ISO/TS 19293:2018-04 (E)

Health informatics - Requirements for a record of a dispense of a medicinal product

Contents

Page

Foreword v

Introduction vi

1 Scope 1

2 Normative references 1

3 Terms,definitionsandabbreviatedterms 1
3.1 Terms and definitions 1
3.2 Symbols and abbreviated terms 4

4 Dispense process and dispense event 4
4.1 General 4
4.2 Dispense record in diverse dispense processes 4
4.3 Dispense record information purposes 5

5 Requirements 5
5.1 General considerations 5
5.2 Issuance of the dispense record 6
5.2.1 General 6
5.2.2 Dispense record scenarios 6
5.2.3 Dispense record uniqueness 6
5.2.4 Dispense process unambiguity 7
5.2.5 Dispense record unequivocal identification 7
5.2.6 Dispense act date/time 7
5.2.7 Dispense location -- Institution/department 7
5.2.8 Confirmations, authorizations, or advice 8
5.2.9 Additional information to support the adequate and legal dispensing 8
5.2.10 Relevant findings elicited during the clinical review 8
5.2.11 Decision not to dispense 8
5.3 Prescription-related 8
5.3.1 General 8
5.3.2 Link to prescription 9
5.3.3 Additional prescription linking data 9
5.3.4 Previous prescription changes/advice 9
5.3.5 Outcome of clinical review of the prescription 9
5.4 Dispenser identification 11
5.4.1 Dispensing professional 11
5.4.2 Dispensing organization 11
5.4.3 Automated and semi-automated dispensing systems 11
5.5 Patient identification 11
5.5.1 General 11
5.5.2 Patient identification verification 11
5.6 Dispensed product 12
5.6.1 General 12
5.6.2 Dispensed product type 12
5.6.3 Dispensed physical item 13
5.7 Quantity 14
5.7.1 Dispensed product quantity 14
5.7.2 Retrieved product quantity 14
5.8 Dispense repeat number 14

5.9 Fulfilment notes 14
5.10 Patient instructions 14
5.10.1 General 14
5.10.2 Reimbursement 15
5.10.3 Transport 15

Annex A (informative) Examples of use cases (from NVN-ENV 13607) 16

Annex B (informative) Examples of use cases (other sources) 22

Annex C (informative) Dispensing processes -- Examples and variation 28

Annex D (informative) Identifying dispensed products across jurisdictions -- Using IDMP andnationalidentifiers 33

Annex E (informative)Usecase-specificconstraintsofusingdispenserecord 35

Annex F (informative)Informativetypicaldatastructures--Elementsandvocabularies 36

Bibliography 38