تقديم

الهيئة جهة مستقلة الغرض الأساسي لها هو القيام بتنظيم ومراقبة الغذاء والدواء والأجهزة والمنتجات الطبية، ومن مهامها وضع اللوائح الفنية والمواصفات في مجالات الغذاء والدواء والأجهزة والمنتجات الطبية سواء كانت مستوردة أو مصنعة محلياً، وقد قام قطاع الأجهزة والمنتجات الطبية بالهيئة ضمن برنامج عمل فريق العمل رقم (SFDA/MDS/TC 215) "فريق عمل مواصفات المعلوماتية الصحية" بتبني المواصفة الدولية رقم (ISO 17523:2016) "المعلوماتية الصحية – متطلبات الوصفات الطبية الإلكترونية" ، والتي أصدرتها "المنظمة الدولية للتقييس" وذلك بلغتها الأصلية. وقد اعتمدت هذه المواصفة كمواصفة سعودية متبناة بالتعديل بلغتها الأصلية وقد تم إقرار اعتماد تبني المواصفة من معالي الرئيس التنفيذي للهيئة بقرار رقم ().

- التعديلات مشار إليها في ملحق التعديلات.

Foreword

The Saudi Food & Drug Authority is an independent organization mainly responsible for regulating imported/locally produced food, drug and medical devices, which includes, inter alia, setting their standards.

(ISO 17523:2016 Health informatics — Requirements for electronic prescriptions), issued by (International Organization for Standardization), has been adopted with modifications in its original language as a national standard and was approved by SFDA CEO decision No ().

- The modifications are mentioned in the Modifications Annex.

Scope

This International Standard specifies the requirements that apply to electronic prescriptions. It describes generic principles that are considered important for all electronic prescriptions.

The scope of this International Standard is constrained to the content of the electronic prescription itself, the digital document which is issued by a prescribing healthcare professional and received by a dispensing healthcare professional. The prescribed medicinal product is to be dispensed through an authorized healthcare professional with the aim of being administered to a human patient. Other messages, roles and scenarios (e.g. validation of a prescription, administration, medication charts, EHR of the patient, reimbursement of care and dispensed products) are out of scope of this International Standard, because they are more or less country or region specific, due to differences in culture and in legislation of healthcare. However, requirements and content of electronic prescriptions within the context of jurisdictions have a relationship with these scenarios. The way in which electronic prescriptions are made available or exchanged also fall outside the scope of this International Standard.

This International Standard is applicable to electronic prescriptions of medicinal products. Although other kinds of products (e.g. medical devices, wound care products) can be ordered by means of an electronic prescription, the requirements in this International Standard are aimed at medicinal products that have a market authorization and at pharmaceutical preparations which are compounded in a pharmacy. An electronic prescription is an information object that authorizes a healthcare professional to legally dispense a medicinal product.

This International Standard specifies a list of data elements that can be considered as essential for electronic prescriptions, depending on jurisdiction or clinical setting (primary healthcare, hospital, etc.).

ملحق التعديلات
Modifications Annex

Project: SFDA.MD.215.DS.ISO 17523:2016

#	رقم الصفحة Page No.	رقم البند/البند الفرعي Clause/Subclause No.	رقم السطر Line No.	فقرة/ صورة/ جدول Paragraph/ Figure/ Table/	نوع الملاحظة Comment type	الملاحظات Comments	التعديل Modification
1	2	3.3			te	There is more scientific and professional definitions for the term "electronic prescription (e-prescription)"	**Modify**: **3.3** **electronic prescription** **e-prescription** prescription entered by the prescriber into an EHR, electronically signed, and sent by secure computer-to-computer electronic data interchange to pharmacy computer using standardized data-fields or a nationally accepted data standard. It replace paper and faxed prescriptions and can be a stand-alone system or part of an integrated electronic health record system. [Source: https://www.uspharmacist.com/article/what-really-is-electronic-prescribing]

2	2	3.6			te	Only a medical specialist or a general practitioner is allowed to prescribe in Saudi Arabia [Source: The executive regulations of pharmaceutic products and facilities law, Article 24, Item 24/4]	**Delete:** ~~Note 1 to entry: Typically, the healthcare professional is a medical specialist or a general practitioner but this differs across legislations. In some countries, pharmacists or nurse practitioners are also authorized to prescribe.~~
3	3	3.9			ge	~~ISO/IEC 24760-1:2011~~ has been revised and updated as **ISO/IEC 24760-1:2019**	**Modify:** [SOURCE: ISO/IEC 24760-1:~~2011~~ **2019**, 3.3.1, modified]
4	3	3.11			ge	~~ISO/IEC 24760-1:2011~~ has been revised and updated as **ISO/IEC 24760-1:2019**	**Modify:** [SOURCE: ISO/IEC 24760-1:~~2011~~ **2019**, 3.2.1, modified]
5	3	3.12			ge	~~ISO/IEC 24760-1:2011~~ has been revised and updated as **ISO/IEC 24760-1:2019** Definition of "***identity information***" has been **modified** in the **new version** of ISO/IEC 24760-1	**Modify:** set of values of attributes ~~that differentiate one entity from others~~ optionally with any associated metadata in an identity [SOURCE: ISO/IEC 24760-1:~~2011~~ **2019**, 3.2.1, modified]

6	4	5.1			ge	~~There is no need to set examples of electronic prescription implementations in other countries~~	**Delete and Modify:** Annex B has ~~three~~ **two** parts: B.1 ~~lists examples of electronic prescription implementations in other countries; B.2~~ provides an overview of data structures and standards; B.~~3~~ **2** lists examples and code snippets belonging to either the core or optional elements.
7	4	5.3			ed	Capitalize the title of the guideline document	**Modify:** The "GUIDELINES ON ePRESCRIPTIONS DATASET FOR ELECTRONIC EXCHANGE UNDER CROSS-BORDER DIRECTIVE 2011/24/EU"

8	4	5.3			te	In Saudi, as part of the eHealth interoperability specifications, the national health information center (NHIC) has a medication use case that documents all actors and processes in the area of health information exchange (HIE). The national standard is mainly for the HIE between healthcare providers and not for within a Healthcare organization	Add: NOTE 3 A complete health information exchange medication use case that includes all actors and processes between healthcare providers is published at the National Health Information Website at https://nhic.gov.sa/en/eServices/STD/Pages/default.aspx
9	6	6.1			te	NHIC publishes the national health ID of the patient, which is a single unique health identification of the patient across all healthcare organizations	**Add:** The identity information shall include the national health identification of the patient as generated by the National Health Information Center (NHIC)
10	6	6.2			te	The NHIC has a national identification of prescribed prescribing healthcare professional	**Add:** Identification of the prescribing healthcare professional shall include the national identification of prescribing healthcare professional as generated by the NHIC
11	7	6.3			ge	ISO 19256 has been published as ISO/TS 19256:2016	**Modify:** derived from a medicinal product dictionary [(ISO/TS 19256:2016~~ (under development)~~].

12	7	6.3			te	The NHIC has a national identification of prescribed medicinal products	**Add:** Identification of the prescribed medicinal product shall include the national identification of prescribed medicinal products as generated by the NHIC
13	11	A.3.9			te	NHIC publishes unique Identifications for each healthcare organization as part of the organizations registry	**Add:** Note Work place identifier shall include the unique organization identifier as issued the by NHIC
14	11	A.4.2			te	Reimbursement information not needed in Saudi Arabia	**Delete:** ~~A.4.2 Reimbursement information~~
15	14	B.2			te	Saudi Arabia has two examples of an active ePriscription projects: - Wasfaty (by NUPCO) - Electronic Prescriptions (by LEAN)	**Add:** **B.1 References to implementations of electronic prescription** **B.1.1 Saudi Arabia**

16	14	B.2			ed		**Modify:** **B.1.~~1~~ 2 England** **B.1.~~2~~ 3 Europe** **B.1.~~3~~ 4 Netherlands** **B.1.4 5 Denmark** **B.1.~~5~~ 6 Norway** **B.1.~~6~~ 7 Australia** **B.1.~~7~~ 8 USA** **B.1.~~8~~ 9 Canada**
17	14	B.2			te	the national health information center (NHIC) has a complete standard regarding medication (prescription and dispensation) for the health information exchange	**Add:** **B.2.1 Saudi Arabia eHealth Interoperability Specification for Medication** https://nhic.gov.sa/en/eServices/STD/Pages/default.aspx
18	15	B.2			ed		**Modify:** **B.2.~~1~~ 2 Danish healthcare datanet** **B.2.~~2~~ 3 HL7** **B.2.~~3~~ 4 IHE Pharmacy** **B.2.4 5 EN ISO 13606**

Comment type: **ge** = general **te** = technical **ed** = editorial