health insight 2018
ARAB PHARMACEUTICAL INDUSTRY BUSINESS DEVELOPMENT FORUM 2018
المنتدى العربي للصناعات الصحية

Value in Healthcare
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Reliance Regulatory procedures
Key development in Emergent markets regulations to ensure fast patient access to innovative medicines

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Presentation outline

- Reliance procedure concept
- MENA region development
- Summary & conclusion

Reliance Pathways concept

Verification review

- This model is used to **reduce duplication** of effort by agreeing that the importing country will allow certain products to be marketed locally once they have been authorized by one or more SRA*.
- In general, review on the basis of **Assessment Reports, GMP inspections reports and/or CPPs** of reference authorities

Abridged review

- This model relies on assessments of scientific supporting data that has been **reviewed and accepted by SRA's***, but includes an 'abridged' independent review of a certain part of the registration dossier of the product (e.g. relevant to use under local condition).
- In general, review on the basis of **Assessment Reports, GMP inspections reports and/or CPPs of reference authorities + part of CTD** (e.g. Module 3)

(*): SRA: stringent Regulatory Authority.

Current WHO definition of Stringent Regulatory Authority (SRA)

A **member** of ICH prior to 23 October 2015, namely:

-**The US FDA**

-**The European Medicine Agency (EMA)**

-The Ministry of Health, Labor and Welfare of Japan (PMDA)

An ICH **observer** prior to 23 October 2015, namely the European Free Trade Association, as represented by:

- **Swissmedic**
- **Health Canada**

A regulatory authority associated with an ICH member through a **legally-binding, mutual recognition agreement** prior to 23 October 2015, namely:

- **Australia**
- **Iceland**
- **Norway**
- **Liechtenstein**

MENA Region: reliance pathways overview (1/2)

First circular issued in Oct 2016 with Implementation date note “Feb 2017”

Detailed guideline issued in Feb 2017

Ministerial decree 820/2016 was issued in Jan 2017.

Officially announced to be implemented in April 2018 with expected guideline in April

Feb 2017 JFDA announced in the official Journal a briefed note about the verification=60 days review process.

July 2017, detailed final guideline was published

UAE:

Ministerial decree issued in **Jan 2018** with immediate implementation effect

Detailed guideline issued in Feb 2017

(*): SRA: stringent Regulatory Authority.

MENA Region: reliance pathways overview (2/2)

	Eligibility Criteria	timelines	Additional specificity
Saudi FDA	USFDA OR EMA approval (Abridged) USFDA & EMA approval (Verification)	60 days 30 days	• Innovative products only. • Less than 2 years • Confidential Assessment report is mandatory!
Jordan FDA	USFDA **&** EMA approvals (Verification)	60 days	• Public Assessment Report • Retroactive for products submitted already • Life cycle maintenance included
Egypt	USFDA **OR** EMA approval (Abridged) FDA **&** EMA approval (Verification)	60 days 40 days	• Launch after 1 year registration in CoO.
UAE	Verification process USFDA approval OR EMA approval Swiss Medic _TGA_ PMDA_ MHRA _ CA	30 days + pricing signature.	• Applicable for innovative and Orphan products.

Overview from SFDA published in Nov 2017

Statistics

Path/type	NCE	Biologics
Verification	7*	8
Abridged	12	0
Registered	0	0
Total	19	8

Overview from JFDA published in Nov 2017

Our Status

Until now , we receive 18 applications

- 6 new applications .
- 12 a fast track request for already submitted but not reviewed applications.
- 7 products were registered within the targeted timeline .

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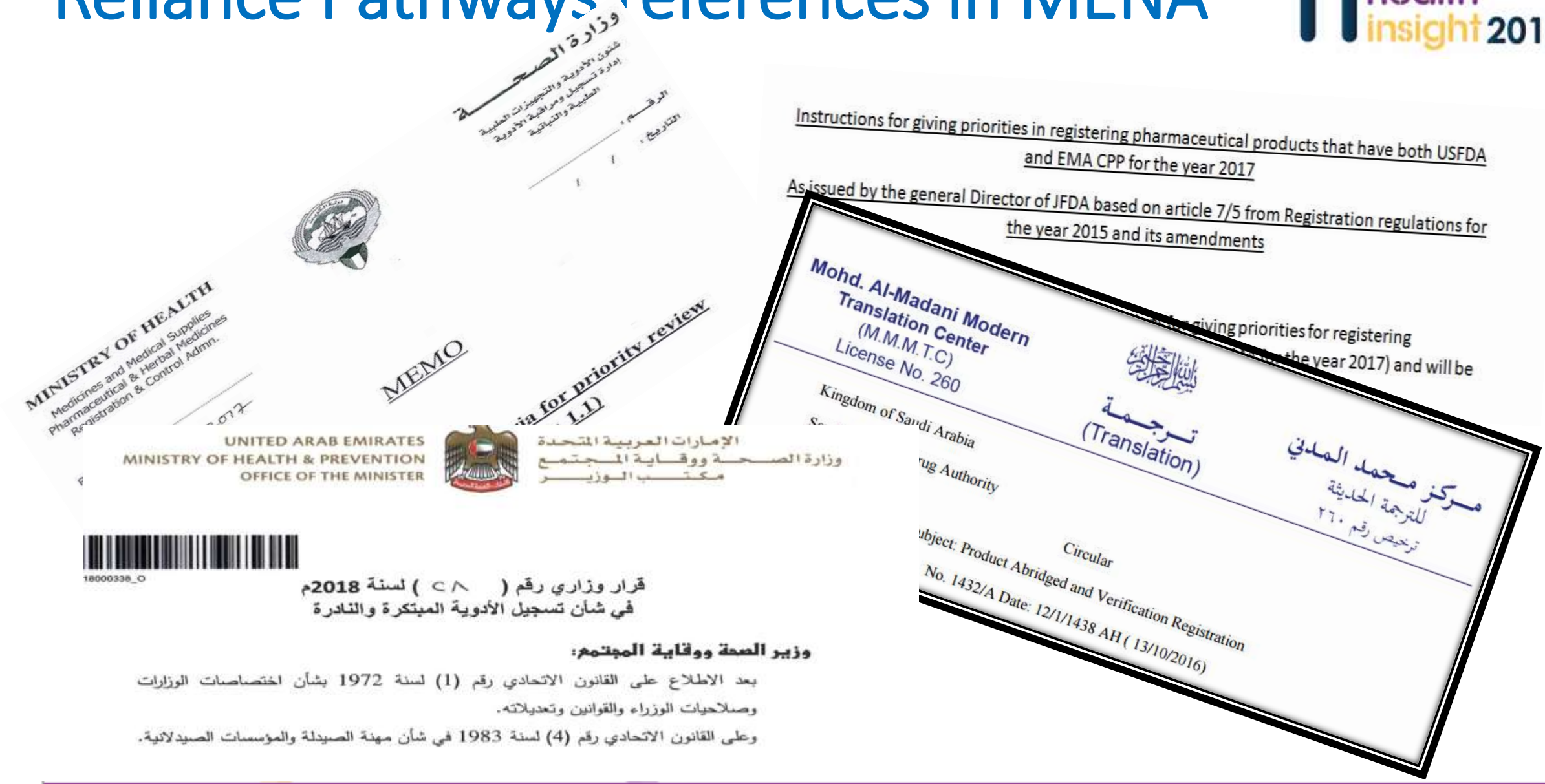
Reliance Pathways references in MENA



وزارة الصحة
شئون الأدوية والتجهيزات الطبية
إدارة تسجيل ومراقبة الأدوية الطبية والنباتية
الرقم :
التاريخ :

MINISTRY OF HEALTH
Medicines and Medical Supplies
Pharmaceutical & Herbal Medicines
Registration & Control Admn.

MEMO

ia for priority review
1.1)

Instructions for giving priorities in registering pharmaceutical products that have both USFDA and EMA CPP for the year 2017

As issued by the general Director of JFDA based on article 7/5 from Registration regulations for the year 2015 and its amendments

giving priorities for registering
the year 2017) and will be

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بسم الله الرحمن الرحيم
ترجمة
(Translation)

مركز محمد المدني
للترجمة الحديثة
ترخيص رقم ٢٦٠

Kingdom of Saudi Arabia
ug Authority

Circular

ubject: Product Abridged and Verification Registration
No. 1432/A Date: 12/1/1438 AH (13/10/2016)

UNITED ARAB EMIRATES
MINISTRY OF HEALTH & PREVENTION
OFFICE OF THE MINISTER

الإمارات العربية المتحدة
وزارة الصحة ووقاية المجتمع
مكتب الوزير

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قرار وزاري رقم (٢٨) لسنة 2018م
في شأن تسجيل الأدوية المبتكرة والنادرة

وزير الصحة ووقاية المجتمع:

بعد الاطلاع على القانون الاتحادي رقم (1) لسنة 1972 بشأن اختصاصات الوزارات وصلاحيات الوزراء والقوانين وتعديلاته.

وعلى القانون الاتحادي رقم (4) لسنة 1983 في شأن مهنة الصيدلة والمؤسسات الصيدلانية.

Summary & take away messages

Regulators play an important role in addressing the patients' needs by establishing appropriate registration pathways.

Reliance pathways (Abridged or Verification) models are used to **reduce duplication** of efforts; it represents a great opportunity for Health Authorities to manage resource constraints and priorities.

Reliance procedures facilitate **patient fast access** to innovative medicines specifically in the area of unmet medical needs.

(*): SRA: stringent Regulatory Authority.

THANK YOU