D6.2 Xt-EHR commenting form Industry X-Net

EU Member State (MS) ISO 3166 two-letter country code **or "EU"** for European stakeholder organisations	**Section/ Subsection** number	**Comment** (justification for change)	**Proposal how to resolve comment**, proposed change
Industry X-Net		**X-Net#1: Strengthen the actors and transactions model in section 7.1**. The benefit of this approach is it allows specifying precise interoperability without constraining member state architecture. With this approach we can cover the different prescription architecture variations that exist today across member states: scenarios where prescription data is in a central repository (NO,DK,FR,...), regional repositories (ES,IT,...) or spread across EHR systems (NL, ...). In order for EHR systems to implement interoperability that meets the EHDS workflow goals, transactions must be defined with precision.	Define explicit transactions between technical actors. These transactions support MyHealth@EU workflows via NCP, as well as other actors acting as prescription consumers (other health professionals, patients, decision support applications). We recommend the following: **1. Search Dispenses** - The Dispense Consumer queries the Dispense Repository for dispenses (using the search parameters in section 8.5) **2. Search Prescriptions** - The Prescription Consumer queries the Prescription Repository for prescriptions (using the search parameters in section 8.5) **3. Send Dispense** - After recording a medication dispense, the Dispense Producer reports the dispense to the Dispense Repository **4. Send Prescription** - After prescribing medication, the Prescription Producer reports the dispense to the relevant Prescription Repository In **7.3 Use Case: Dispensing,** adjust the "Process Steps" in the table to take advantage of these transactions in order to to dispense: The EHR system used for Dispensing SHALL implement: (1) The **Search Prescriptions** transaction as Prescription Consumer (2) The **Search Dispenses** transaction as Dispense Consumer, and (3) The **Send Dispense** transaction as Dispense Producer. + the repository sides of these transactions. Task IHE and HL7 EU with implementing

			these transactions in the FHIR specification, in the existing implementation guide.
Industry X-Net		**X-Net#2:** The **Prescription/Dispense Repository** high-level technical actors should be clarified and expanded. The concept of repository is useful, since it determines who is the "owner" of up to date prescription information, and thus the actor responsible for responding to the "Search Prescriptions" transaction. For example, in a cross-border dispensing use case - the cross-border pharmacy (acting as a **Prescription Consumer**) would query the home country NCP, which would in turn query the home country **Prescription Repository** in order to retrieve the prescription). As noted, depending on the member state architecture, the repository could be a national prescription database(s) or individual EHR system(s). Note that it is possible for an EHR system to be one or multiple actors (Prescription Producer + Prescription Repository) depending on it's role in the architecture. Additionally, it is not necessarily true that the repository actor does not display or alter data. For example, Repositories could enable the Health Professional Access Service to access and edit stored prescriptions.	Bold the Repository actor in line with other technical actors, and include something like the following descriptions: **Prescription Consumer**: (unchanged) This actor represents an entity that handles or processes the order, typically for dispensing, but can also be for further authorization, verification, etc. For example, a prescription system may be a prescription consumer, to read prescriptions for validation, or checking previous prescriptions. JEP: Consumer could be patient. **Dispense Repository**: A system functionality for storing up-to-date dispense data and making it available for Dispense Consumers, without necessarily displaying or altering this data in any way.
Industry X-Net		**X-Net#3: 7.3 Use Case: Dispensing workflow clarifications:** Workflow clarifications are needed in order to enable safe cross-border dispensing **Substitutions:** The substitution	**Substitutions:** In order to enable safe dispensing, the specification should either agree on how the "allow substitution?" field should be interpreted if blank, or make it a required field. **Overrides**: More clarification is needed in how to reconcile differences in local laws

		field is optional, but the interpretation of receiving no substitution field is ambiguous: it can mean different things in different countries. **Overrides:** Override of a prescription by the dispenser might not be allowed, or might be restricted to certain cases, depending on local practices and laws. For example: Does the prescriber need to approve an override request? If a prescription is overridden to another product, how is that reconciled against the remaining fills of the prescription? **Reconciliation:** In the cross-border dispense case, the medication dispensed is often different from what is prescribed and may not be able to be automatically subtracted from the remaining refills on the Prescription. How is this reconciled against the prescription in order to prevent duplicative fills?	between the prescriber and dispenser. If the cross-border overridden dispense use case is not resolved with policy, consider not allowing it via electronic exchange. Additionally, in the case of a dispense override, it should be clarified that the dispense event (with the overridden medication) is reported back to the source, not that the original prescription is modified by a potentially cross-border pharmacist (editing Country A's prescriptions from Country B is a large increase in scope and we recommend against including it). **Reconciliation**: Because the remaining medication calculation cannot be automated in every case, there should be a workflow expectation on the Dispenser to first check for existing dispenses using a "Search Dispenses" transaction.
Industry X-Net		**X-Net#4: 7.2 Use Case: Prescribing significantly expands scope** - The EHR and workflow requirements in this section expand scope from sharing authorized prescriptions (required and sufficient for meeting the EHDS goals) into workflow orchestration between actors in a national ePrescription network, which is stated earlier in the document (Section 2.2) as out of scope. Defining these workflows is useful for standardizing future national ePrescription implementations, but technical and regulatory requirements for transfering a Prescription from a prescribing system to dispenser vary greatly by member state, and harmonizing national ePrescription infrastructure is not in EHDS scope.	We recommend keeping *Send Prescription* workflow requirements **optional** at the EU level, and removing the workflow requirements from lines 595-622. For the EHDS cross-border dispense workflow, we recommend starting from a precondition: *an authorized prescription is available in a Prescription Repository - h*ow a prescription gets from a prescription source to a prescription repository is the scope of member state national infrastructure. However, we encourage (1) member states building new ePrescription infrastructure to adopt this specification and make it required as their compatible ePrescription network demands it and (2) continuing development of the MPD specification to support such national deployments.

Industry X-Net		**X-Net#5: 7.3 Use Case: Prescibing workflow clarifications:** If the prescribing *workflow (*specifically, transfer of a prescription from a *Prescription Source* to a *Prescription Repository,* and further a *Dispensing EHR*) remains in scope, workflow clarifications are needed related to cancellation and modification rules, as well as data model support for reimbursement data elements.	**Canceling prescriptions after dispense**: Line 611 states that a prescription cannot be canceled after it has been dispensed. Is the expectation that the prescribing system needs to receive the dispense and restrict cancellation, or that the dispensing system should reject cancellations after dispense? **Canceling prescriptions after dispense for refills**: Line 611 states prescriptions can only be revoked before they've been dispensed, but what if the prescription has been partially filled and there are refills remaining? It is still clinically useful to prevent dispensing of the remaining refills, but the current text does not allow a prescription to be revoked after the first dispense. The recommendation to adjust the wording to "entirely dispensed" resolves this issue as well. **Modifying prescriptions after dispense:** While it's stated that prescriptions can't be revoked after being dispensed, there aren't similar restrictions for modifying prescriptions. Prescriptions should not be allowed to be modified after dispense. **Data elements needed for reimbursement:** Although this deliverable doesn't handle reimbursement workflows, which vary by member state, there could be common data elements required for reimbursement that should be considered for inclusion in the specifications.
Industry X-Net		**X-Net#6: Multiline prescriptions should be represented as unique, linked prescriptions:** Introducing multiline prescriptions (multiple medical products authorized under a single prescription) into the data model imposes sizeable technical and compliance costs on all implementers, including those in locales where multiline prescriptions are disallowed, without adding additional clinical value, to maintain compatibility with legacy paper workflows used in a few member states.	We recommend aligning with MyHealth@EU and the FHIR standard by requiring unique single line prescriptions, removing the distinction between prescription and prescriptionItem in the logical model and instead supporting multiline prescriptions locally where needed as unique prescriptions with a shared identifier (the approach taken in the MPD FHIR Implementation Guide). Local implementations can also define workflow rules for these linked multiline prescriptions as needed (e.g. linked PrescriptionItems must share the same status, linked PrescriptionItem A must not be dispensed if PrescriptionItem B is dispensed), but these rules cannot be safely applied when the prescription crosses borders.
Industry X-Net		**X-Net#7: Patient identification:** Lines 598 and 628 refer to patient	Patient authorization and lookup requirements should be further defined,

		identification requirements in D5.1, but the section of D5.1 referenced is about provider identification only.	most likely in D5.1 or accompanying API conversation since the need spans priority categories.
Industry X-Net		**X-Net#8: Proxy Access:** If Proxy (person entrusted by the patient to help in the patient's care) access is in scope, additional requirements need to be considered. How is proxy access granted? At what level is proxy access defined (e.g. patient, priority category, etc.)? How are proxies identified and verified? Is this communicated in the exchange model or tracked and enforced in a national system?	This is a consideration across all priority categories and we recommend handling it with a broader group, such as D5.1.
Industry X-Net		**X-Net#9: Prescription Search Parameters** Some adjustments to the Prescription search parameters are proposed.	The "status" and "identifier" field should only be defined at the prescriptionItem level. Allowing both only creates confusion and implementation burden "are both status's needed? how are they different? if they disagree which takes precedance?". As in **X-Net#6**, we recommend meeting the needs of multi-line prescriptions with separate, linked Prescription entries. This way, the data model only needs one status and identifier and this ambuguity is greatly simplified.
Industry X-Net		**X-Net#10: Prescription Dispense Parameters** Some adjustments to the Dispense search parameters are proposed.	The "status" and "identifier" field should only be defined at the prescriptionItem level. Allowing both only creates confusion and implementation burden "are both status's needed? how are they different? if they disagree which takes precedance?". As in **X-Net#6**, we recommend meeting the needs of multi-line prescriptions with separate, linked Prescription entries. This way, the data model only needs one status and identifier and this ambuguity is greatly simplified.