Premarket Submission and Approval Requirements in Kingdom of Saudi Arabia

Presented By:

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SFDA History

- Saudi Food & Drug Authority (SFDA) was established on March 10th, 2003.
- A royal decree was issued on Feb. 13th, 2007 to establish the law of SFDA.
- A council of ministers decision number 181 was issued on June 18th, 2007 giving the SFDA a full authority to regulate the medical device market in Saudi Arabia.
- SFDA is an independent body with an independent budget.
- SFDA reports directly to the premier of the council of ministers.

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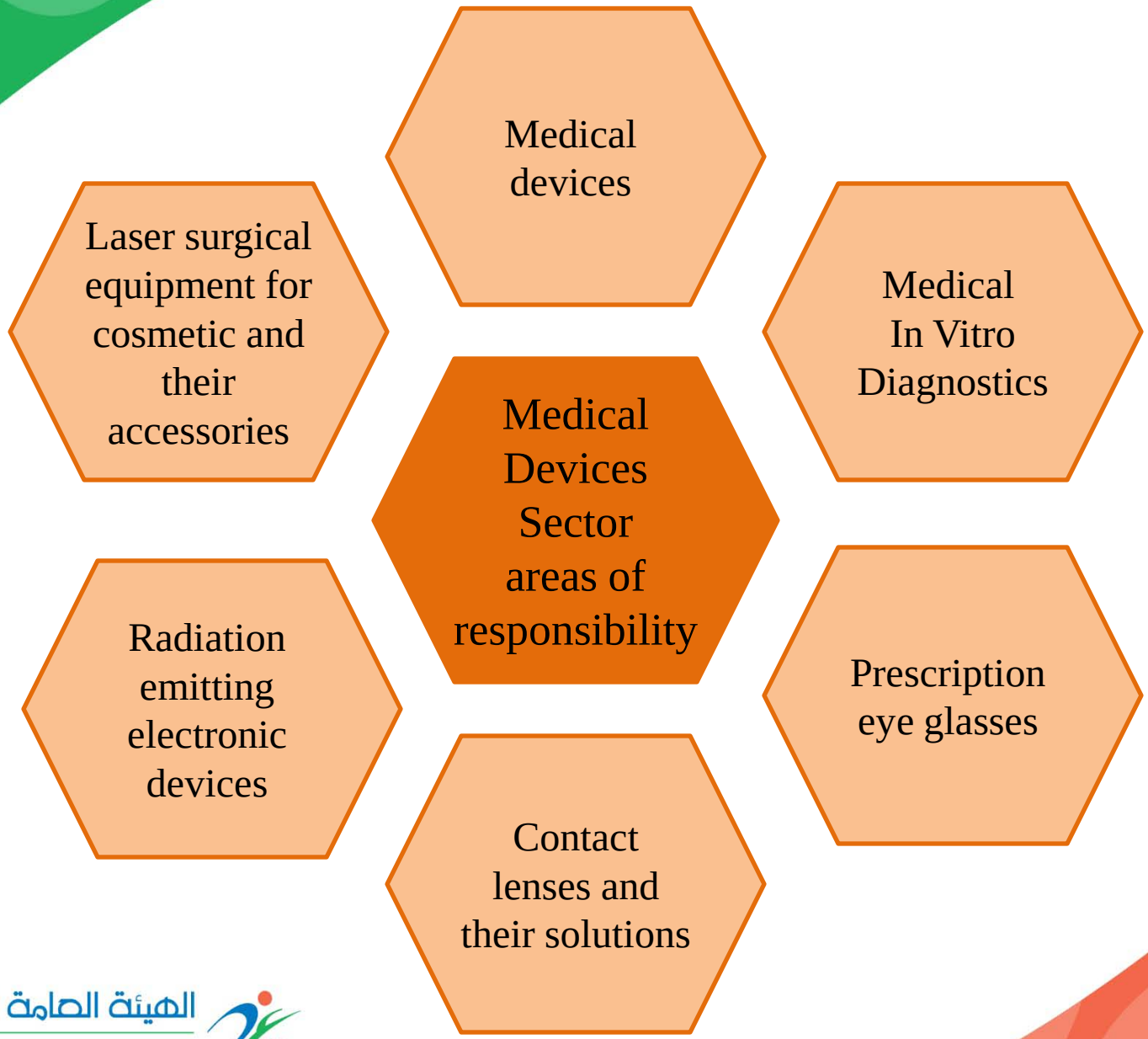
Medical Device

Any instrument, apparatus, implement, machine, appliance, implant, in vitro reagent or calibrator, software, material or other similar or related article:

a) Intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the specific purpose(s) of
   - Diagnosis, prevention, monitoring, treatment or alleviation of disease,
   - Diagnosis, monitoring, treatment, alleviation of or compensation for an injury,
   - Investigation, replacement, modification, or support of the anatomy or of a physiological process,
   - Supporting or sustaining life,
   - Control of conception,
   - Disinfection of medical devices,
   - Providing information for medical purposes by means of in vitro examination of specimens derived from the human body,

b) Which does not achieve its primary intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means.



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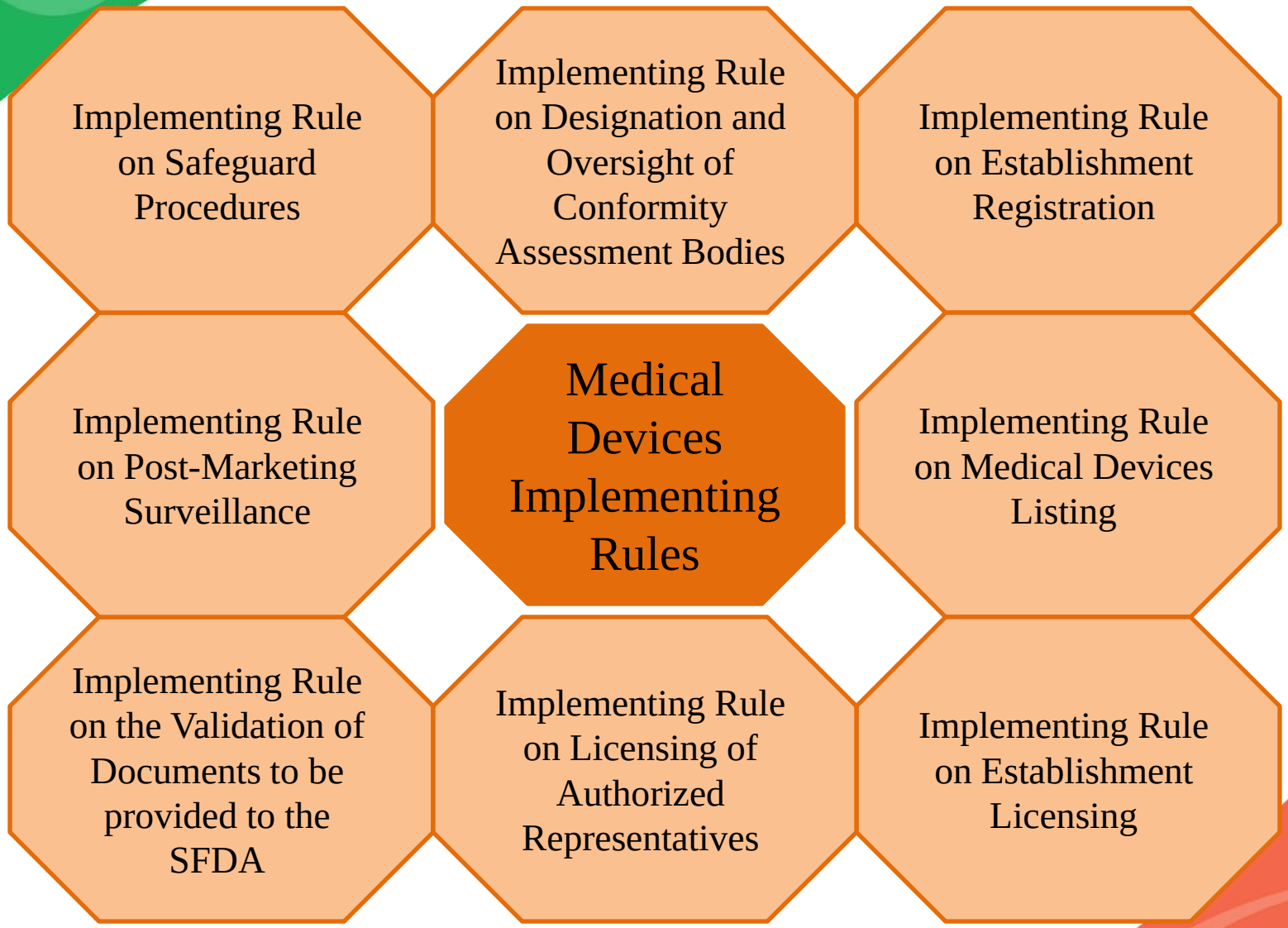

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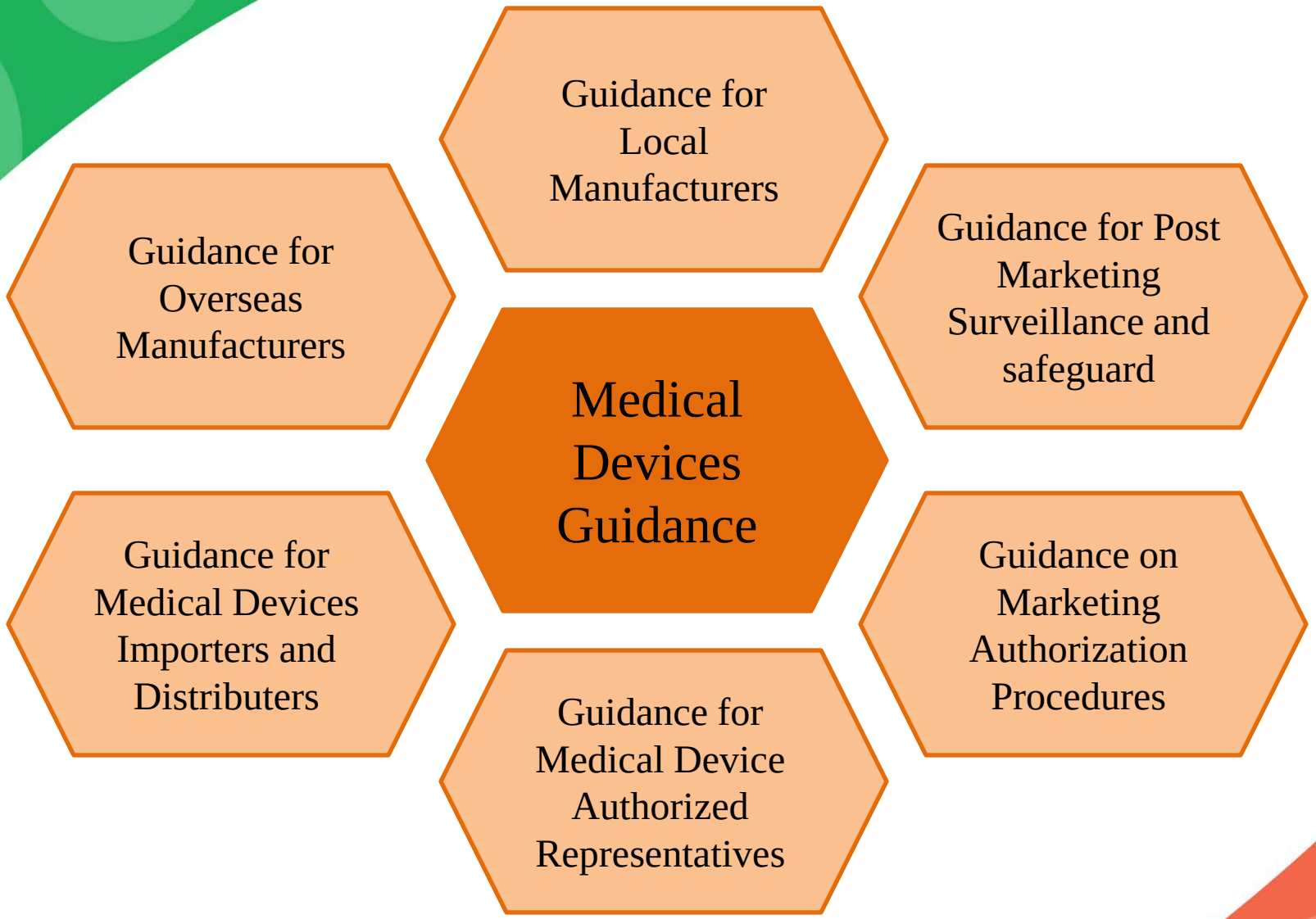

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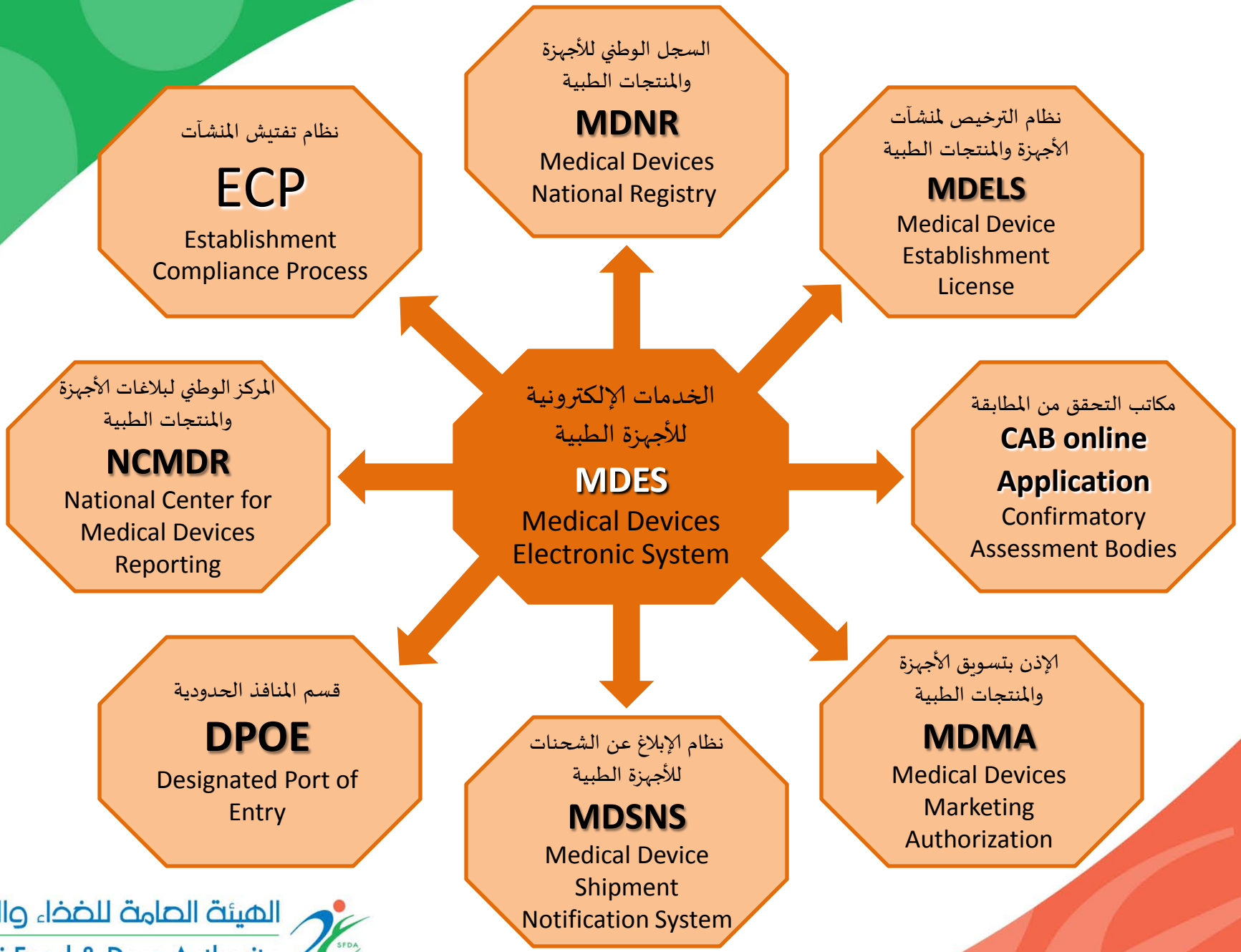

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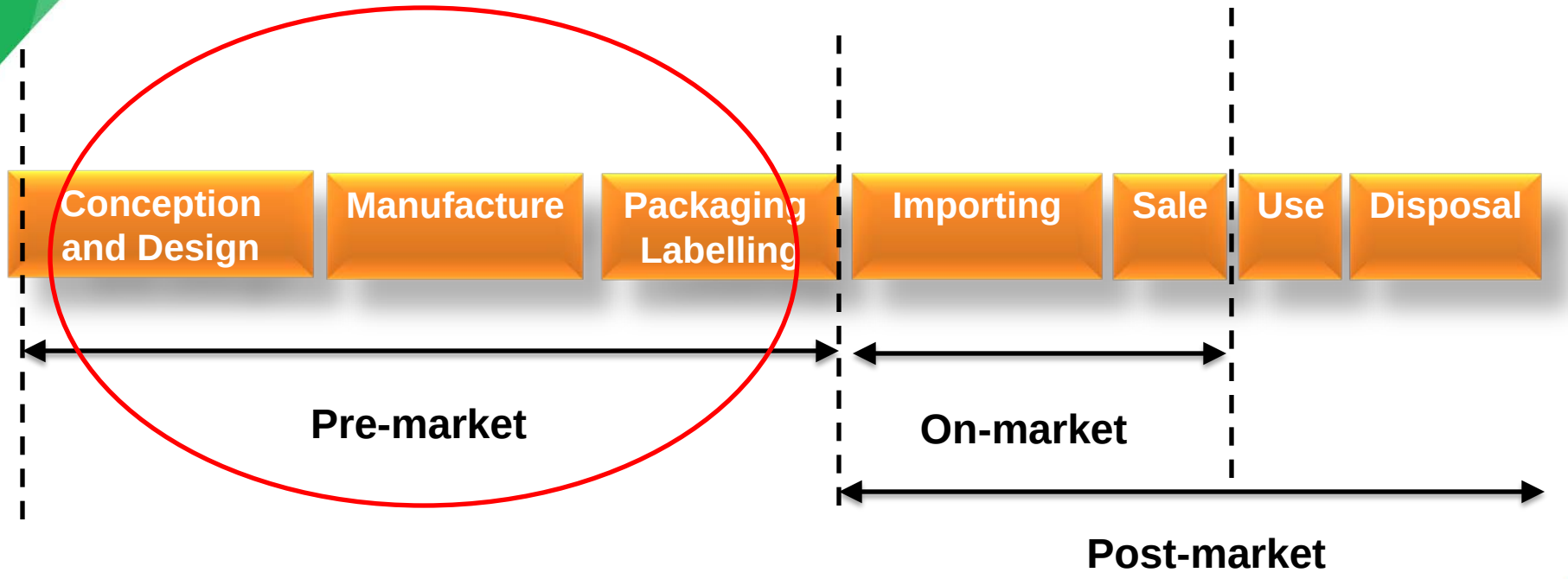
Medical Devices Life Cycle



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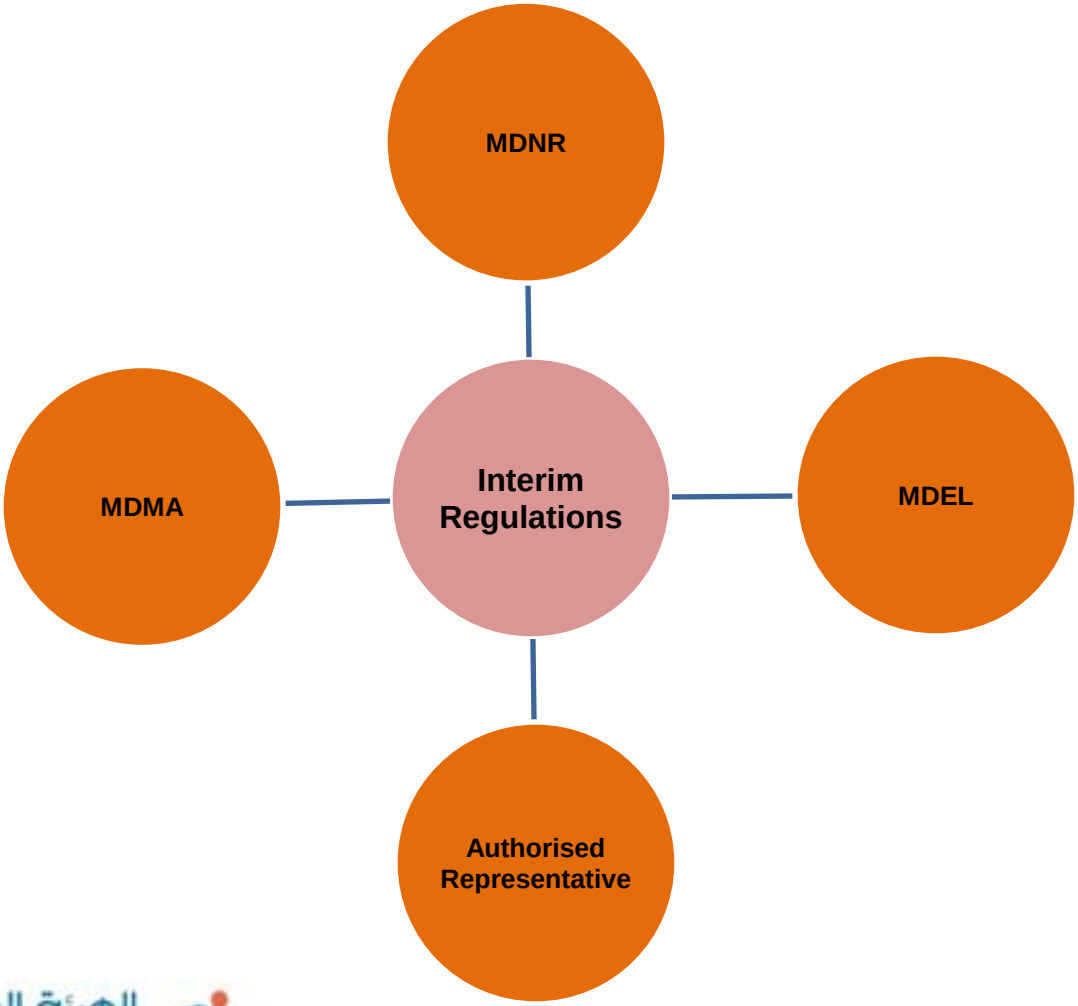
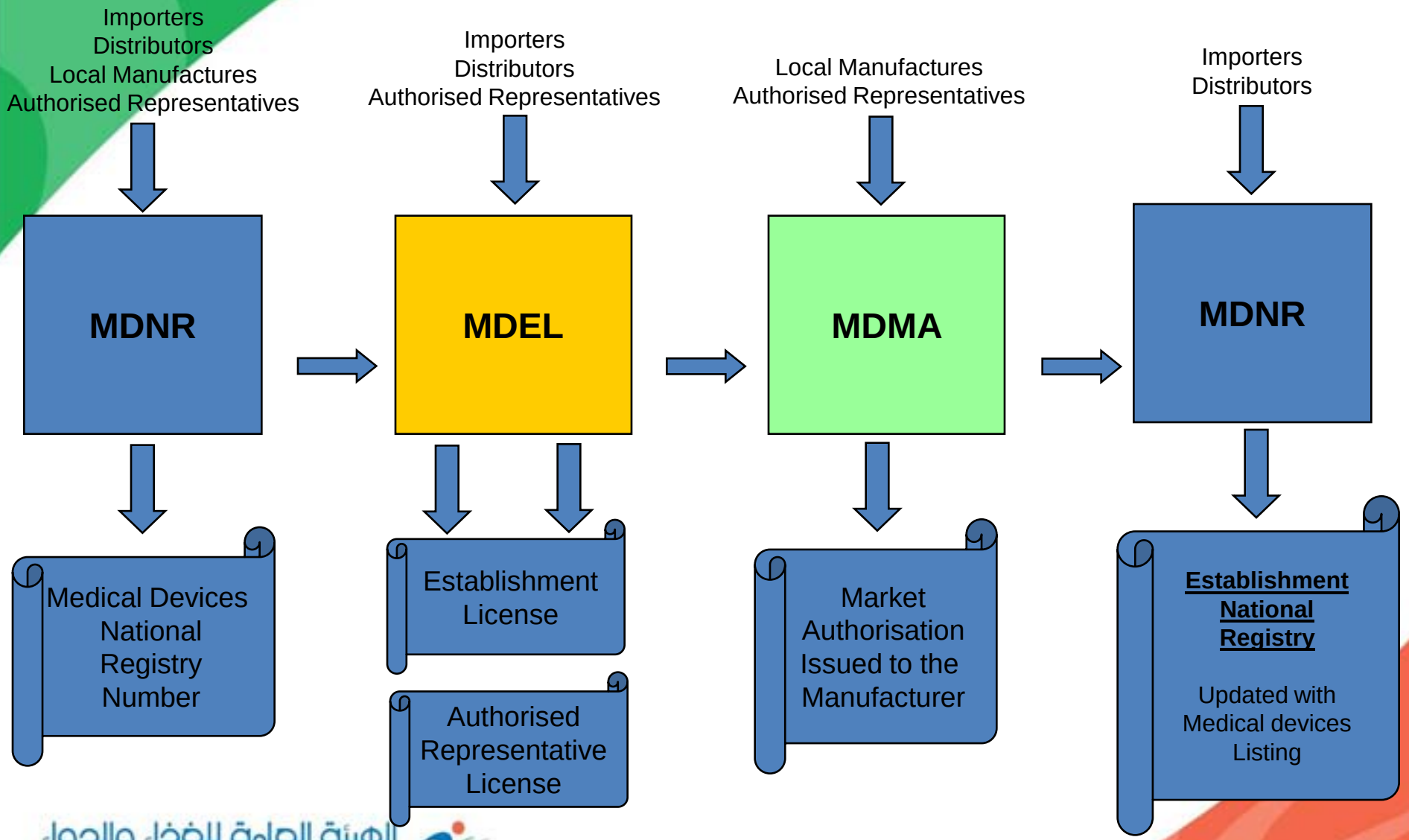
Requirements for Medical Device to be replaced in Saudi market



SFDA On-line System



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Medical Device National Registry (MDNR)

- MDNR is an on-line REGISTRATION scheme includes the medical device establishments information and devices listing
  - manufacturers, exporters, importers, distributors, authorised representative of
    - *medical devices and their accessories,*
    - *in vitro diagnostics,*
    - *prescription eye glasses,*
    - *contact lenses and their solutions,*
    - *laser surgical equipment for cosmetic rather than medical purposes and their accessories.*

Medical Device National Registry (MDNR)

- To register these organisations with the SFDA.
- Retail pharmacy, Healthcare Providers that distribute medical devices are required to enrol for these activities alone
- It is not an approval system
- It is mandatory & its Free to register

Medical Device Establishment License (MDEL)

- Medical Device Establishment License (MDEL)
  - Interim Regulation: Chapter 5
  - Implementing Rules: IR4

WHAT?

- MDEL is an on-line enrolment scheme for importers, distributors and authorised representative of medical devices, located in the Kingdom of Saudi Arabia. Local manufacturer involved in distribution must also apply.

Medical Device National Registry (MDEL)

WHO?

- The following parties who operate their business in Saudi Arabia are required to be enrolled. Importers, Distributors of
  - *medical devices and their accessories,*
  - *in vitro diagnostics,*
  - *prescription eye glasses,*
  - *contact lenses and their solutions,*
  - *laser surgical equipment for cosmetic rather than medical purposes and their accessories.*

- Local Manufactures who Import / Distribute Medical Device will require an Establishment License It is mandatory

- Authorised Representative who Import / Distribute Medical Device will require an Establishment License

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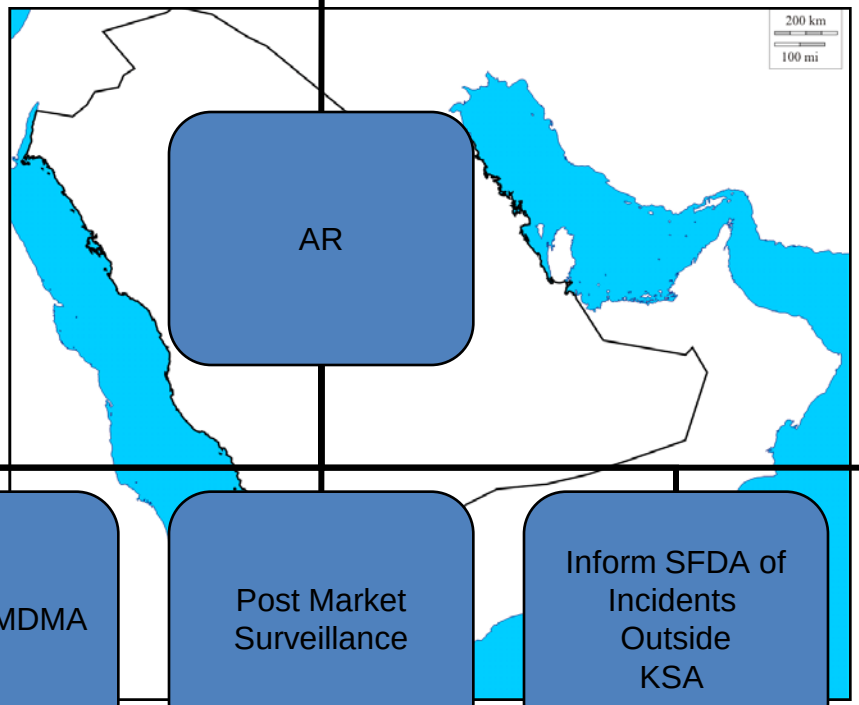
Medical Device Establishment License (MDEL)

Manufacturer



AR

- Dealing with SFDA
- Complete MDMA
- Post Market Surveillance
- Inform SFDA of Incidents Outside KSA
- Cooperate with Importers Distributors Installation Maintenance

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MDEL- Authorised Representative responsibility

The mandate shall, at a minimum, allow the authorised representative to:

1. Represent the manufacturer in its dealings with the SFDA.

2. List each medical device category intended to be supplied to the KSA market.

3. Complete the Marketing Authorisation on-line application form (MDMA)

4. Cooperate with the SFDA on evaluations and actions taken during market surveillance and/or vigilance procedures

6. Inform the SFDA of any incidents that have occurred outside the KSA

7. Inform the SFDA of all field safety corrective actions resulting from post-market surveillance

8. Cooperate with parties involved in distribution activities, installation and maintenance of medical devices that have been placed on the KSA market under its mandate.

Authorized Representative (AR)

Definition:

- *Authorised Representative (AR):*

means any natural or legal person established within the KSA who has received a written mandate from the manufacturer to act on his behalf for specified tasks including the obligation to represent the manufacturer in its dealings with the SFDA.

(Article 1, Chapter 1, MDIR)

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General Principles

- When the manufacturer is located outside the KSA he shall appoint an authorised representative to act on his behalf. (Article 11, MDIR)

- Chapter Six of the Medical Devices Interim Regulation requires organizations authorised by a manufacturer to act on his behalf in the KSA to have an establishment license for this activity, issued by the SFDA. (Article 4A, MDS-IR 5)

Activities to be performed by an AR

Part I: Pre-License Activities

- Designation of Authorized Representatives
- Applying for establishment registration
- Mandate between the manufacturer and Authorized Representative

Part II: Applying for a License

- Applying for establishment Licensing

Part III: Post-License Activities of Authorized Representatives

- Medical Device Marketing Authorization – General Provisions
- Post-Marketing Responsibility for Advertising and Marketing Material
- Post-Marketing Surveillance of Medical Devices

Applying for a License

Applications for Medical Devices Systems can be applied online through The Medical Device Electronic Services .

1st. Apply for Establishment registration and obtain MDNR number through MDNR system.

2nd. Apply for Authorized Representative license online through MDEL system.

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Medical Devices Marketing Authorization (MDMA)

It is a pre-market process of validation & evaluation of a medical device by which SFDA, if applicable, will issue a written Marketing authorization to the manufacturer that allows placing the medical device on Saudi market.

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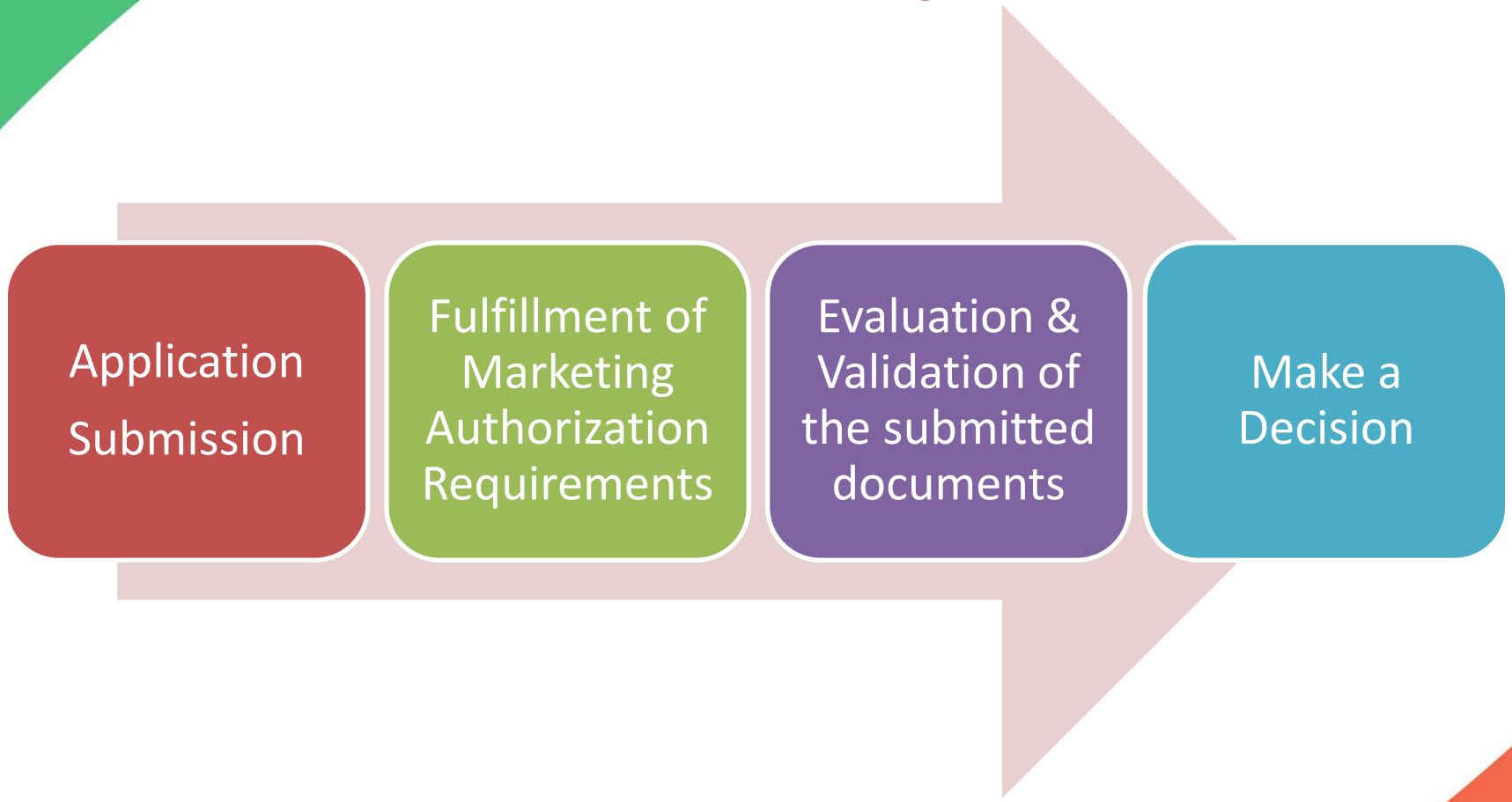
Steps toward obtaining Medical Devices Marketing Authorization



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Application Submission

- Medical devices may be placed on the market and/or put into service ***only if*** they **comply with** the applicable provisions of this **Interim Regulation,** as signified by the SFDA issuing the manufacturer with a written marketing authorization.


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Medical Devices Sector

MEDICAL DEVICES
INTERIM REGULATION

Issued by the Saudi Food and Drug Authority Board of Directors
Decree number 1-8-1429 and Dated 27 December 2008

The Interim was Published in Umm AL-QURA Journal year 86 Issue No:4249 dated in 17 April 2009

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Application Submission

Same User Name & Password from the MDNR

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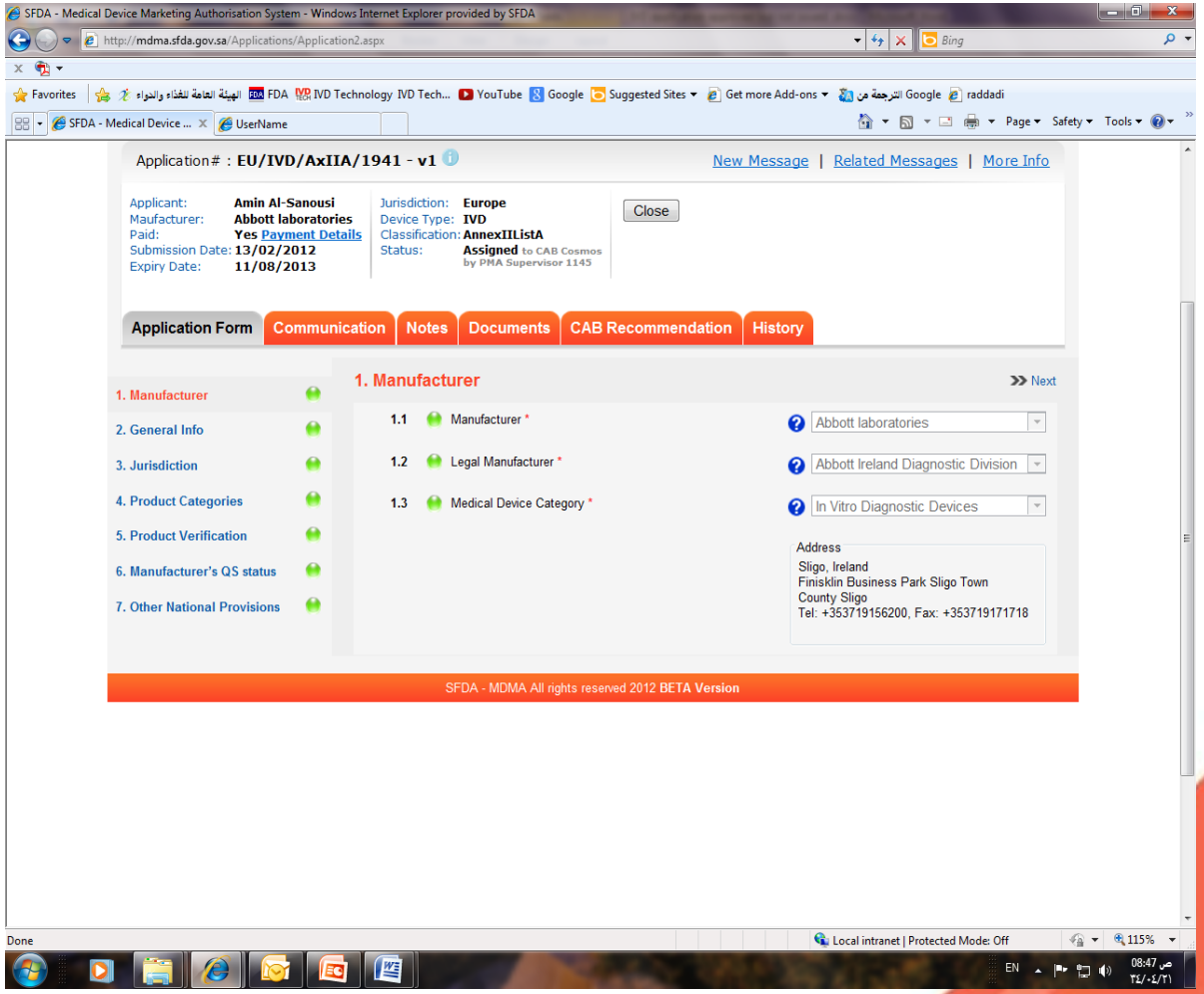
Application Submission

New Application

1. *Manufacturer*
2. *General Info*
3. *Jurisdiction*
4. *Product Categories*
5. *Product Verification*
6. *Manufacturers QS status*
7. *Other National Provisions*



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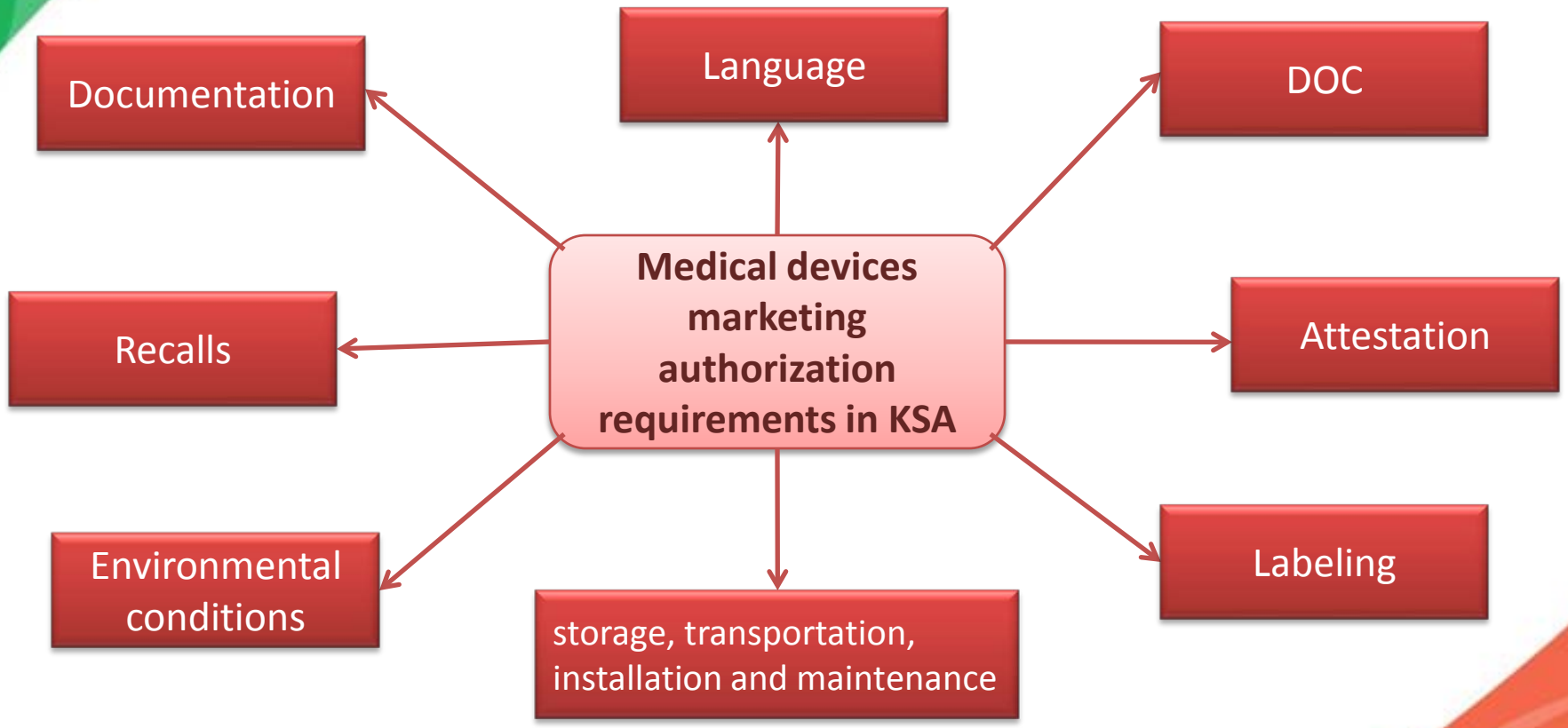
Fulfillment of Marketing Authorization Requirements



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Fulfillment of Marketing Authorization Requirements

MDMAs Incorporating More Than One Medical Device Type

- Where the applicant's MDMA groups more than one medical device type (referred to as '**bundling**' in some jurisdictions) within a single application procedure,

* MDS-G5 ((GUIDANCE ON MARKETING AUTHORIZATION PROCEDURES))

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Fulfillment of Marketing Authorization Requirements

Bundling/Grouping Criteria MD

There are **FOUR TYPES FOR MDMA APPLICATION SUBMISSION** for medical devices other than IVD medical devices as follow:

1. SINGLE medical device.
2. FAMILY of medical devices.
3. System:
    A. Medical device SYSTEM.
    B. Medical device SYSTEMS GROUP
4. PROCEDURE PACK of medical devices.

- Guidance on Medical Devices Bundling/ Grouping Criteria (MDS-G7) is published on SFDA website: http://www.sfda.gov.sa/en/medicaldevices/regulations/DocLib/MDS-G7.pdf

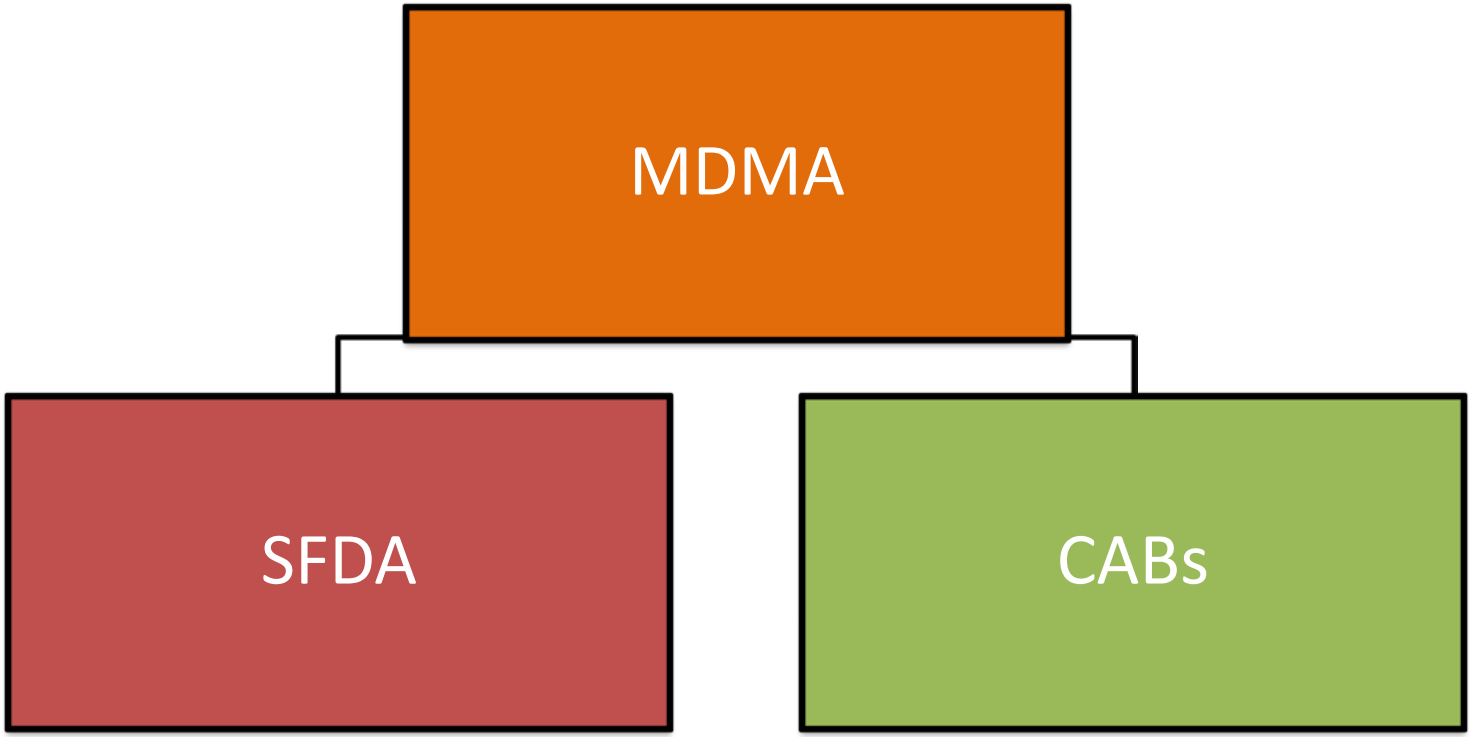
Fulfillment of Marketing Authorization Requirements

Bundling/Grouping Criteria IVD

- IVD medical devices that are grouped/bundled within a single application of MDMA shall:
  - Be under **SAME MANUFACTURER.**
  - Have **SAME RISK CLASS.**
  - Have **SAME INTENDED USE/ purpose.**
  - Be in **SAME ORIGINAL APPROVAL/ CERTIFICATE (if applicable).**
  - The total **number of items shall not exceed 50 items**.

- Guidance on Medical Devices Bundling/ Grouping Criteria (MDS-G7) is published on SFDA website: http://www.sfda.gov.sa/en/medicaldevices/regulations/DocLib/MDS-G7.pdf

Evaluation & validation of the submitted documents



Evaluation & validation of the submitted documents

SFDA : Ensure that the medical device complies with the relevant provisions of MDIR(Article 18,Chapter 6,MDIR)

CABs : MD Sector at SFDA has signed Service Agreements with (5) International Conformity Assessment Bodies:

- The *British* Standards Institution
- TUV Rheinland
- SGS
- COSMOS Corporation
- UL

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Make a decision

➢ **When satisfied**, the SFDA shall *issue a written marketing authorization*, in both Arabic and English.

➢ It will **indicate**:

- the details of the manufacturer
- sufficient information to identify the medical devices
- the period of its validity

➢ The Authorization **remains the property of the legal manufacturer**, whether local or overseas, and not of an authorized representative or importer.

Medical Devices Marketing Authorization (MDMA)

Who Should Apply

1. Local manufacturers.
2. Overseas Manufacturers Authorised Representative

Certificates

Two types of Authorisation :

1. For multiple devices.
2. For single device.

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Validity of MDMA

The validity of MDMA is:

- The **same** as that of the marketing authorization granted in the CE approval or US FDA

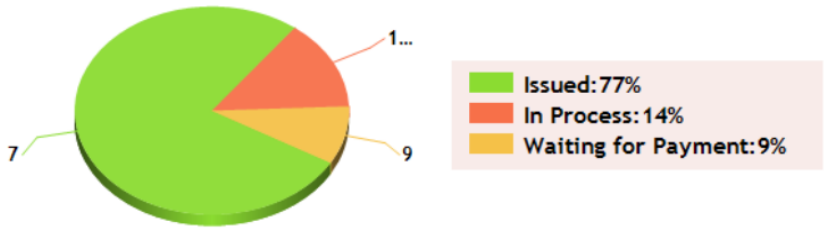
UNLESS

- It has **an open end**, or Where the device has been marketed through **a self-declaration process** (e.g. Class I devices that are not sterile or having a measuring function under EU regulations), MDMA should be valid for **3 years**.

Medical Devices Marketing Authorization

MDMA Medical Devices Marketing Authorization

Medical Devices Marketing Authorisation			
Issued	Under Process	Wating for Payment	Expires within 2 Months
2590	481	294	213



Current Applications in System

Establishments		R & L Department			PMA Department					Managers	
Draft	Returned	Supervisor	Reviewer	Supervisor	Supervisor	Reviewer	Supervisor	CAB	Supervisor	PMA	R & L
Awaiting Submission	Awaiting Re-Submission	Awaiting Assignmnet	Awaiting Decision	Awaiting Decision	Awaiting Assignment to Reviewer	Awaiting Decision	Awaiting Assignment to CAB	Awaiting Decision	Awaiting Decision	Awaiting Decision	Awaiting Decision
3161	2451	103	35	106	23	31	88	42	13	14	39

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Summary

MDS Roadmap

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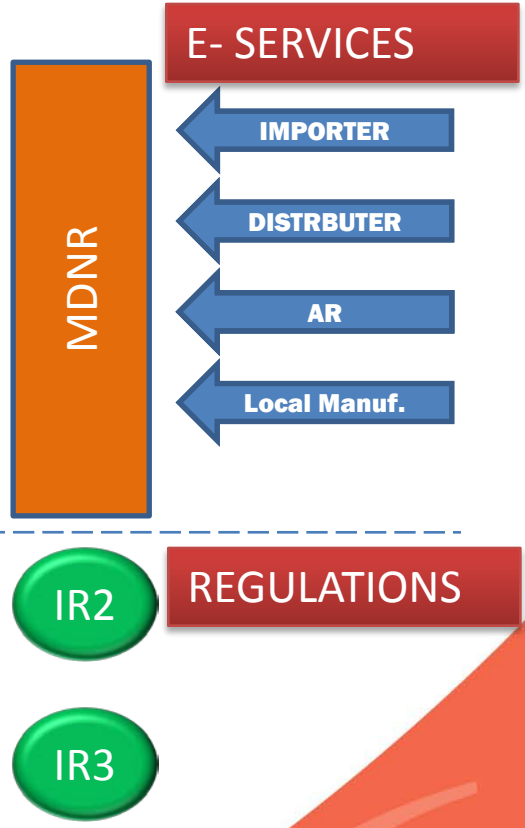
Cont. MDS Roadmap

OUTPUTS



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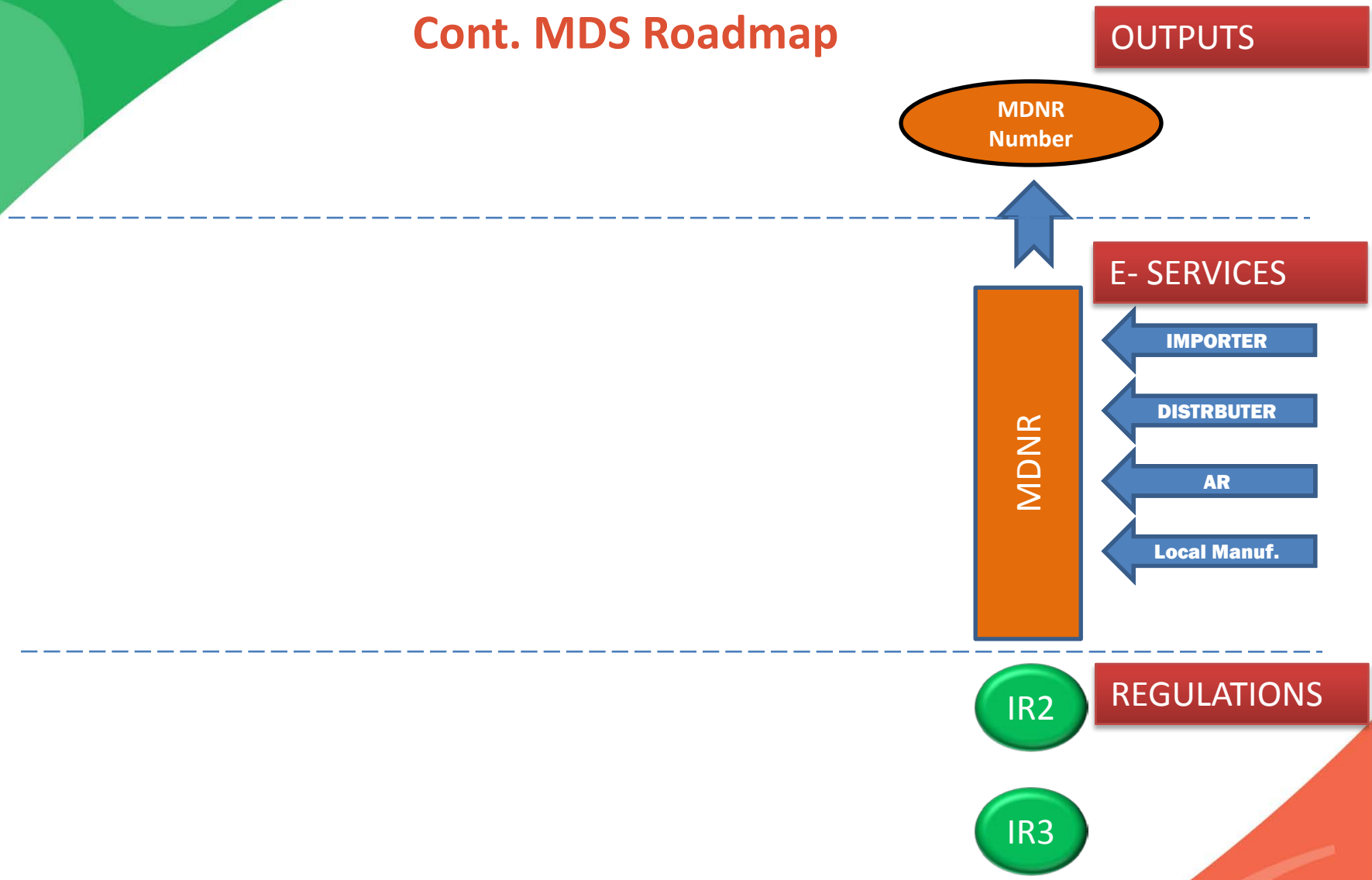
Cont. MDS Roadmap



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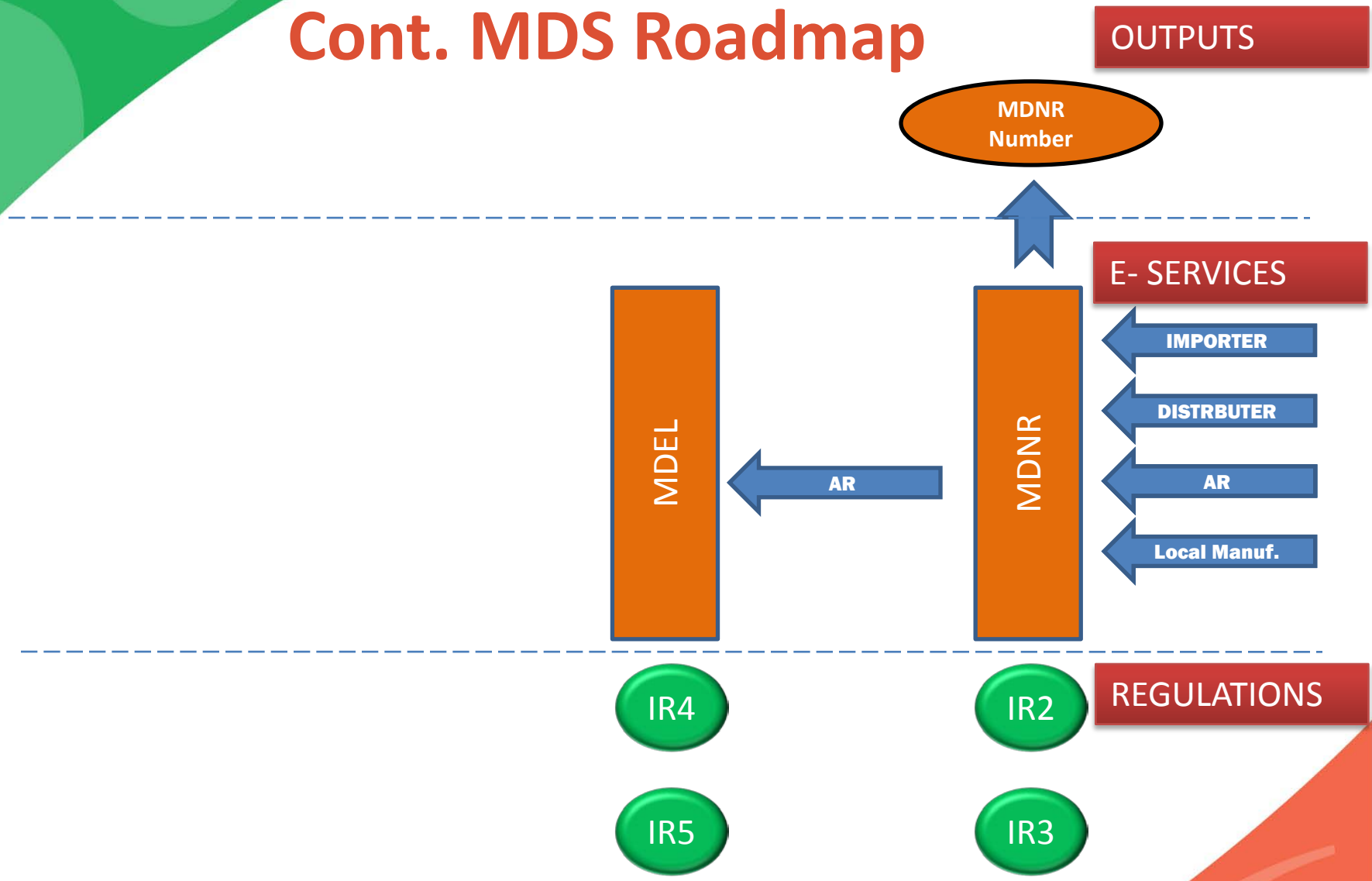

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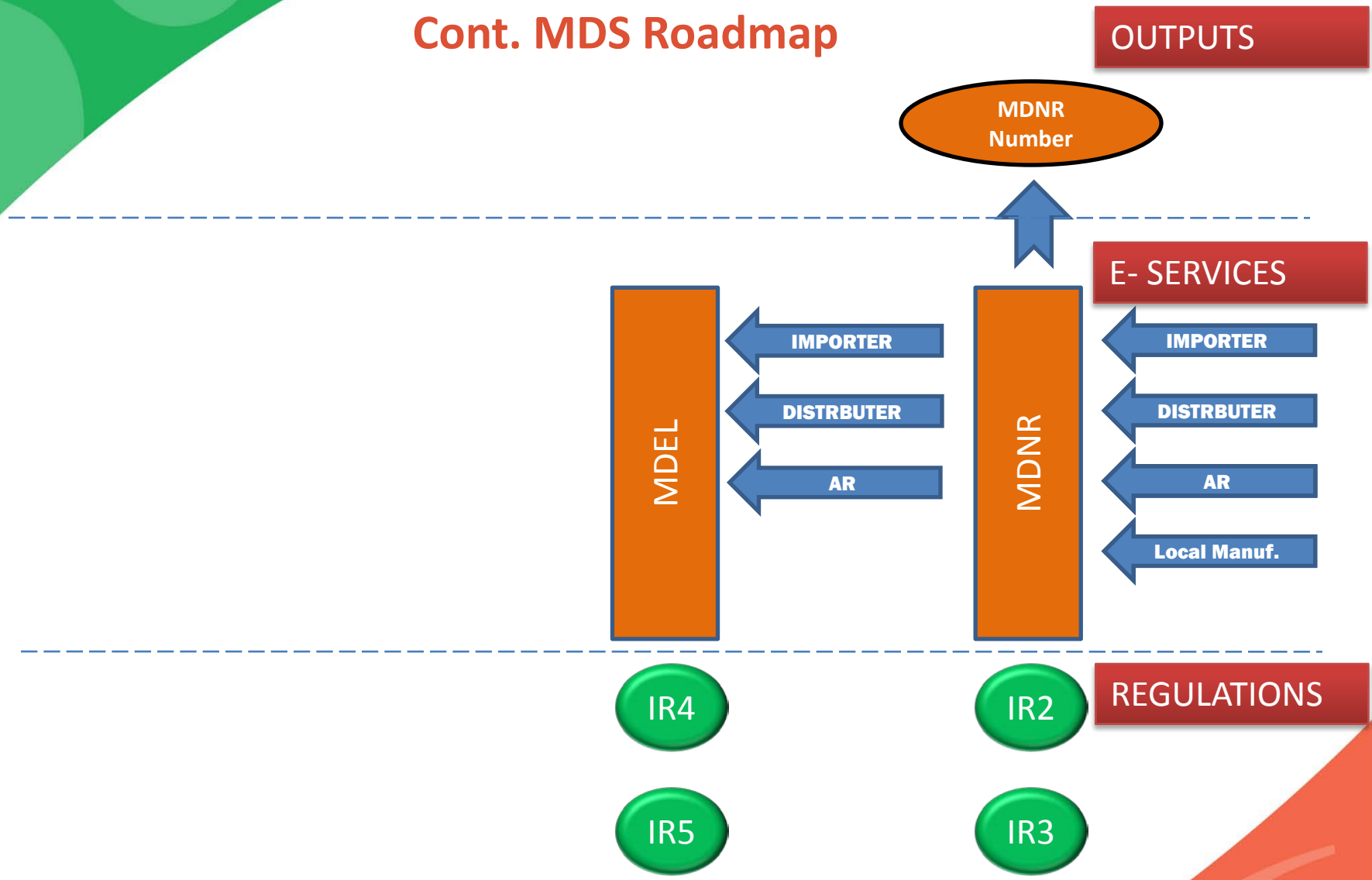

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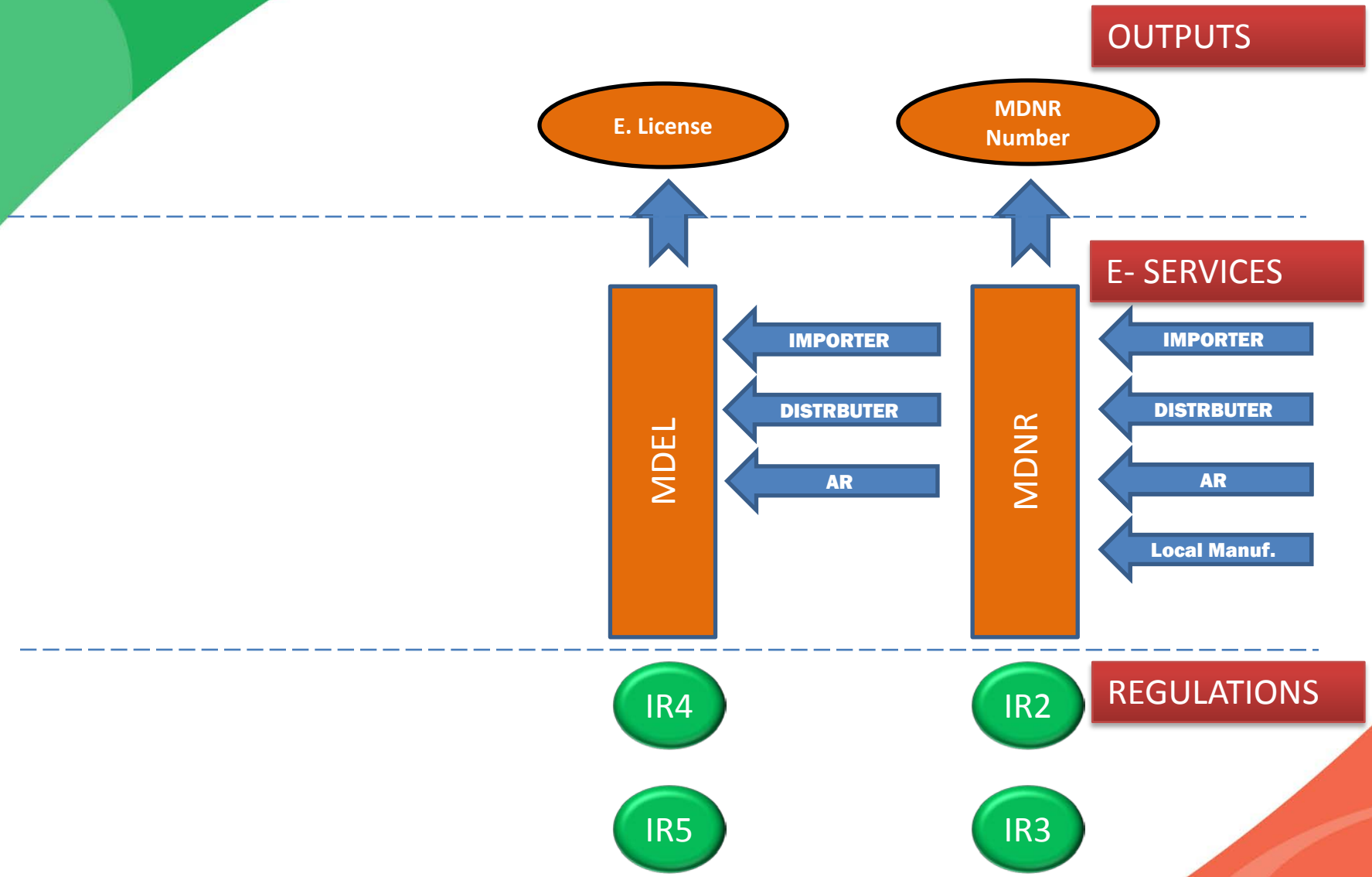

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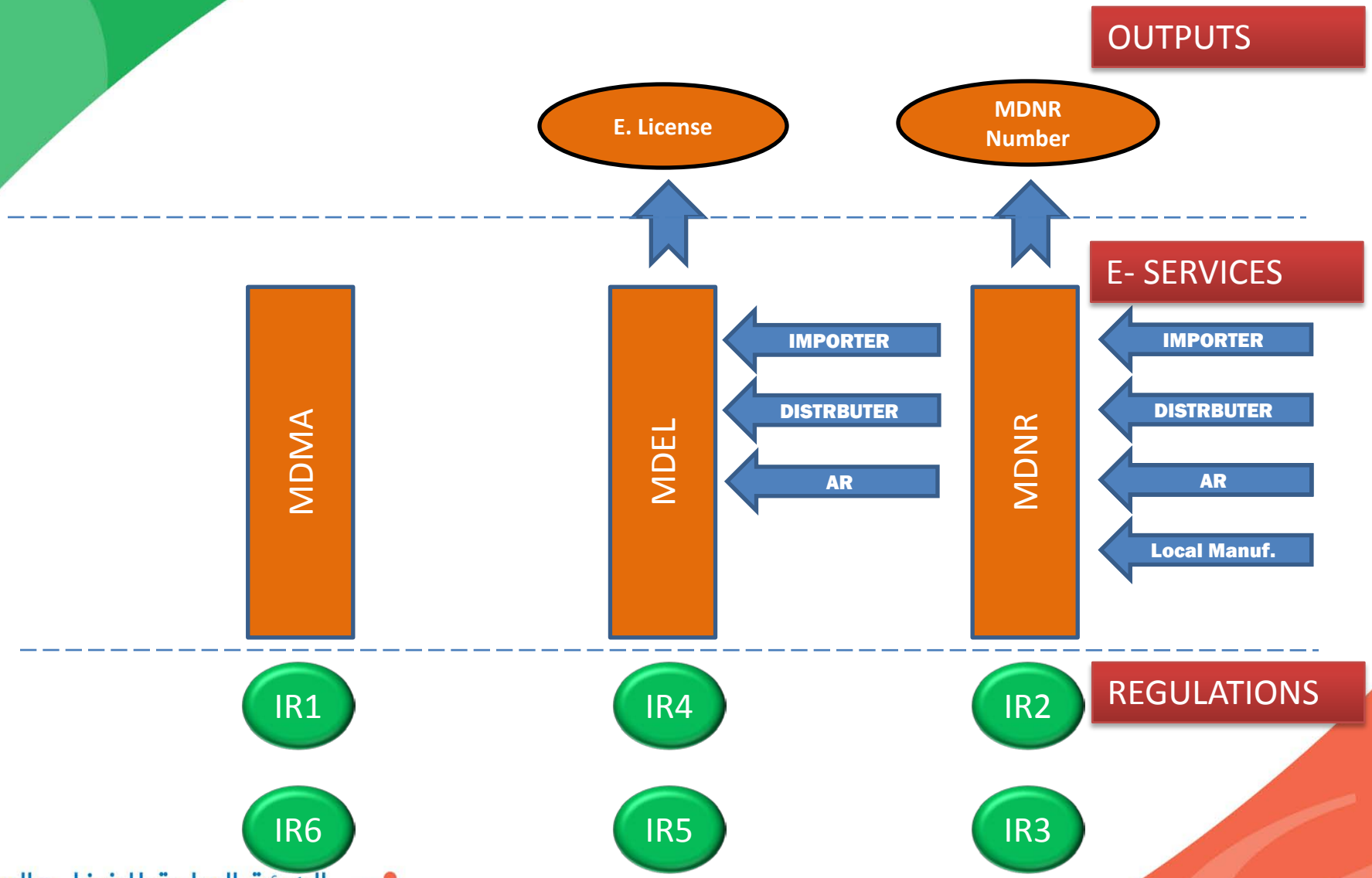

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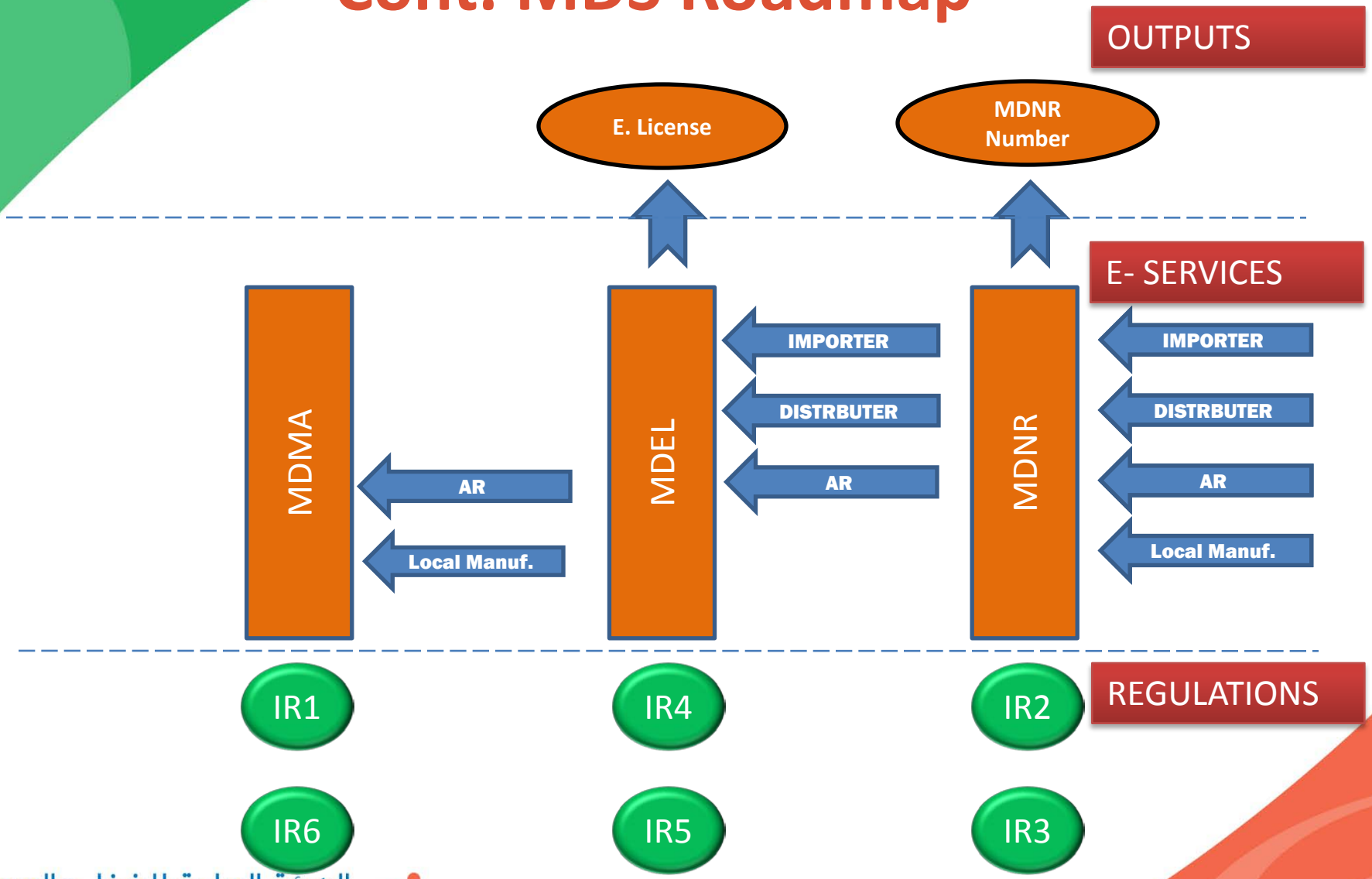

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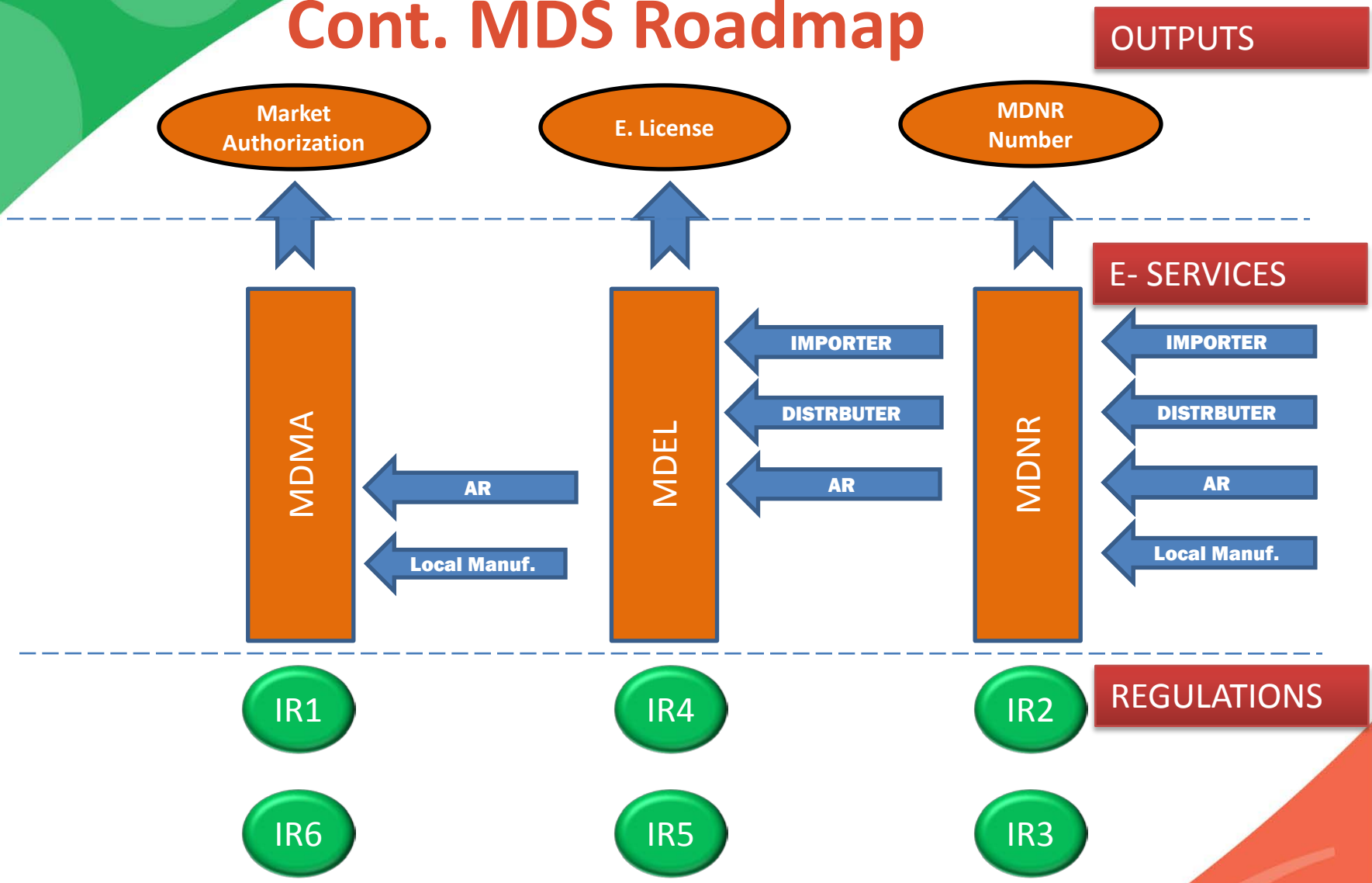

Thank you

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