

Post-marketing Activities

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Key Concepts

- The primary objective of a medical devices regulatory strategy is to safeguard public health. Post-marketing controls are a vital part of the strategy.
- Predominantly post-marketing procedures are imposed in the customer's market rather than where the premarket regulatory controls are applied.



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Why Aren't Premarketing Controls Sufficient?

- Manufacturers seek to design and manufacture medical devices that are safe and perform as intended. Medical devices regulations establish procedures to help ensure this outcome with the RA providing oversight.
- What could possibly go wrong?
 - No device is absolutely safe. Even a 'low risk' one can seriously harm the patient. Premarket oversight of 'low risk' devices is lower than for 'high' & 'moderate risk' ones.
 - Since many medical devices are manufactured in low volumes by small companies, the number of devices subject to prototype testing is low and may be insufficient to explore all possible variations.
 - The long term safety & performance of some devices is established only after many years of use rather than during the premarket phase (e.g. orthopaedic implants).

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Why Aren't Premarketing Controls Sufficient?

- Individual patients differ and clinical trials or performance evaluation examine only a small proportion of them.
- Professional device users (e.g. clinicians, nurses, dentists, laboratory technicians) have different levels of training and skill – some make unexpected mistakes, others use them in unintended ways.
- Labelling may be unclear or in an unfamiliar language thereby leading to user errors (such as those used by lay persons).
- The industry is highly competitive which encourages manufacturers to regularly change the product's design to improve performance or reduce cost. This may cause the manufacturer to take short-cuts during the premarketing phase.
- Manufacturers may act fraudulently or take advantage of inexperienced customers.
- Distributors may act irresponsibly and without the agreement of the manufacturer.



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Controlling the Supply Chain / Importers

- In general, importers are responsible for:
 - ensuring the consignment corresponds to the documentation,
 - ensuring packaging appears undamaged,
 - ensuring the consignment is accompanied by any documentation required by the RA (e.g. declaration of conformity / marketing authorization / traceability information / instructions for use etc.),
 - completing customs procedures applying at the point of entry,
 - storing, handling & transporting medical devices according to the manufacturer's instructions,
 - record information for traceability purposes.

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Controlling the Supply Chain / Importers

- The local RA may establish performance standards for importers by requiring them to be registered (step 1) and licensed (step 2).
- For example, importers will be licensed only if they undertake to carry out the activities identified in the preceding slide and have the necessary procedures in place. This is the approach taken by the Saudi FDA (see <http://www.sfda.gov.sa>).



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Controlling the Supply Chain / Distributors

- In general, distributors are responsible for:
 - transporting, storing, handling & installing devices according to the manufacturer's instructions,
 - ensuring devices are accompanied by any documentation required by the RA (e.g. declaration of conformity / marketing authorization), or user (e.g. instructions for use),
 - recording information for traceability purposes,
 - servicing them thereafter (where applicable),
 - training medical device users (where applicable),
 - providing ongoing customer support,
 - implementing any field safety corrective actions.

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Controlling the Supply Chain / Distributors

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Controlling the Supply Chain / Authorized Representatives (ARs)

- When the legal manufacturer is based overseas, it may be required to appoint a local agent (i.e. the AR) to represent it in the local market before it provides medical devices to the market.
- In general, ARs are responsible for:
 - representing the manufacturer in its dealings with the RA,
 - provide the RA with the information it requires when the manufacturer seeks authorization to market its devices in the market,
 - inform the RA of any reportable adverse events that have occurred either within the local market (or outside it, if there are any consequences for the local market) and provide information on the corrective action the manufacturer has taken or intends to take,
 - inform the SFDA of any field safety corrective actions to be taken within the local market,
 - cooperating with the manufacturer's importers and distributors,
 - cooperate with the RA and provide it with any information it requires during market surveillance activities,
 - recording information for traceability purposes.

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Controlling the Supply Chain / Authorized Representatives

- The local RA may establish performance standards for ARs by requiring them to be registered (step 1) and licensed (step 2).
- The AR and manufacturer should be signatories to a legal contract that meets minimum requirements specified by the RA.
- For example, ARs will be licensed only if they undertake to carry out the activities identified in the preceding slide and have the necessary procedures in place. This is the approach taken by the Saudi FDA (see <http://www.sfda.gov.sa>).
- If the device manufacturer appoint its distributor to act also as its AR, there should be separate registration and licensing procedures for each activity.



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Marketing Surveillance & Vigilance

- **PREMARKETING REQUIREMENT:** the overseas RA will expect the manufacturer to track medical devices through the supply chain to the end user, and subsequently monitor device performance (i.e. market surveillance). It will also require any 'adverse event' to be investigated and corrective action taken to prevent re-occurrence (i.e. vigilance).
- **POST-MARKETING:** to safeguard public health in the importing country, the local RA may require a manufacturer (through its local agent) to report immediately to it any serious adverse event that occurs within its jurisdiction. The local RA may then monitor the subsequent investigation and any corrective action.



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Safeguarding Procedures

- Basic controls include the local RA:
 - establishing a procedure to withdraw unsafe medical devices from the market and to issue safety alerts to users.
 - establishing a procedure to alert healthcare facilities and device users of adverse incidents where a patient or user has died or been seriously injured, or where an IVD produces erroneous results which can pose significant risks to patient or public health, and advise them of the actions they should take.
 - requiring manufacturers or their local agents to report any Field Safety Corrective Actions they are undertaking in the jurisdiction.



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Networking

- Local RA's will benefit from developing a productive working relationship with their overseas counterparts.
- Developing a two-way relationship with one or more experienced RAs could lead to secondments or other training opportunities.
- Local RA's should monitor the GHTF Founding Members websites, and that of the WHO, as well as those with relevance to their particular circumstances (e.g. Saudi FDA).
- Once it has developed an effective national adverse event reporting procedure, a local RA may become eligible for, and consider joining, the GHTF's National Competent Authority Report (NCAR) exchange program. This forum manages the two-way exchange of information concerning adverse events that offer a serious public health threat.



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Thank You



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