



Serial Number handling with WWKS 2

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EU Falsified Medicines Directive

Becomes effective Feb 9th, 2019

Serial number validation obligations:

	Pharmacies	Hospitals	Distribution Centers		Packaging Centers
Action	Validation & Check-out	Validation & Check-Out	Validation	Validation & Check-Out	Validation & Check-Out
Items	All Rx	All Rx	All items not received directly from manufacturer	All Rx delivered to special recipients (national definition)	All Rx
When	Handover to Patient	While in stock	While in stock	Before Delivery	When opening the pack

Input validation in Pharmacies

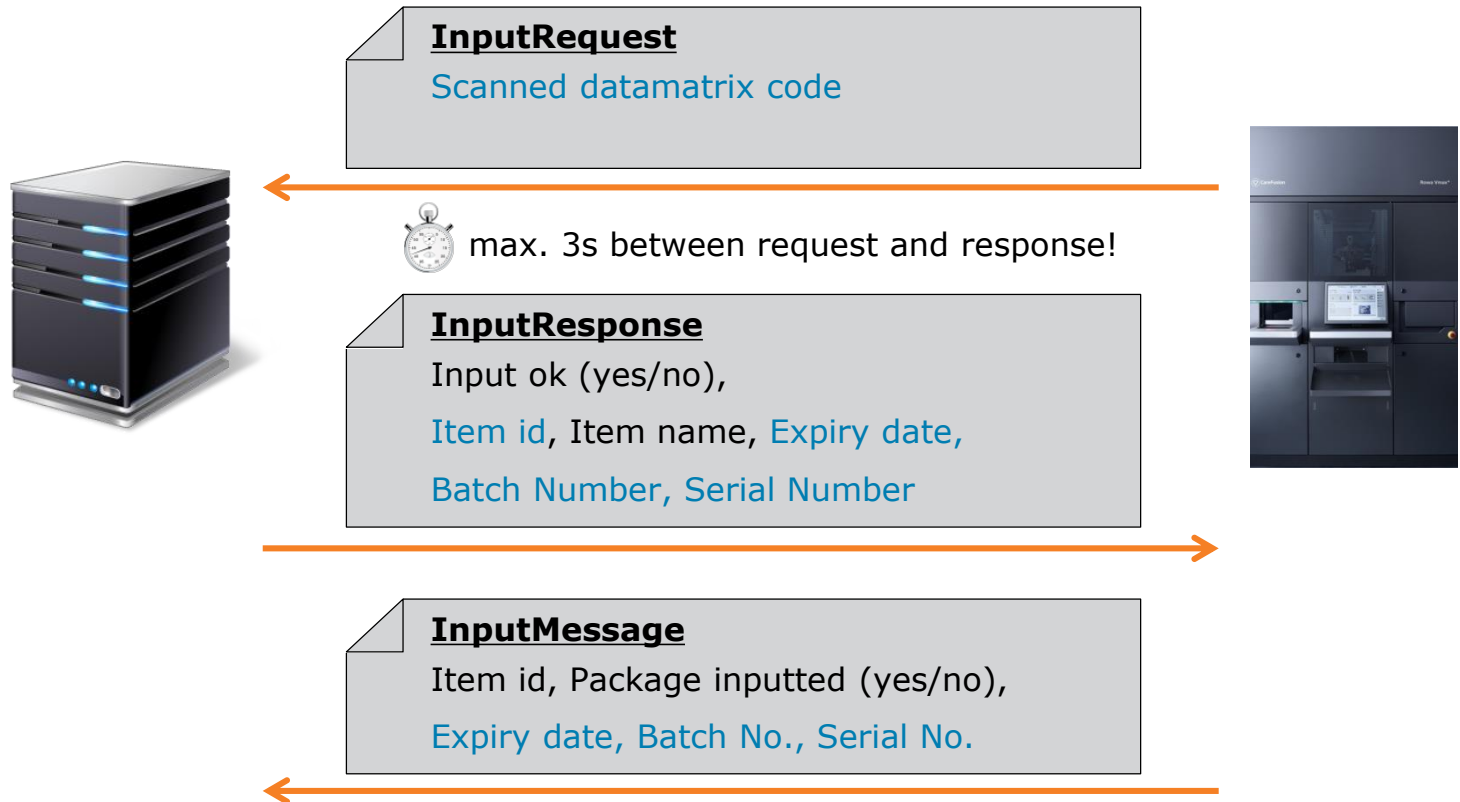
Why doing an input validation in pharmacies?

No „bad surprises“
when performing check-out
in front of the customer.

No additional manual effort for robot items.

Forwarding datamatrix code

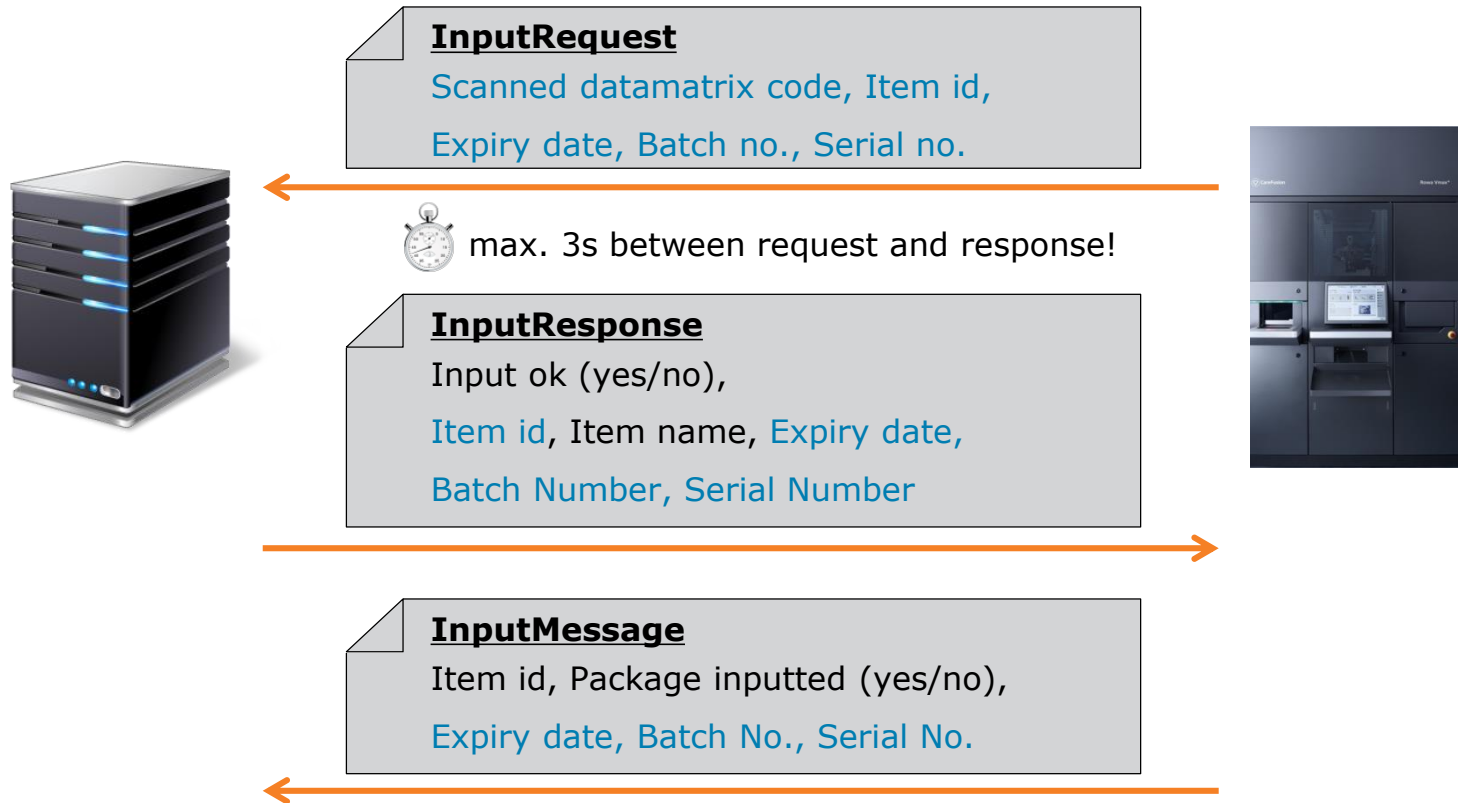
Option 1: IT system parses datamatrix code



- Returning expiry date, batch and serial number allow storing and processing of these data in the robot (First expiry first out strategy, Forwarding data in dispensing process)
- Coding of special characters in datamatrix code (e.g. GS1 field separator Ascii #29 → \0x1D)

Forwarding datamatrix content

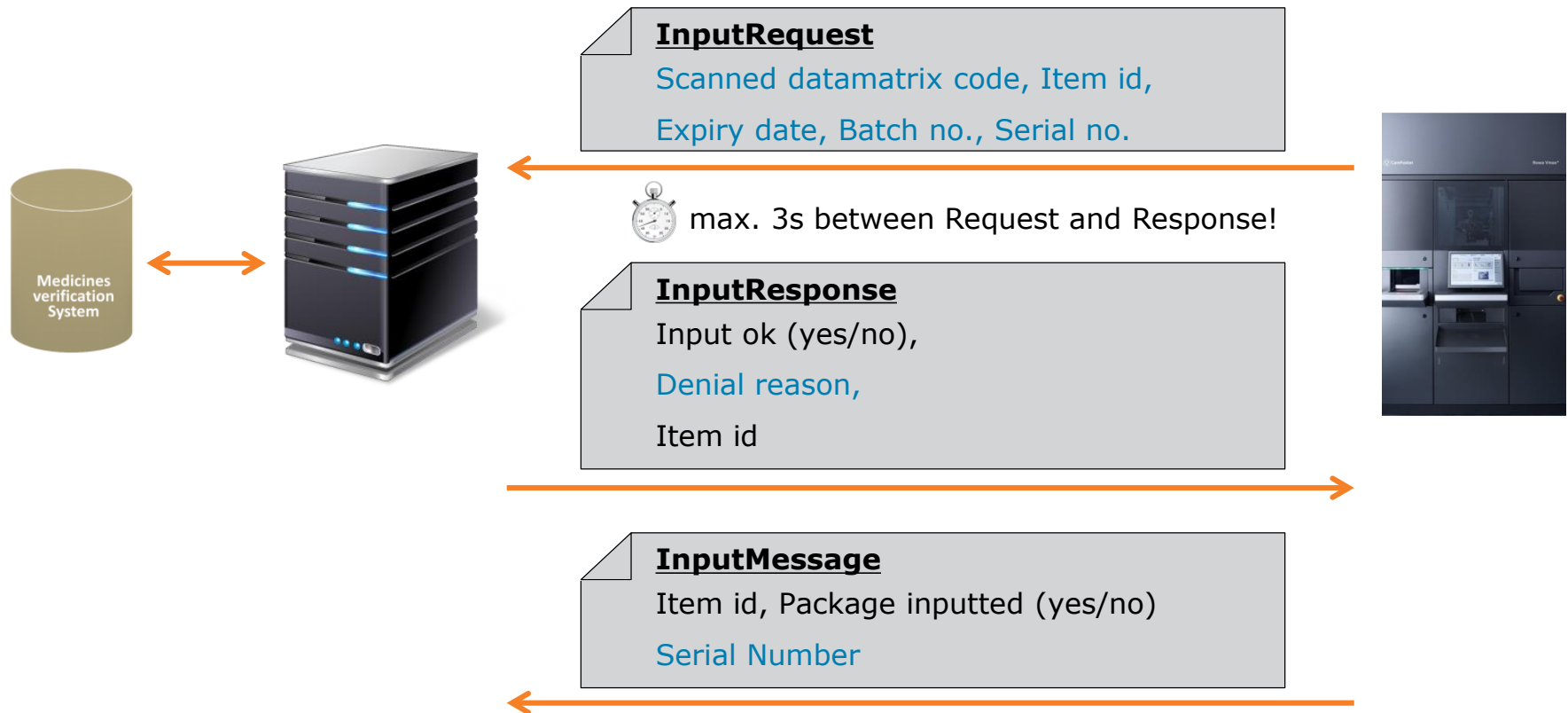
Option 2: Robot parses datamatrix code



- IT system may modify requested item id, expiry date, batch and serial number in InputResponse

Input validation

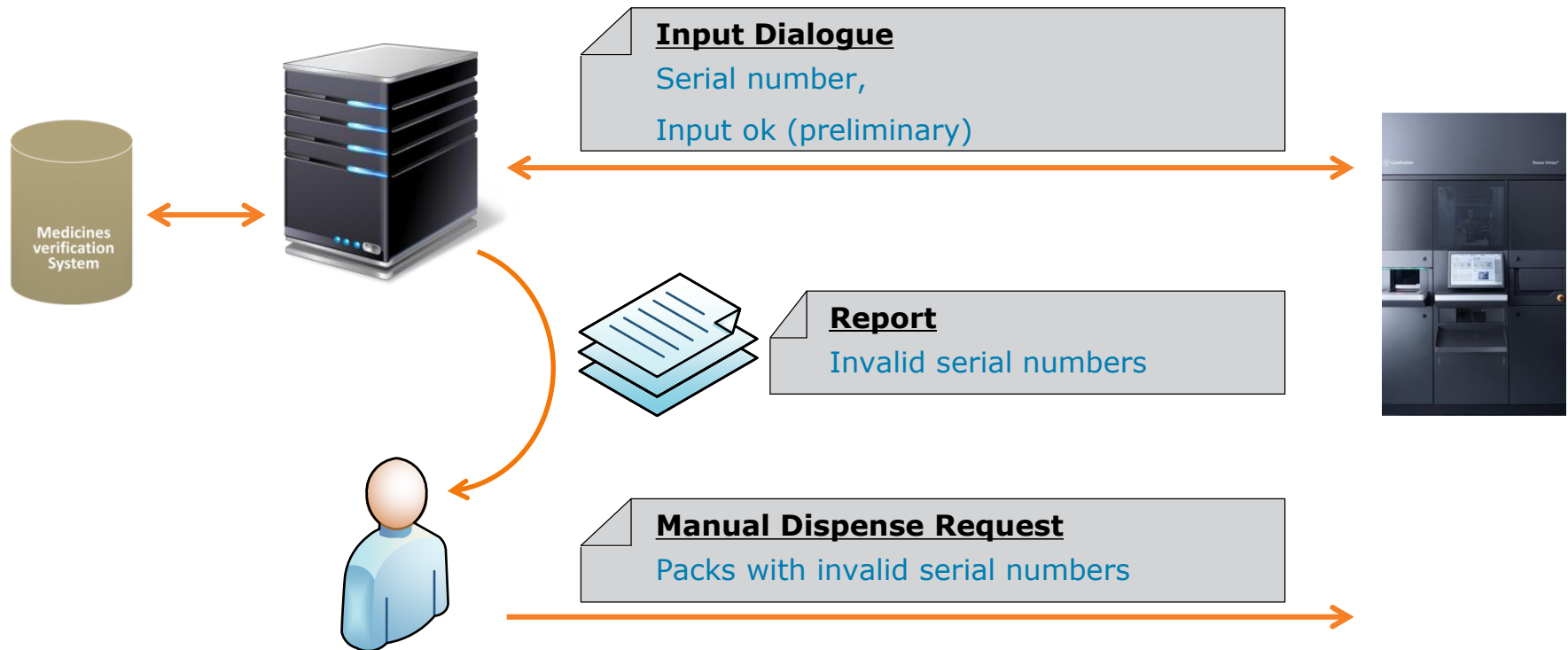
Option 1: Denial of input in case of invalid serial number



- Validation against national database by pharmacy It system
- National database has to answer within 300 ms

Deferred validation

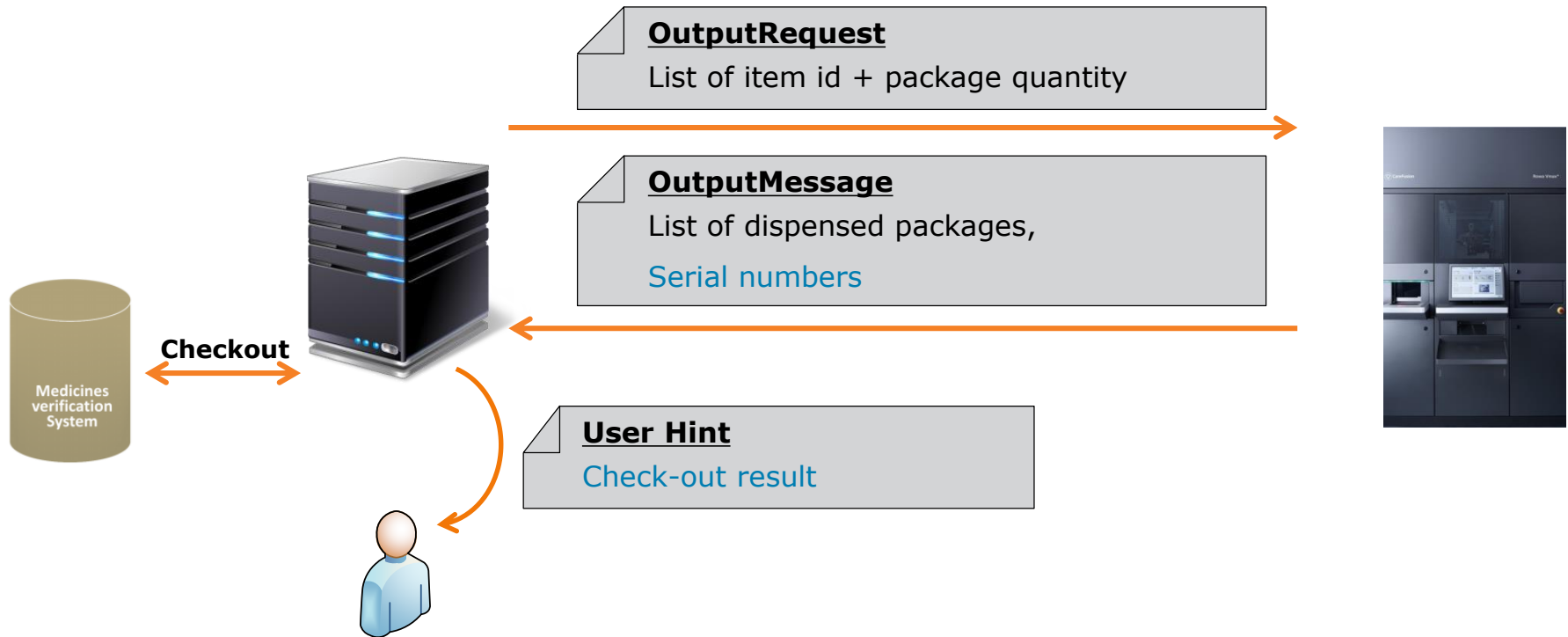
Downstream validation by pharmacy IT system



- Allows batch validation
- Increased risk of bad surprise in front of the customer if item is dispensed quickly

Check-out after dispensing

Independent of input process



- Forwarding serial numbers by robot eliminates need to scan pack again

