Legislative and Regulatory Modernization Framework for Therapeutic Products

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imagination at work

DRUG PRODUCT ACCESS

- Drug Shortages
- Drug Discontinuances
- Special Access

Access Issues – Drug Shortages

Important global area of concern.

Highly regulated and controlled supply chain:

- Manufacture
- Transport/importation
- Distribution/Wholesalers/Retailers

Limited flexibility with unexpected major market changes

Access Issues – Drug Shortages and Drug Discontinuances

Notification

- Support for Notification process when there is a public health impact.
- Support for publically available website with key information.
- Ability to provide Clinical guidance may be limited within pharmaceutical companies
  - Partnering with Health Care professional associations.

Special Access Programme

- Framework must meet the needs of the physicians/ patients and therefore flexibility is important.
- A gradient approach to application requirements is reasonable but it should be set out in guidance rather than regulations.
- Need to balance the amount of information outlined in application requirements for SAP with timely access to products for physicians/patients
- The HC proposed model appears to limit the flexibility.

MEDICAL DEVICE ACCESS

- Special Access
- Investigational Testing
- Exports

Special Access

MEDEC agrees that Special Access should be open to both manufacturers and importers.

The current regulations allow importation only if a product has a license for sale or for investigational testing or is authorized under Special Access need to be changed so that importers can also bring product in for inventory.

This would be level playing field with domestic manufacturers.

Special Access (cont'd)

MEDEC disagrees with the following components of the modernization framework:

- Special Access products cannot be made unavailable – maybe applicable for drugs but not for devices
- Manufacturers should give 6 months' notice prior to discontinue a SAP product
- Manufacturers should be mandated to file an application for license after SAP had been in place for some time or he should indicate at SAP request when a license application would follow.

Suggested changes around Investigational Testing for Devices

- MEDEC agrees that the term be changed to

"Clinical Investigation"

MEDEC strongly recommends further harmonization with GHTF and the USA – 21 CFR 812

Interpretation of Definitions

- MEDEC requests that the definition of a Medical Device as well as the definition of a Manufacturer be further harmonized with GHTF.
- The definition of Sell should be modified to allow unlicensed product to participate in RFPs provided that physical sale (i.e. transfer of ownership) only takes place after a license was obtained.

Exports of Devices

- MEDEC strongly disagrees with the requirement that products imported for export should need to carry a label ‘not manufactured and/or authorized by Canada’
- This would be understood as a negative statement and the eventual target market would not need this label.

ADVERTISING OF PRESCRIPTION MEDICINES

Advertising – Prescription Medicines

LRM proposal to regulate vaccine advertising and drug awareness activities.

- Prescription product advertising of name, price and quantity to consumers should be retained.
- Preventative vaccines should continue to be able to advertised to the public (by manufacturers, Public Health officials, vaccination clinics etc.).

Framework for Advertising of Medical Devices

Currently, there is no requirement for preclearance of advertising for medical devices in Canada. However, medical devices are subject to the provisions of the Food and Drugs Act (specifically Sections 3 and 19 – 21) and the Medical Devices Regulations (MDRs), as they pertain to advertising.

ADVERTISING OF MEDICAL DEVICES

- Trade Shows
- Offer for Sale
- Requests for Information
- Advertising Messages

Advertising Medical Devices

- Health Canada has in past communicated to MEDEC the extension of the interpretation of Section 27 for Trade Shows and devices used for demonstration purposes as long as the following 5 conditions are met:
  - *No selling whatsoever, no testing of individuals, labeled clearly and visibly "Not Licensed in Accordance with Canadian Law", always in direct and continuous control of company, shipped back to manufacturer after show is over".*
- This should be reflected clearly in regulation

Offer for Sale

MEDEC would like the exemption for Trade Shows to be extended also to RFPs provided that no sales transaction is included or product (sample, leased) will be made physically available.

Unsolicited Requests for Information

MEDEC requests that same principle be reflected in regulation for devices and drugs as per HC Guidance Document:

"Information provided to an individual about a drug treatment(s) by a pharmaceutical manufacturer in response to a request for information that has not been solicited in any way (by the manufacturer of the drug) is not considered to be advertising for the sale of a drug."

Special Treatment of Advertising Messages

- MEDEC disagrees that any advertisement shall be set out in such a way that it is clear that the message is an advertisement.
- This is a Canadian unique requirement and should not be mandatory.

Special Conditions of Approval

- MEDEC disagrees that *"Advertising of devices that have a market authorization with special conditions shall indicate the special conditions of authorization in the advertisement".*
- Consistent with the rationale provided against inclusion of symbols on labelling, this should not be a requirement, as it will introduce a Canadian unique requirement.
- Health Canada could include this information on its website (MDALL) if there is a need.

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