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# Recent Registration Experiences with International Authorities – IVD Perspective

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# 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) | IIA, IIB | 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 |
| | IIA, IIB | 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

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