Oracle Argus Safety

South Korea MFDS E2B(R3) Best Practices

Release 8.2.3

F42264-01

April 2021

Oracle Argus Safety South Korea MFDS E2B(R3) Best Practices, Release 8.2.3

F42264-01

Contents

Preface

This preface contains the following sections:

Documentation accessibility

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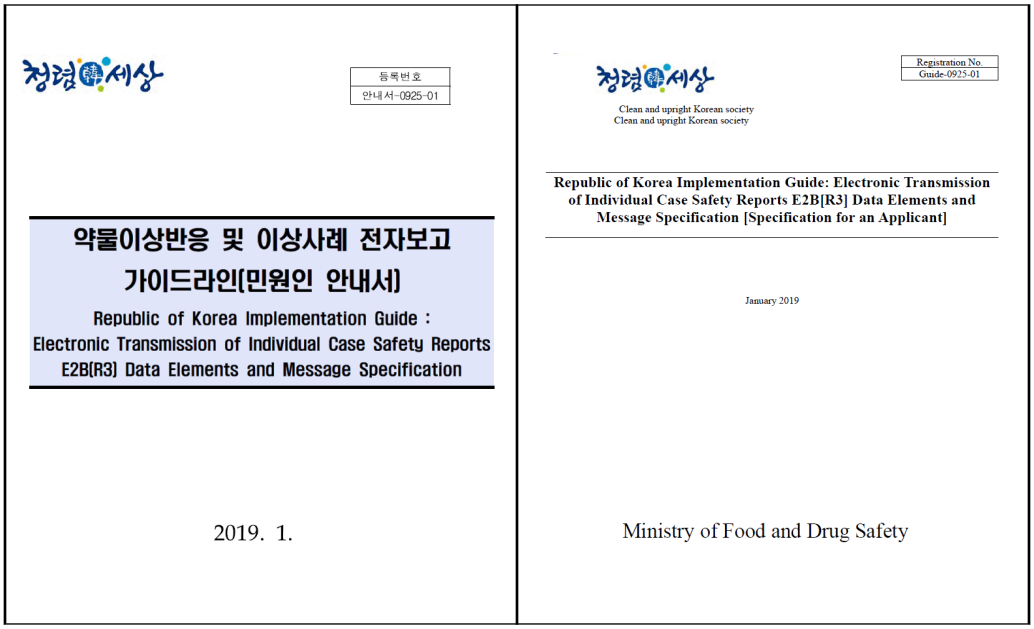
1 Revision History

Argus Version	Description
8.2.2	First release
8.2.3	• Added the "About the study name (C.5.2) for the Study cases" chapter. • Added a note about WHODrug Link Korea in the "MFDS codes for Products and Ingredients in Post-marketed Domestic Cases" chapter.

2 Introduction

MFDS, the South Korean Health Authority, published guidelines for Electronic Transmission of Individual Case Safety Reports E2B(R3) Data Elements and Message Specification [Specification for an Applicant] in January 2019. The revised version of this guideline was published in November 2020.


청렴세상

등록번호
안내서-0925-01

약물이상반응 및 이상사례 전자보고
가이드라인[민원인 안내서]
Republic of Korea Implementation Guide :
Electronic Transmission of Individual Case Safety Reports
E2B(R3) Data Elements and Message Specification

2019. 1.

청렴세상
Clean and upright Korean society
Clean and upright Korean society

Registration No.
Guide-0925-01

Republic of Korea Implementation Guide: Electronic Transmission of Individual Case Safety Reports E2B[R3] Data Elements and Message Specification [Specification for an Applicant]

January 2019

Ministry of Food and Drug Safety

Oracle Argus Safety is enhanced to support out-of-the-box E2B(R3) profile to submit PMSR and CT cases to South Korean Health Authority MFDS (Ministry of Food and Drug Safety). Pharma companies must submit ICSRs in E2B(R3) format starting June 2021.

There are 14 Regional elements added to those specified in the ICH E2B(R3):

Element ID	Element Description (English)	Element Description (Korean)
C.2.r.4.KR.1	Other Health Professional Type	기타 의료전문가 구분
C.3.1.KR.1	Health Professional Type	의료 전문가 상세구분
C.5.4.KR.1	Other Studies Type	기타 시험 상세구분
D.8.r.1.KR.1a	Medicinal Product Version	의약품 코드 버전

Element ID	Element Description (English)	Element Description (Korean)
D.8.r.1.KR.1b	Medicinal Product ID	의약품 코드
D.10.8.r.1.KR.1a	Medicinal Product Version	의약품 코드 버전
D.10.8.r.1.KR.1b	Medicinal Product ID	의약품 코드
G.k.2.1.KR.1a	Medicinal Product Version	의약품 코드 버전
G.k.2.1.KR.1b	Medicinal Product ID	의약품 코드
G.k.2.3.r.1.KR.1a	Substance ID Version	성분 코드 버전
G.k.2.3.r.1.KR.1b	Substance ID	성분 코드
G.k.9.i.2.r.2.KR.1	MFDS Method of Assessment	평가 방법
G.k.9.i.2.r.3.KR.1	WHO-UMC Result of Assessment	WHO-UMC 평가 결과
G.k.9.i.2.r.3.KR.2	KRCT Result of Assessment	KRCT 평가 결과

This document lists the best practices and the recommendations for generating the MFDS E2B(R3) report from Oracle Argus Safety.

3

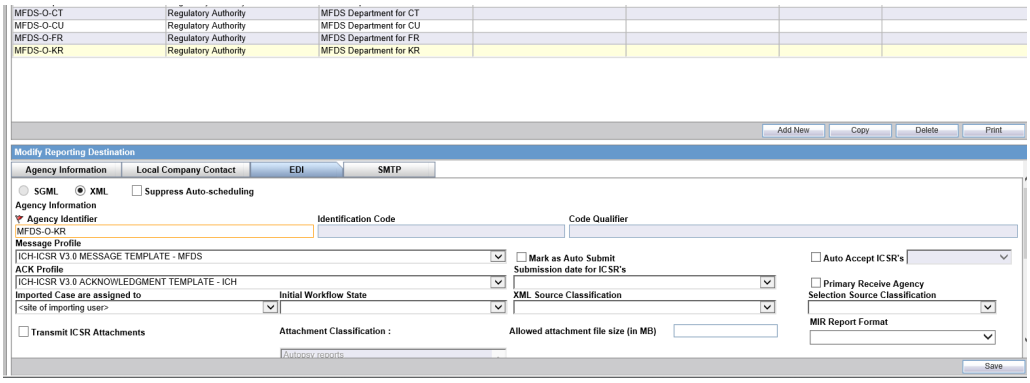
Reporting Destinations setup

As per the Business rules for E2B(R3) published by MFDS (약물이상반응 및 이상사례 개별 항목 검증 룰.xlsx), the reports have to be submitted to 4 different offices, based on the case data.

Therefore, N.1.4 Batch Receiver Identifier and N.2.r.3 Message Receiver Identifier should have one of the below values:

- Clinical Trial: **MFDS-O-CT** (Test environment-MFDS-T-CT)
- Compassionate Use: **MFDS-O-CU** (Test environment-MFDS-T-CU)
- Domestic Post-marketed: **MFDS-O-KR** (Test environment-MFDS-T-KR)
- Foreign Post-marketed: **MFDS-O-FR** (Test environment-MFDS-T-FR)

To achieve this, set up four different **Reporting Destinations** with **Agency Identifiers** in Oracle Argus Safety.



4
Reporting Rules setup

Each report to MFDS has to be routed to CT/CU/KR/FR Receiver Identifier depending on the case data such as Drug/Vaccine license country, Report type, Primary reporter country, Type of study.

We recommend that you set up Reporting Rules with Advanced Conditions in Oracle Argus Safety.

Below are sample reporting rules for understanding:

Country	License Type	Agency	Rule Name	Timeframe Calendar days	Advanced Condition
South Korea	Marketed Drug	MFDS-O-KR	Serious ADR Domestic	15	Primary Reporter Country = South Korea Report Type = Spontaneous
Germany	Marketed Drug	MFDS-O-FR	Serious ADR Foreign	15	Primary Reporter Country <> South Korea Report Type = Spontaneous
South Korea	Investigational Drug	MFDS-O-CT	Death/LT SUSAR	7	Primary Reporter Country = South Korea Report Type = Sponsored Trial
South Korea	Investigational Drug	MFDS-O-CT	Serious Unexpected MFDS Clinical Trial rule	15	Primary Reporter Country = South Korea Report Type = Sponsored Trial
Germany	Investigational Drug	MFDS-O-CT	Death/LT SUSAR	7	Primary Reporter Country <> South Korea Report Type = Sponsored Trial

Country	License Type	Agency	Rule Name	Timeframe Calendar days	Advanced Condition
Germany	Investigational Drug	MFDS-O-CT	SUSAR MFDS Clinical Trial rule	15	Primary Reporter Country <> South Korea Report Type = Sponsored Trial
South Korea	Investigational Drug	MFDS-O-CU	SUSAR MFDS Therapeutic Study rule	15	Primary Reporter Country = South Korea Report Type = Sponsored Trial Observe Study Type = Compassionate Use
European Union	Investigational Drug	MFDS-O-CU	SUSAR MFDS Therapeutic Study rule	15	Primary Reporter Country <> South Korea Report Type = Sponsored Trial Observe Study Type = Compassionate Use
South Korea	Marketed Drug	MFDS-O-KR	SADR domestic	15	Primary Reporter Country = South Korea Report Type = Spontaneous Clinical Trial Observe Study Type = Other Studies

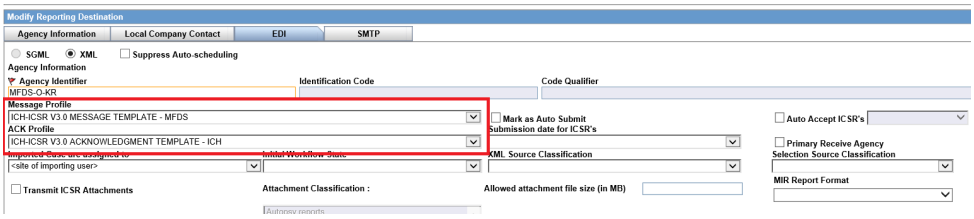
5

Set up an E2B(R3) profile for ICSR and ACK

To generate MFDS E2B(R3):

1. Set the **Message Profile** in the Modify Reporting Destination window to **ICH-ICSR V3.0 MESSAGE TEMPLATE - MFDS**.

To import MFDS ACK:

1. Set the **Acknowledgment Profile** in the Modify Reporting Destination window to **ICH-ICSR V3.0 ACKNOWLEDGEMENT TEMPLATE – ICH**.
2. 

> **Note:**
>
> The **ACK ICH-ICSR V3.0 ACKNOWLEDGEMENT TEMPLATE – ICH** profile is created using the new R3 framework, and is designed to be used with ICSR R3 profiles like MFDS. It cannot be used as an ACK profile along with **ICH- ICSR V3.0 MESSAGE TEMPLATE**, as the ICSR template is based on the old framework.

6

MFDS codes for Products and Ingredients in Post-marketed Domestic Cases

MFDS has published a Regional Drug Dictionary with Product code and Ingredient code assigned for each Product and the set of Ingredients in that Product.

MFDS Product Code – 9-digit unique code per Product

MFDS Ingredient Code – 7-digit unique code per Ingredient

MFDS uploads the Drug Product License details spreadsheet in `nedrug.mfds.go.kr`, and this is refreshed in real time (on a daily basis). The location for file download is:

Drug Product License details

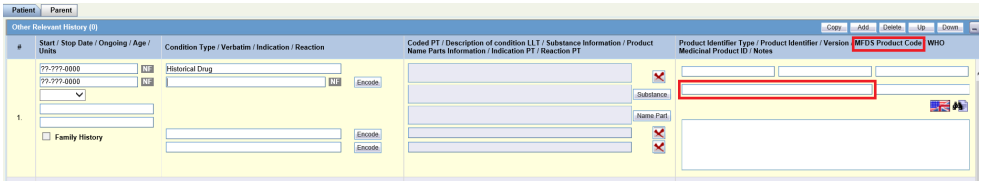
For post-marketed domestic cases, it is mandatory to transmit the MFDS Product code or MFDS Ingredient code for every Company and Non-company Product in the KR specific regional data elements (outlined in the table below) in E2B(R3) report as per the Business rules.

To achieve this, four new Case Form fields are introduced in Oracle Argus Safety.

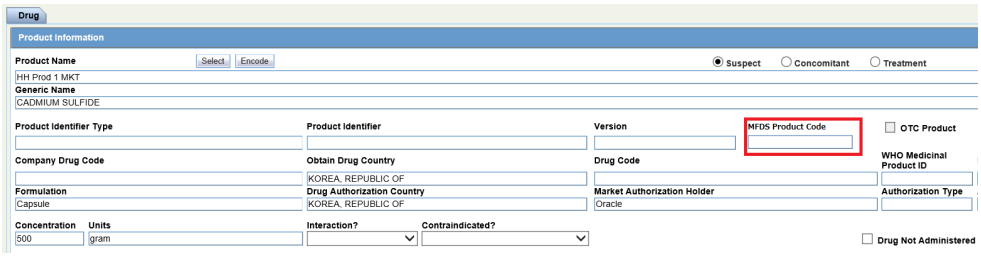
It is required that companies manually enter the MFDS assigned Product code and Ingredient code in the Case Form fields as outlined in the table below.

Element ID	Element Description	Case Form Field
D.8.r.1.KR.1b	Medicinal Product ID (Patient Past drug Therapy)	**Patient** tab > **Other Relevant History** > **MFDS Product Code**
D.10.8.r.1.KR.1b	Medicinal Product ID (Parent Past drug Therapy)	**Parent** tab > **Other Relevant History** > **MFDS Product Code**
G.k.2.1.KR.1b	Medicinal Product ID (Suspect/Concomitant/ Interacting Products)	**Product** tab > **Product Information** > **MFDS Product Code**
G.k.2.3.r.1.KR.1b	Substance ID (Ingredients of Suspect/ Concomitant/Interacting Products)	**Product** tab > **Substance Information** > **MFDS Ingredient Code**

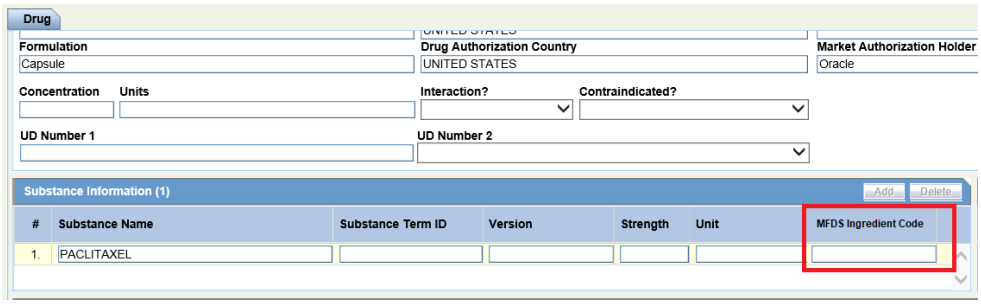
1. **Patient/Parent** tab > **Other Relevant History** > **MFDS Product Code**:



2. **Product** tab > **Product Information** > **MFDS Product Code**



3. **Product** tab > **Substance Information** > **MFDS Ingredient Code**



> **Note:**
>
> It is in Oracle Argus Safety roadmap to enhance data entry and to provide a way to automatically populate MFDS Product Code and MFDS Ingredient Code when any Product is added to case.
>
> - For company products, this requires association of MFDS-specific codes in **Console** > **Product** > **License Configuration**.
> - For non-company products, this requires association of MFDS-specific codes in WHO drug dictionary tables. Based on the discussions with WHO-UMC, it is understood that WHO-UMC is working with MFDS to provide this mapping between WHO drug/ingredient codes and MFDS specific codes.
> - The official release date of the WHODrug Link Korea first version is March 1st, 2021. This release is compatible with the March 2021 WHODrug Global release.

7

WHO codes for Products and Ingredients in Post-marketed Foreign Cases

For post-marketed foreign cases, it is mandatory to transmit the WHO Medicinal Product ID for every Company and Non-company Product, and the WHO CAS Number for every Ingredient of the Product in the KR specific regional data elements (outlined in the table below) in the E2B(R3) report as per the Business rules.

> **Note:**
>
> Based on the discussion with MFDS, only WHO Global C3 coding is accepted while submitting foreign ICSRs. ICSRs using other formats (e.g. B3 format) will be rejected.

Element ID	Element Description	Data Original
D.8.r.1.KR.1a	WHO-DD version	WHO-DD version
D.8.r.1.KR.1b	Medicinal Product ID (Patient Past drug Therapy)	WHO Medicinal Product ID
D.10.8.r.1.KR.1a	WHO-DD version	WHO-DD version
D.10.8.r.1.KR.1b	Medicinal Product ID (Parent Past drug Therapy)	WHO Medicinal Product ID
G.k.2.1.KR.1a	WHO-DD version	WHO-DD version
G.k.2.1.KR.1b	Medicinal Product ID (Suspect/Concomitant/ Interacting Products)	WHO Medicinal Product ID
G.k.2.3.r.1.KR.1a	WHO-DD version	WHO-DD version
G.k.2.3.r.1.KR.1b	Substance ID (Ingredients of Suspect/ Concomitant/Interacting Products)	WHO CAS Number

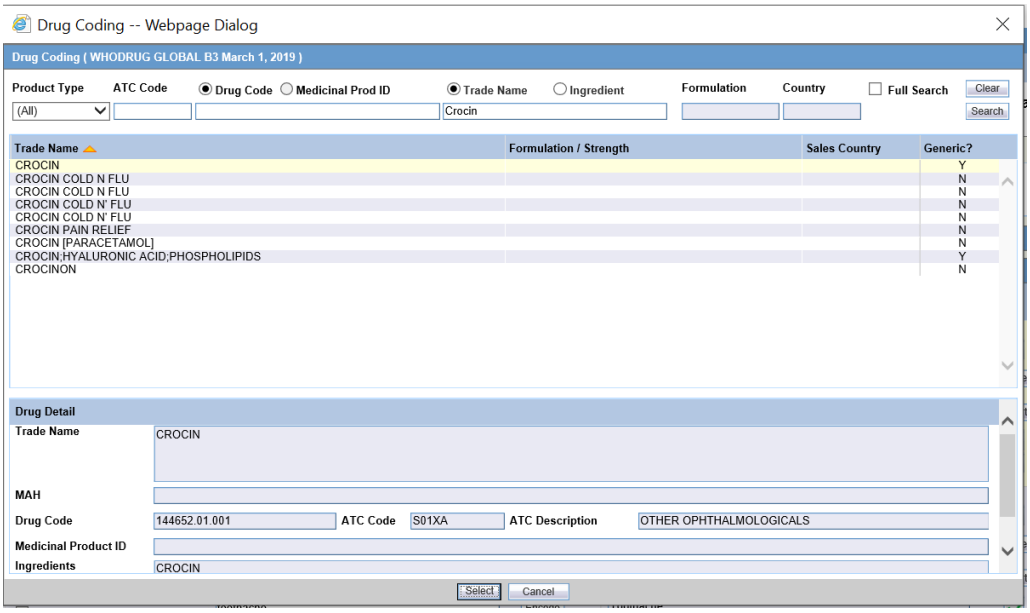
Difference between B-format and C-format

B-formats contain information about trade names, ingredients and ATC classification(s). The unique key is the alphanumeric **Drug Code**.

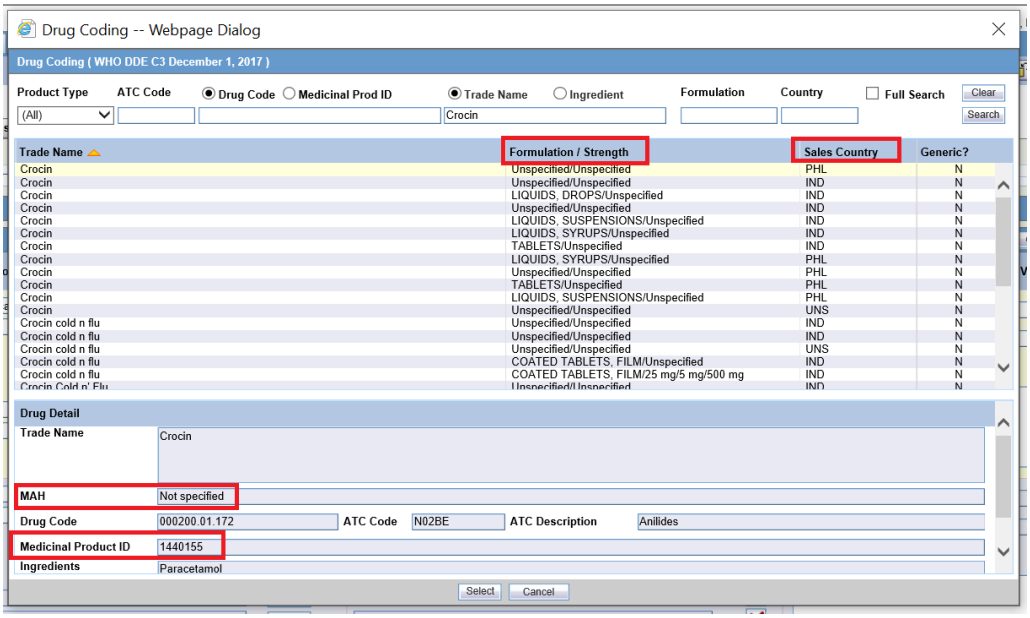
C-formats contain all the B-format information (including the Drug Code), but has additional information regarding the countries where the product is marketed,

Marketing Authorization Holders, pharmaceutical forms and strengths. The unique key is the alphanumeric **Medicinal Product ID**.

WHO B3 coding in Oracle Argus Safety



WHO C3 coding in Oracle Argus Safety

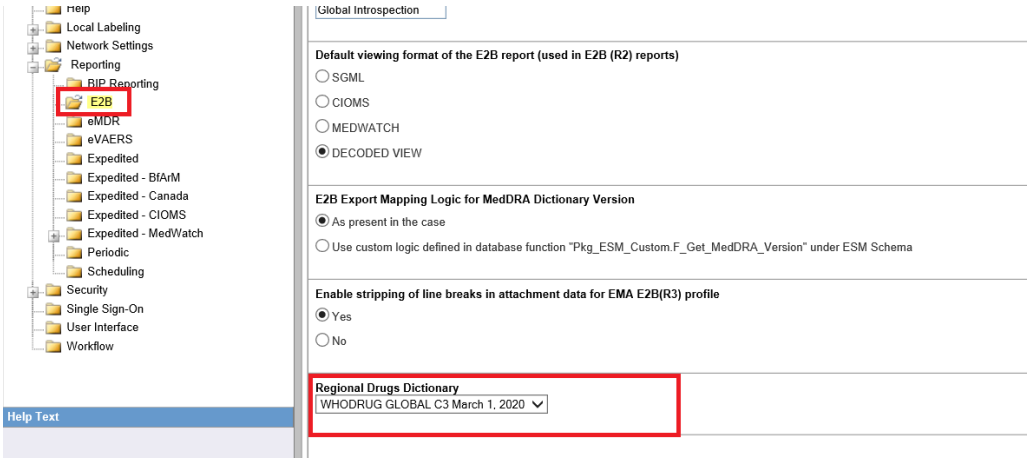


For Companies using WHO-DD C3 format

For drugs auto encoding during case processing with WHO-DD C3 format, the dictionary is set in **Argus Console** > **System Configuration** > **System Management (Common Profile Switches)** > **Case Form Configuration** > **Auto Encoding** section.

Set the same WHO-DD C3 dictionary in the newly introduced Common Profile Switch in **Console** > **Common Profile Switch** > **E2B** > **Regional Drugs Dictionary**.

> **Note:**
>
> This switch will have no impact on case processing and it is used only for MFDS E2B R3 reporting.



WHO Medicinal Product ID and WHO CAS Number are captured and transmitted as outlined in the table below.

For details, refer to the Business Rules defined in the E2B(R3) export mapping document.

Element ID	Element Description	Data Capture and Transmitted From
D.8.r.1.KR.1a	WHO-DD version	**Console** > **Common Profile Switch** > **E2B** > **Regional Drugs Dictionary**
D.8.r.1.KR.1b	Medicinal Product ID (Patient Past drug Therapy)	**Case Form** > **Patient** > **Other Relevant History** > **WHO Medicinal Product ID**
D.10.8.r.1.KR.1a	WHO-DD version	**Console** > **Common Profile Switch** > **E2B** > **Regional Drugs Dictionary**
D.10.8.r.1.KR.1b	Medicinal Product ID (Parent Past drug Therapy)	**Case Form** > **Parent** > **Other Relevant History** > **WHO Medicinal Product ID**
G.k.2.1.KR.1a	WHO-DD version	**Console** > **Common Profile Switch** > **E2B** > **Regional Drugs Dictionary**
G.k.2.1.KR.1b	Medicinal Product ID (Suspect/Concomitant/ Interacting Products)	**Case Form** > **Product** > **WHO Medicinal Product ID**
G.k.2.3.r.1.KR.1a	WHO-DD version	**Console** > **Common Profile Switch** > **E2B** > **Regional Drugs Dictionary**

Element ID	Element Description	Data Capture and Transmitted From
G.k.2.3.r.1.KR.1b	Substance ID (Ingredients of Suspect/ Concomitant/Interacting Products)	WHO CAS Number is retrieved from WHO-DD C3 dictionary WHO_DRUG_C_SUBSTANCE table using **Case Form** > **Product** > **Substance Information** > **Substance Name**

For WHO drugs

To facilitate the capture of WHO Medicinal Product ID for Historical drugs, 2 Case Form fields are newly introduced, namely:

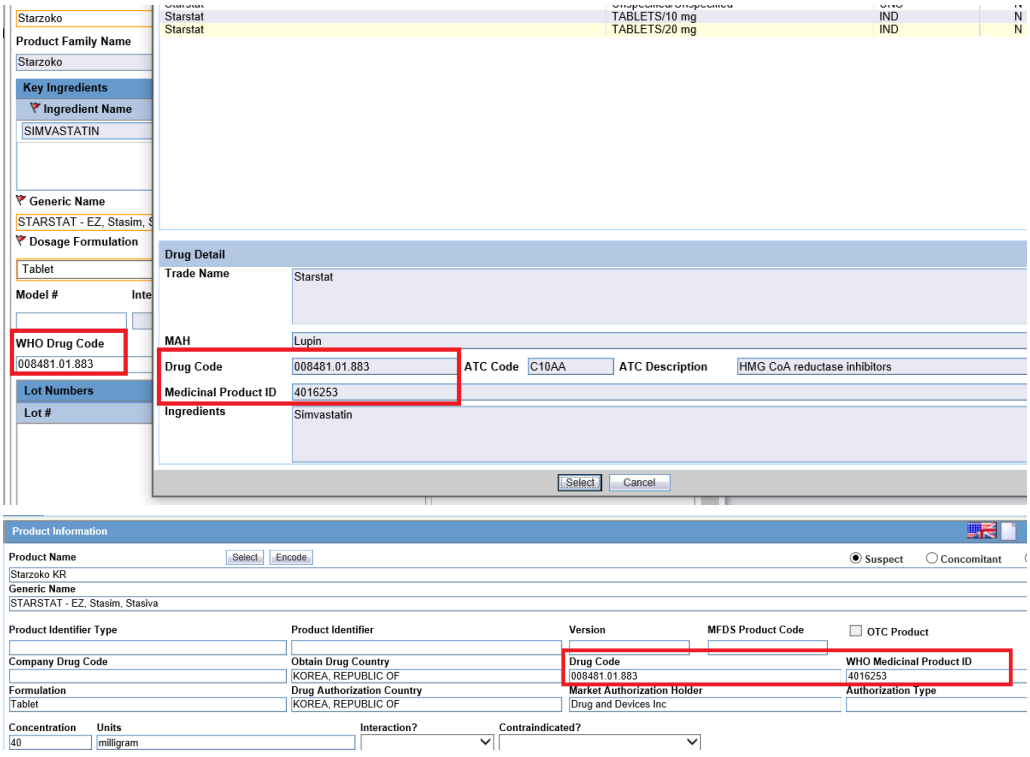
- **Case Form** > **Patient** > **Other Relevant History** > **WHO Medicinal Product ID**
- **Case Form** > **Parent** > **Other Relevant History** > **WHO Medicinal Product ID**

When drugs are coded during case processing with the WHO-DD C3 format, the WHO Medicinal Product ID is automatically populated from the WHO Drug browser.

For Company drugs

In Oracle Argus Safety Console, set the WHO Drug Code for company products. This will store the WHO Drug Code in LM_PRODUCT.DRL_ID and also the corresponding Medical Product ID in LM_PRODUCTS.MEDICINAL_PROD_ID.

When this Product is added in the case, the WHO Medicinal Product ID would be populated in **Case Form** > **Product**.



> **Note:**
>
> During the E2B R2/R3 import, the WHO Medicinal Product ID will not be populated even if the incoming XML contains a WHO Drug product. This is because, with the elements available in the XML file, it is not possible to determine the correct WHO MPID. Similarly, the system has not been populating WHO Medicinal Product ID in **Case Form** > **Product** during the E2B R2/R3 import.

For Companies using WHO-DD B3 format

For drugs auto encoding during case processing with WHO-DD B3 format, the dictionary is set in **Argus Console** > **System Configuration** > **System Management (Common Profile Switches)** > **Case Form Configuration** > **Auto Encoding** section.

For MFDS E2B(R3) reporting, since it is mandatory to send the WHO Medicinal Product ID and the WHO CAS Number from C3 format, it is recommended to load the WHO-DD C3 dictionary into Oracle Argus Safety. Technically, Oracle Argus Safety supports loading multiple WHO dictionary versions and formats.

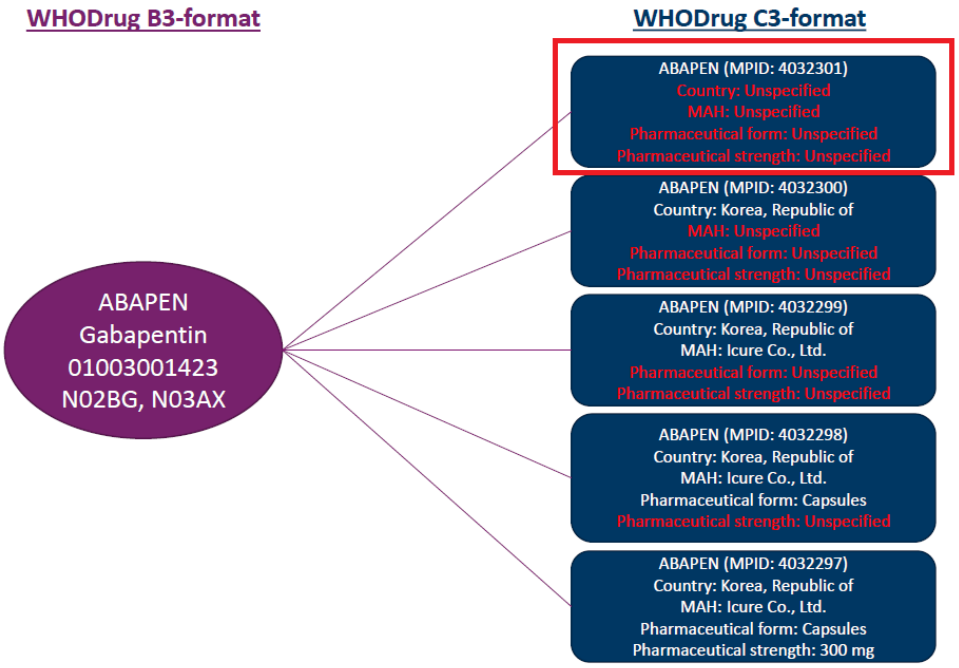
Set the WHO-DD C3 dictionary in the newly introduced Common Profile Switch in **Console** > **Common Profile Switch** > **E2B** > **Regional Drugs Dictionary**.

> **Note:**
>
> This switch shall not impact the Case processing and is used only for MFDS E2B(R3) reporting. Hence, companies can continue to code drugs with the WHO-DD B3 format as usual.

MFDS E2B(R3) mapping logic is designed to automatically fetch the WHO Medicinal Product ID and the WHO CAS Number from the C3 dictionary set in the Regional Drugs Dictionary based on the WHO Drug Code in the Oracle Argus Safety Case Form.

This mapping is designed in discussion with WHO-UMC to fetch the match from C3 where Country = Unspecified, MAH = Unspecified, Formulation = Unspecified, Strength = Unspecified.

For example, for the ABAPEN drug coded using B3 format, Oracle Argus Safety mapping logic fetches the corresponding C3 format data, as in the image below:



Note:

WHO-UMC does not provide official mapping between B format and C format. Oracle discussed this challenge with WHO-UMC, and they acknowledge the challenge. WHO-UMC are currently engaging with MFDS with the ultimate aim to create mappings between WHODrug B3 and WHODrug C3 format.

Until official mapping between B format and C format is provided, it is recommended to use out-of-the-box MFDS E2B(R3) mapping logic in Oracle Argus Safety.

Note:

The customization of B3 to C3 mapping can be achieved by the customizing export mapping query for the below elements in **Console** > **Interchange Mapping** > **MFDS profile**:

- PATIENTPASTDRUGTHERAPY
- PARENTPASTDRUGTHERAPY
- DRUG
- ACTIVESUBSTANCE

The `pkg_mfds.sql` file is unwrapped for this purpose.

WHO Medicinal Product ID and WHO CAS Number are captured and transmitted as outlined in the table below.

For details, refer to the Business Rules defined in E2B(R3) export mapping document.

Element ID	Element Description	Data Capture and Transmitted From
D.8.r.1.KR.1a	WHO-DD version	**Console** > **Common Profile Switch** > **E2B** > **Regional Drugs Dictionary**
D.8.r.1.KR.1b	Medicinal Product ID (Patient Past drug Therapy)	WHO Medicinal Product ID is retrieved from WHO-DD C3 dictionary WHO_DRUG_C_MASTER table using Drug code of the Patient past drug details
D.10.8.r.1.KR.1a	WHO-DD version	**Console** > **Common Profile Switch** > **E2B** > **Regional Drugs Dictionary**
D.10.8.r.1.KR.1b	Medicinal Product ID (Parent Past drug Therapy)	WHO Medicinal Product ID is retrieved from WHO-DD C3 dictionary WHO_DRUG_C_MASTER table using Drug code of the Parent past drug details
G.k.2.1.KR.1a	WHO-DD version	**Console** > **Common Profile Switch** > **E2B** > **Regional Drugs Dictionary**
G.k.2.1.KR.1b	Medicinal Product ID (Suspect/Concomitant/ Interacting Products)	WHO Medicinal Product ID is retrieved from WHO-DD C3 dictionary WHO_DRUG_C_MASTER table using **Case Form** > **Product** > **Drug Code**
G.k.2.3.r.1.KR.1a	WHO-DD version	**Console** > **Common Profile Switch** > **E2B** > **Regional Drugs Dictionary**
G.k.2.3.r.1.KR.1b	Substance ID (Ingredients of Suspect/ Concomitant/Interacting Products)	WHO CAS Number is retrieved from WHO-DD C3 dictionary WHO_DRUG_C_SUBSTANCE table using **Case Form** > **Product** > **Substance Information** > **Substance Name**

8

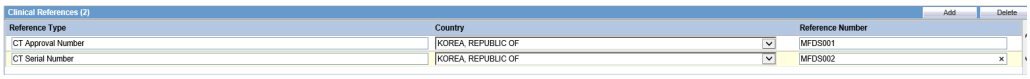
Clinical Trial Approval Number (C.5.1.r.1) and Clinical Trial Serial Number (C.5.3) for Study cases

For Study cases where Study Type is Clinical Trial study (C.5.4 OBSERVESTUDYTYPE = 1 Clinical trials) or Study Type is Compassionate Use study (C.5.4 OBSERVESTUDYTYPE = 2 Individual patient use), it is mandatory to transmit the data as outlined in the table below.

Element ID	Element Description	Data to Transmit
C.5.1.r.1	Study Registration Number	Clinical Trial Approval Number issued by MFDS
C.5.3	Sponsor Study Number	Clinical Trial Serial Number issued by MFDS

To achieve this, set up the MFDS specific numbers in **Console** > **Study Configuration** > **Clinical References** section:

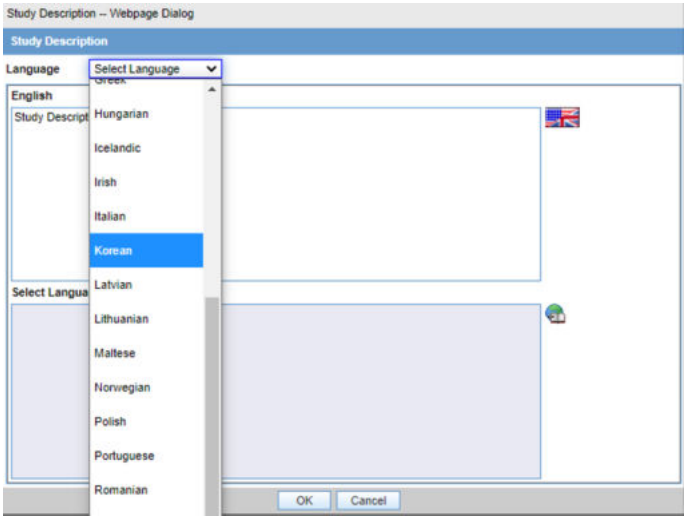
- To transmit Clinical Trial Approval Number issued by MFDS in C.5.1.r.1, select **Reference Type = CT Approval Number**, and enter the Reference Number for Country = Korea, Republic of
- To transmit Clinical Trial Serial Number issued by MFDS in C.5.3, select **Reference Type = CT Serial Number**, and enter the Reference Number for Country = Korea, Republic of



9

About the study name (C.5.2) for the Study cases

For the studies that need to be reported to MFDS, the study name should be configured to Korean language in **Argus Console** > **Business Configuration** > **Studies** > **Studies Configuration** > **Study Description**. If the configured data are available in Korean language, the same information is transmitted in C.5.2 STUDYNAME. Otherwise, the configured data are transmitted in English language.



10

Other Health Professional Type (C.2.r.4.KR.1) for cases reported by Other Health Professional

Whenever a case is reported by Other Health Professional, **Case Form** > **General** > **Reporter Information** > **Reporter Type** is selected as **Other Health Professional**.

This transmits C.2.r.4 QUALIFICATIONR3 = 3 (Other health professional), it is mandatory to transmit C.2.r.4.KR.1 Other Health Professional Type.

Element ID	Element description	Allowed Values
C.2.r.4.KR.1	Other Health Professional Type	1=Nurse 2=Other

To achieve this, Oracle Argus Safety Flexible code list is enhanced with additional values in **Console** > **Code Lists** > **Flexible re-categorization** > **REPORTER_TYPE**:

- The new MFDS attribute is added.
- The existing E2B(R3) attribute is updated for the additional values.

If a case is reported by a Nurse, then select **Case Form** > **General** > **Reporter Information** > **Reporter Type = Nurse**. MFDS E2B(R3) will transmit C.2.r.4 = 3 Other health professional and C.2.r.4.KR.1 = 1 Nurse.

If a case is reported by any other Health Professional, then select **Case Form** > **General** > **Reporter Information** > **Reporter Type = Other or Hospital**. MFDS E2B(R3) will transmit C.2.r.4 = 3 Other health professional and C.2.r.4.KR.1 = 2 Other.

What this means to business users: No additional data entry required (and derived from configuration).

English Description	E2B	Ja	MFDS
Physician	1	医薬情報担当者	-
Company Representative	5	企業代表者	-
Other Health Professional	3	その他の医療専門家	2
Non-Health Professional	5	消費者またはその他の非医療専門家	
Nurse	3	看護師	1
Pharmacist	2	薬剤師	-
Consumer	5	消費者	-

English Description	E2B	Ja	MFDS
Lawyer	4	弁護士	-
Other	5	その他	-
Professor	5	教授	-
Hospital	3	病院	2
Specialist	1	専門家	-

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Health Professional Type (C.3.1.KR.1) for cases with Health Professional Sender Type

Whenever Sender Type is Health Professional with C.3.1 = 3 (Health professional) as set in the **Console** > **Reporting Destination** > **Local Company Contact** > **Sender Type**, it is mandatory to transmit C.3.1.KR.1 Health Professional Type.

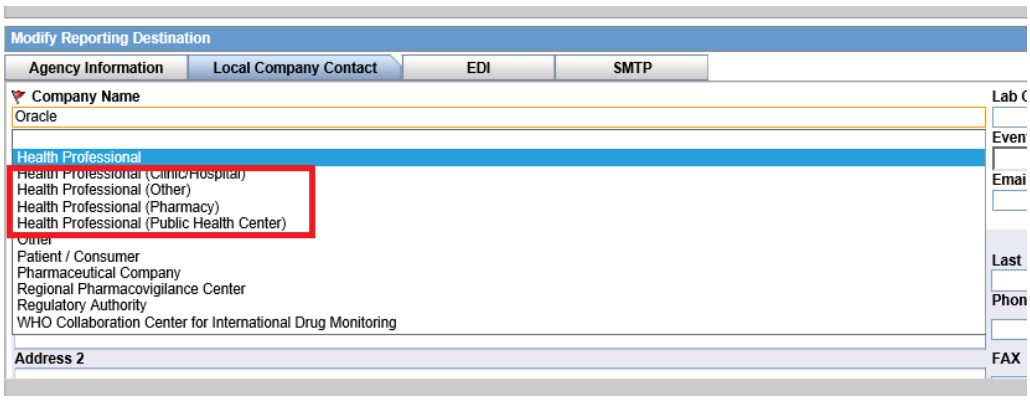
Element ID	Element Description	Allowed Values
C.3.1.KR.1	Health Professional Type	1=Clinic/Hospital 2=Pharmacy 3=Public Health Centre 4=Other

To achieve this, Oracle Argus Safety Flexible code list is enhanced with additional values in **Console** > **Code Lists** > **Flexible re-categorization** > **REPORTING_DESTINATION_TYPE**:

- The new MFDS attribute is added.
- The existing E2B(R3) attribute is updated for the additional values.

It is recommended to set the **Console** > **Reporting Destination** > **Local Company Contact** > **Sender Type** according to the Sender Type, so that C.3.1 will be transmitted as 3 (Health professional) and C.3.1.KR.1 will be transmitted as corresponding MFDS attribute value.

What this means to business users: No additional data entry required (and derived from configuration).



CODE	En	Ja	E2B_R3	MFDS
1	Pharmaceutical Company	製薬企業	1	-

CODE	En	Ja	E2B_R3	MFDS
2	Regulatory Authority	規制当局	2	-
3	Health Professional	医療専門家	3	4
4	Regional Pharmacovigilance Center	地域薬剤監視センター	4	-
5	WHO Collaboration Center for International Drug Monitoring	WHO 国際医薬品モニタリングセンター	5	-
6	Other	その他	6	-
7	Patient / Consumer	患者 / 消費者	7	-
8	Health Professional (Clinic/Hospital)	医療専門家(診療所/病院)	3	1
9	Health Professional (Pharmacy)	医療専門家(薬局)	3	2
10	Health Professional (Public Health Center)	医療専門家(保健所)	3	3
11	Health Professional (Other)	医療専門家(その他)	3	4

12

Study Type (C.5.4.KR.1) for studies other than Clinical Trial or Compassionate Use studies

For studies other than Clinical Trial or Compassionate Use, Study Type C.5.4 = 3 Other studies (e.g., pharmacoepidemiology, pharmacoeconomics, intensive monitoring, post marketed surveillance), it is mandatory to transmit C.5.4.KR.1 Other Studies Type.

Element ID	Element Description	Allowed Values
C.5.4.KR.1	Other Studies Type	1 = Investigation into usage when reporting for a review 2 = Post-marketing clinical study when reporting for a review 3 = Special investigation when reporting for a review 4 = Other

To achieve this, Oracle Argus Safety Flexible code list is enhanced with additional values in **Console** > **Code Lists** > **Flexible re-categorization** > **CASE_CLASSIFICATION**:

- The new MFDS attribute is added.
- The existing E2B(R3) attribute is updated for the additional values.

It is recommended to set the **Console** > **Business configuration** > **Studies** > **Observe Study Type** according to the Other Study Type so that C.5.4 will be transmitted as 3 (Other studies) and C.5.4.KR.1 will be transmitted as corresponding MFDS attribute value.

What this means to business users: No additional data entry required (and derived from configuration)

CODE	En	E2B	Ja	MFDS
1	Clinical Trial	1	臨床試験	-
2	Individual Patient Use	2	患者個人使用	-
3	Other Studies	3	その他の試験	4
4	CIRM Case	-	CIRM 症例	-
5	SAW not applicable to device	-	SAW（機器は非該当）	

CODE	En	E2B	Ja	MFDS
6	SAE not applicable to drug	-	SAE（薬品は非該当）	
7	Combination Product	-	組合せ製品	-
8	Investigation into usage	3	使用量の調査	1
9	Post-marketing clinical study	3	製造販売後治験チェック	2
10	Special investigation	3	特別調査	3

13

Regional Causality Assessment (G.k.9.i) for post-marketed Domestic cases and Study cases

There are 3 regional KR elements described for Regional Causality Assessment.

For Study cases with C.1.3 Report Type = 2 (Report from Study), it is mandatory to transmit G.k.9.i.2.r.2.KR.1 MFDS Method of Assessment and G.k.9.i.2.r.3.KR.2 KRCT Result of Assessment.

For Post-marketed Domestic cases, preference is given to Regional causality elements over ICH standard causality elements: G.k.9.i.2.r.2.KR.1 MFDS Method of Assessment and G.k.9.i.2.r.3.KR.1 WHO-UMC Result of Assessment.

Element ID	Element Description	Allowed Values
G.k.9.i.2.r.2.KR.1	MFDS Method of Assessment	1=WHO-UMC 2=KRCT
G.k.9.i.2.r.3.KR.1	WHO-UMC Result of Assessment	1 = Certain 2 = Probable 3 = Possible 4 = Unlikely 5 = Conditional/unclassified 6 = Unassessable/ unclassifiable nullFlavor: NA
G.k.9.i.2.r.3.KR.2	KRCT Result of Assessment	1 = Related 2 = Unrelated

To achieve this, Oracle Argus Safety Flexible code list is enhanced with additional values in **Console** > **Code Lists** > **Flexible re-categorization** > **CAUSALITY_CATEGORY**:

- The new MFDS attribute is added.
- The existing E2B(R3) attribute is updated for the additional values.

When a Medical Reviewer assesses **Case Form** > **Event** > **Event Assessment** > **Causality as Reported Result** and **Causality as Determined Result**, the MFDS specific codes are populated by out-of-the-box mapping logic in Regional Causality Assessment elements.

> **Note:**
>
> For Null flavor [NA], configure a flex code list with MFDS code as [NA]. This is not provided out-of-the-box.

For details, refer to the Business Rules defined in the E2B(R3) export mapping document.

What this means to business users: No additional data entry required (and derived from existing Causality Result).

CODE	En	REPORTABILITY	Ja	EU_CODE	MFDS
1	Almost Certain	1	ほぼ確実に関連あり	1	1
2	Probable	1	おそらく関連あり	1	2
3	Possible	1	関連があるかもしれない	1	3
4	Unlikely	0	関連はありそうにない	2	4
5	Not Related	0	関連なし	2	4
6	Unknown	1	不明	1	5
7	Not Reported	1	未報告	1	6
8	None	0	なし	2	6

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Reporting to MFDS for legacy cases

No upgrade scripts are provided for reporting legacy cases to MFDS in E2B(R3) format. It is recommended to review the case data and ensure data is updated to satisfy the MFDS business rules.