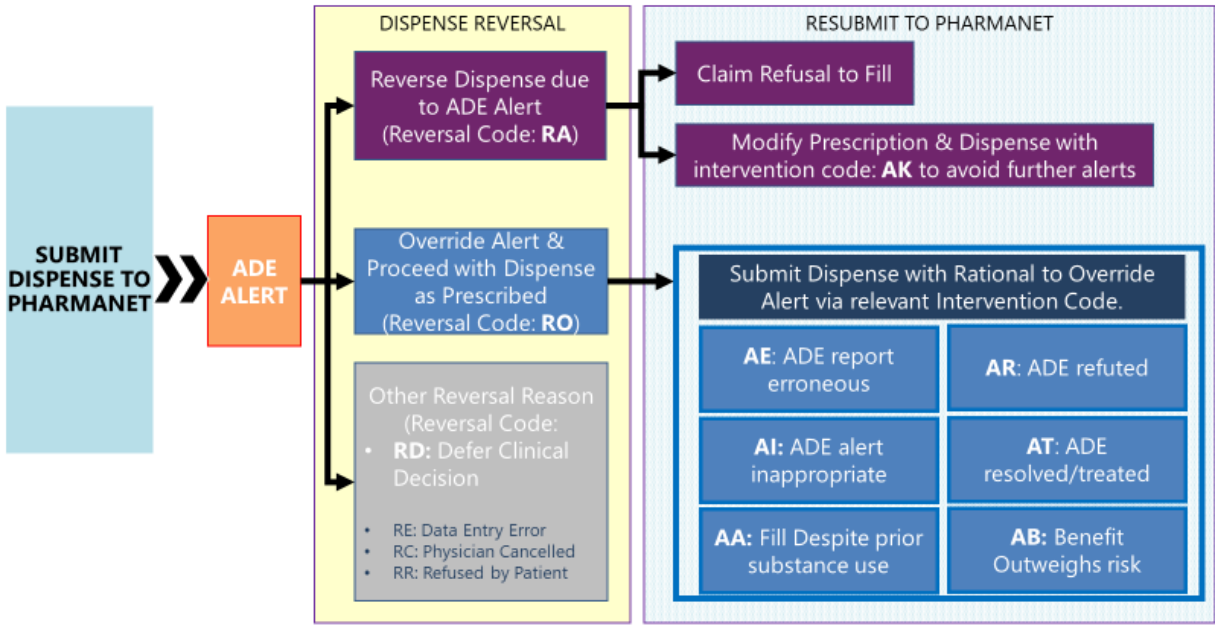


A special ADE alert is created, when relevant, based upon the drug being dispensed and ADE type, and option buttons with automated actions to record the clinical response to the intervention are present.

To record these interventions in previous Kroll versions the pharmacist must manually reverse and resubmit with appropriate PharmaNet intervention codes.

Appendix 1 – Workflow to record clinical decisions due to ADE information by pharmacists in PharmaNet.

A) Workflow if decision made at time of claim adjudication and display of PharmaNet DUE alert



B) Workflow if decision made at time of profile view, prior to submission of claim adjudication.