IHE Work Item Proposal (Detailed)

# Proposed Work Item: Adverse Drug Event Reporting

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Version: 1

Domain: Pharmacy

# Summary

This proposal is to create a content profile to report an adverse event for which a drug is suspected.

# The Problem

Adverse events where drugs are suspected to be a cause are often not reported in a standardized way. The requirement is to facilitate the reporting which can be transferred to a national central point that collects all adverse drug event reports ( see also ISO/TS22224).

New medicinal products are brought to the market in a shorter time span and thus increase the risk of unknown effects. Adverse events of new ( experimental) drugs can occur incidentally ( for example once in a million times). Therefore we need to collect data on a global scale to gather sufficient evidence . The data from several countries need to be identical to be comparable for research.

The profile is intended to cover the process of collecting the necessary information when an adverse event occurs where a drug is suspected to be the cause. The second step is registering and reporting the data in a standardized way. This is set up in a way to structure the data to the needs of the national organizations, such as Lareb (NL) or FAGG/AFMPS (BE) and thus reduce the burden of inquiring details from the care providers. Care Providers are now often annoyed, when they are being interrogated intensively after submission of an event report. The standard should preferably reduce the burden of inquiry.

Patients

## Nursing Deliverables en producten Geboortezorg

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| Product | Activiteit | Periode | Resources | Kwadrant |
| Nieuwe uitgave PWD 4 | Beheer voorstellen, organiseren Redactieraad, uitgave nieuwe versie | Q3 | PM 0,2  IA 0,2  HL7 0,4 | I-1 |
|  | POC en Pilots voor kernset Neonatologie | Q3-Q4 | PM 0,2  IA 0,4  HL7 0,4 | I-2 |
|  | Support RSO en VSV’s voor overdracht Integrale Geboortezorg, Alternatieve standaarden | Q1-Q4 |  |  |
| ICHOM versie 1 | Eerste harmonisatieslag met ICHOM | Q3 |  | B-2 |
| MedMij set voor PGO | Eerste set voor PGO geboortezorg | Q4 |  | I-2 |
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## GP Deliverables en producten Geboortezorg

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| Product | Activiteit | Periode | Resources | Kwadrant |
| Nieuwe uitgave PWD 4 | Beheer voorstellen, organiseren Redactieraad, uitgave nieuwe versie | Q3 | PM 0,2  IA 0,2  HL7 0,4 | I-1 |
|  | POC en Pilots voor kernset Neonatologie | Q3-Q4 | PM 0,2  IA 0,4  HL7 0,4 | I-2 |
|  | Support RSO en VSV’s voor overdracht Integrale Geboortezorg, Alternatieve standaarden | Q1-Q4 |  |  |
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## hospital Deliverables en producten Geboortezorg

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| Product | Activiteit | Periode | Resources | Kwadrant |
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## hospital Deliverables en producten Geboortezorg

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National bodies

ICSR

WHO

The focus of the IHE profile is for the transactions between care providers and the national body. It is not the transfer of data between the national body and the WHO.

# Key Use Case

We envision the following use cases so far:

* Care Providers are legally obliged to report adverse drug events. This has to be facilitated in a simple and easy way that does not consume too much time from the care provider.
* Patients in certain countries are also consumers that are allowed to report adverse events where drugs are suspected to be a cause. Data can also be extracted from an PHR and completed by the patient before submitting the data to a national collecting point.
* Nurses that administer medication to patients, for example in a home nursing setting, encounter certain adverse events, which they need to register in an EHR. The data could initially be registered in a tablet which then is transferred to the EHR.

# Standards & Systems

* IHE Pharmacy – CMPD
* IHE Pharmacy - HMW
* HL7 FHIR STU 4
* EMA Yellow Card
* [WHO Vigibase Monitoring Centre](https://www.who-umc.org/vigibase/vigibase/)

# Technical Approach

The technical approach will be based on the FHIR resources and paradigms. Likely the RESTful approach would be preferred given the fact of having mobile applications.

The workflow management (statuses, updates) will not be document-based nor message-based but looking at the FHIR mechanisms.

The existing alignment between hospital and community pharmacy semantics will be kept.

# Risks

FHIR is a standard with the status of Trial Use. This means that there is a risk that the standard can change. The FHIR resource for Adverse Event has maturity of level 0 which means that development of this resource is still fully in course.

The knowledge of the FHIR standard is not readily available in the implementers’ community, and this may need to be overly documented and communicated to gain traction.

# Open Issues

This should be incorporated into the Technical Framework, aligning with the Hospital and Community profiles.

# Effort Estimates

This should require about 300 man-hours besides the continuous alignment to HL7 and ITI domains.