



IMDRF
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RUSSIA

Recent Registration Experiences with International Authorities – IVD Perspective

17 | September | 2019

Agenda

- **Current approval timelines**
- **Observed commonalities**
- **Observed differences**
- **Changes to products**
- **What works well**
- **What could work better**
- **IVD-R expectations**
- **Closure**

Current approval timelines

Assumptions:

- Timelines do not include in-country specific testing required as part of the dossier
- Timelines vary due to additional information requests, and response times from sponsor
- Timing reflect published timelines where available. Where no timelines are published, timing is based on own experiences

Country	Class	New Application	Non-Significant/ Administrative Change	Significant Change	Renewal
China	1	30	30	30	30
	2	360	30	300	180
	3	360	30	300	180
Japan	1	1	1	1	1
	2	180		180	N/A
	3	240-480		240-480	N/A
Singapore	B	0-100-160	30	45	N/A
	C	120-16-220	30	75	N/A
	D	180-220-310	30	90	N/A
India	A	240	Exempt	180	240
	B	240	Exempt	180	240
	C	365	Exempt	180	365
	D	365	Exempt	180	365
South Korea	1	30	15	15	N/A
	2	180	15	60	N/A
	3	240	15	120	N/A
	4	540	15	180	N/A
EU (Annex II)	I IA, I IB	NB dependent (90)	15	30	30
Canada	4	240	21	200	N/A
	3	200	21	180	N/A
	2	30	21	30	N/A
Mexico	I, II	365	180	365	180
Mexico (3P)	I, II	180	180	180	180
Brazil	IV	120	90	90	120
	III	120	90	90	120
	II	120	90	90	N/A
	I	30	30	30	N/A
Turkey	SD	45	Exempt	15	15
	I IA, I IB	60	Exempt	30	30
Russia	All	210	74	150	N/A
Saudi Arabia	All	180	60	90	120

Observed commonalities

Classification Rules - (Principles of In Vitro Diagnostic (IVD) Medical Devices Classification)

Standards - (Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices)

Symbols/Labelling - (Principles of Labelling for Medical Devices and IVD Medical Devices)

Observed differences

Depth of detail as part of technical documentation

Response timing for Additional Information requests

Registration/License structure (Product name, catalogue number, accessories, non-IVD components)

Acceptance of EU legal documents

Product changes

Manufacturability improvements

Shelf-life (dating) extensions

Labelling updates

What works well

Communication

Direct Engagement

Trade Association Engagement

What could work better

Administrative changes

Significant changes

Transition timing of product changes

IVD-R expectations

Expected changes:

- Product classification system
- Labeling and Technical Documentation
- Clinical Evidence
- Post Market Surveillance
- Economic Operators
- EUDAMED (European Database on Medical Devices)

Regulator acknowledgement of transition strategy

- ALL manufacturers will be making labeling and technical documentation changes and re-issuing CE certificates for all IVDs in the EU
- Industry and Country authorities need to work together on practical strategies for implementation
- Without cooperation, IVDR changes have the possibility of overwhelming the systems of both manufacturers and agencies

Closure

Continued engagement

Open and transparent communication

Common goal realization



Abbott