

DIN CEN ISO/TS 19293:2018-08 (E)

Health Informatics - Requirements for a record of the dispense of a medicinal product (ISO/TS 19293:2018); English version CEN ISO/TS 19293:2018

| Contents | | Page |
|--|--|-----------|
| Foreword | | v |
| Introduction | | vi |
| 1 Scope | | 1 |
| 2 Normative references | | 1 |
| 3 Terms, definitions and abbreviated terms | | 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 and national identifiers | | 33 |
| Annex E (informative) Use case-specific constraints of using dispense record | | 35 |
| Annex F (informative) Informative typical data structures — Elements and vocabularies | | 36 |
| Bibliography | | 38 |