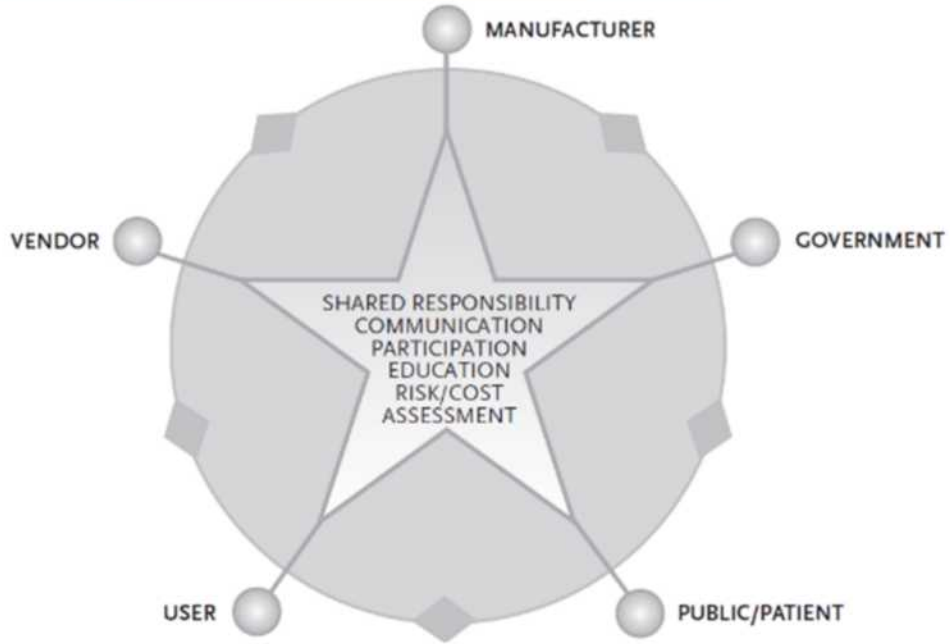
Participants in ensuring the safety of medical equipment

- Manufacturer
- Vendor
- User
- Government
- Public
- Communication and interactions between participants



17.1.3 Identify participants in ensuring the safety of medical equipment

17.1.4 Explain the role of each participant in ensuring safety

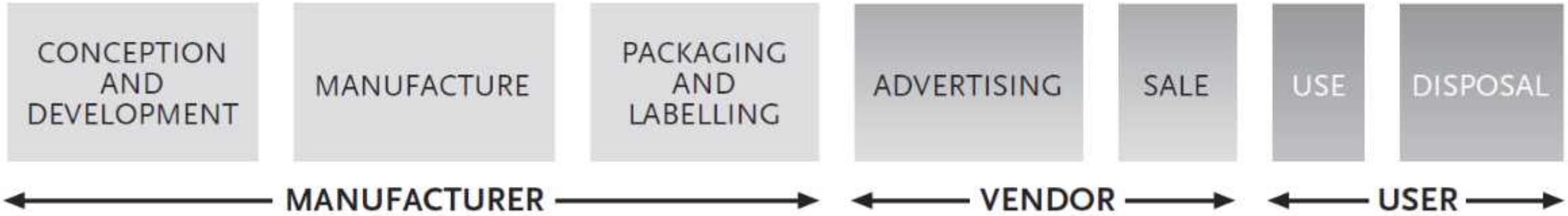
17.1.5 Identify areas of shared responsibility

Unit C 17.1 Medical Equipment Safety

Module 279-17-C Regulations, Standards and Ethics

Participants in ensuring the safety of medical equipment

1. Participants that directly manage phases in the equipment life cycle: **Manufacturer, Vendor** and **User**



2. **Government** that is ultimately responsible for making the regulations that must ensure safety

3. The **Public** (patient) that is the direct beneficiary ('customer') of equipment safety.

All five play critical roles in ensuring the safety of medical devices

Responsibilities of stake holders: examples

It is the task of the medical device manufacturer **to prove that a device is clinically effective**.

For example, if a device is intended for pain relief, the manufacturer needs to possess objective, scientific evidence, such as clinical test results, that the device does in fact relieve pain.

It is also the task of the medical device manufacturer to demonstrate that **all possible risks associated with the device are identified and adequately addressed.**

A role of the **regulatory authority** (‘government’) is to ensure that the manufacturer has effectively implemented the risk management process

Manufacturer

The Manufacturer is responsible for the three phases:

- design/development/testing,
- manufacturing,
- packaging and labelling.

that lead to a product being ready for the market.

In addition, **sometimes** the manufacturer is also responsible for:

- after sales support: **training, maintenance, spare parts delivery.**
- disposal: **take back the product to dispose of it.**

The manufacturer, the creator of the device, must ensure that **the device is manufactured to meet the required standards of safety and performance.**

That means that the medical device manufacturer must be able to demonstrate that **all possible risks** associated with the device are identified and adequately addressed.

Manufacturer: design/development/testing

The term "**user error**" is defined as an action that has a different result than that intended by the manufacturer or expected by the operator. User error may result from a mismatch between variables, for example the operator, device, task, or environment.

By **incorporating human factor engineering principles in design**, and **appropriate training for users**, the risk of user errors can be minimized.

The manufacturer must be able to demonstrate that he has implemented this approach…

The Purpose of a device: intended use

Every device has a designed Purpose

can have undesirable side effects
which may be foreseeable…

may be used for other purposes,
which may not always be foreseen…

The manufacturer is responsible for safety when the product is used for its designed purpose

the users are mostly responsible for any other use…..

Manufacturer: Manufacturing

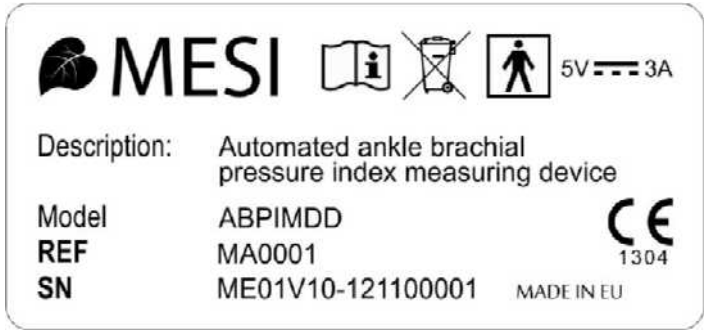
Good Manufacturing Practices (GMP) contains an enormous amount of regulations on how a manufacturing operation needs to be run to deliver consistent quality and continuous improvement of processes.

For example: **descriptions must be available** of

- all (construction) work,
- all testing work,
- when to approve a product,
- when to repair or throw away,
- how suppliers are managed,
- how product problems in the field should be investigated in manufacturing,
- .....

Manufacturer: Packaging and Labelling

Medical devices must be packaged so that the products **pose little risk** to individuals that handle the product, even if the medical device is biohazardous. Shipping is one of the hazards a medical device and its packaging must survive.
Well-sealed packaging is essential for those medical devices that must be maintained sterile.



Labelling is crucial in **identifying** the medical device and **specifying instructions** for its proper use. As for drugs, mislabelling of medical devices can result in serious consequences for the user. Hazard warnings or cautions and clear **instructions for use** are very important.

Vendor

The **Vendor** provides the interface between the product and the user. The term Vendor includes **importers**, **distributors**, **retailers** and
manufacturers who sell medical equipment.

He/she should **make certain** that the products he/she sells comply with regulatory requirements. I.e. he has to check the manufacturer !

Vendor: Advertising

Vendors should not make **misleading or fraudulent claims** about their products or **issuing false compliance certificates**.

Used or refurbished devices should be clearly labelled as such.

Medical device marketing and advertising are regulated to prevent misrepresentation of a medical device and its performance.

Vendor: After Sales Support

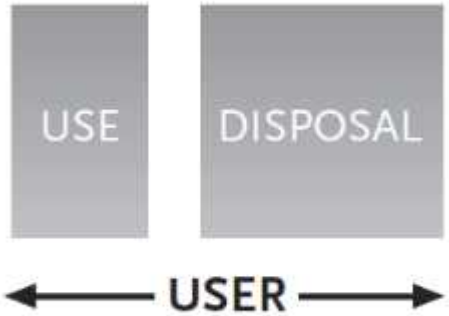
Vendors should provide **after-sale service**.

Medical devices often require specialized **training** from the manufacturer for proper use and service; therefore, the **vendor should make training a condition to the manufacturer** or importer in accepting to sell the device. In turn, vendors should take responsibility in supporting or training their customers.

Participating in **post-market surveillance** (receiving and reporting customer complaints/incidents) is critical for ensuring medical device safety and performance. The vendor must fulfil these obligations specified by the regulatory authority. For example, the vendor must **make arrangements for processing complaint/incident reports** relating to medical device safety and performance.

In the case of **home-use medical devices**, the vendor should recognize that the device being sold might end up in the hands of a **lay-person** who may need special instructions for the proper use and maintenance of the device. In this situation, efforts must be made to provide **non-technical instructions** and to **educate and help** the customer.

User: use



The User is usually a **professional** in a health care facility, but may also be the **patient**.

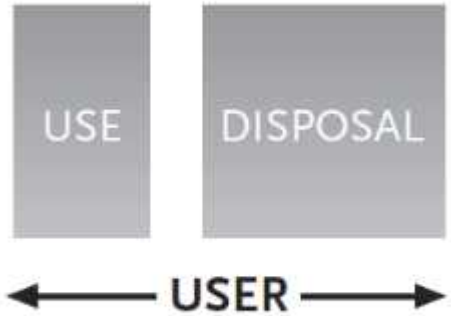
The user should make sure that he/she has **qualifications** and **training** in the proper use of the device, and is familiar with the indications, contra-indications and operating procedures recommended by the manufacturer.

It is crucial that experience gained with medical devices be shared with other users, the vendor and manufacturer to **prevent future problems**. This can be done by **reporting any incidents** to a coordinating centre from which warnings can be issued.

When using medical devices, users should always bear in mind that the safety and health of the patients are in their hands. The user has the responsibility to employ the medical device only for the **intended indications** (or to assure that any non-indicated use of the medical device does not compromise the safety of the patient and other users).

The user also has the responsibility to ensure proper maintenance of medical devices during active use.

User: disposal



The user has the responsibility to **ensure** safe disposal of obsolete medical devices

Disposal of certain types of devices should follow specific and stringent safety rules. For example, devices that are **contaminated** after use (e.g. syringes) or devices that contain toxic chemicals, can present hazards to people or the environment and must be disposed of properly.

Public

The public are the ultimate beneficiary of medical devices.

They should be fully aware that all devices carry a certain risk and that they can help to promote safety and performance through **self education** and by putting "**customer pressure**" on manufacturers to comply with standards.

Medical devices are increasingly available for home use, **making the Public also the User**. Purchasers of home-use medical devices should be aware of associated risks and take the responsibility **to become educated** in the functions and correct operating procedures for those devices.

The government

The government has the responsibility to **oversee the efforts of manufacturers and vendors** and ensure that medical devices sold or made available in the country are safe and effective.

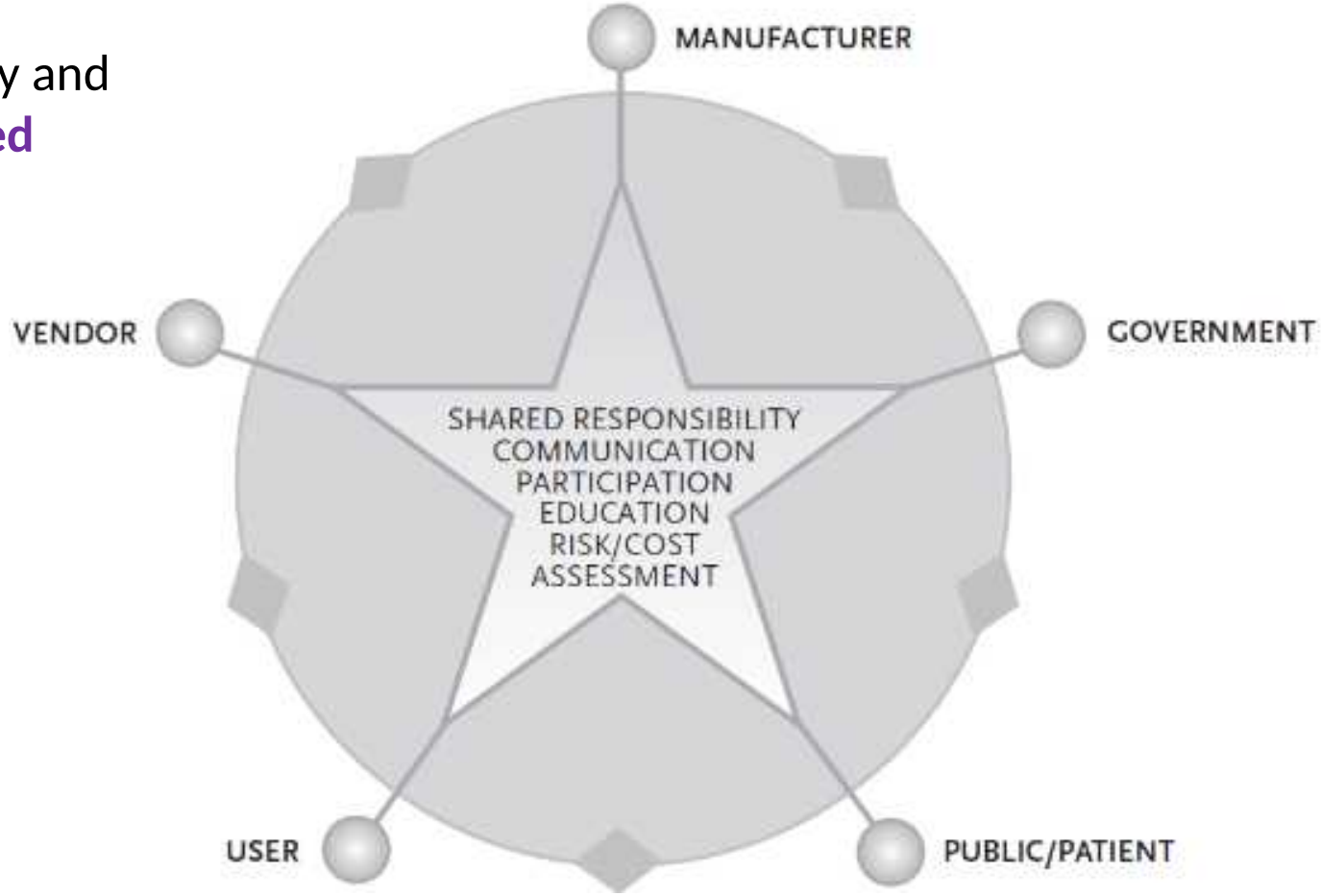
It should provide leadership in **creating healthy cooperation among stakeholders** in establishing policies and regulations that are fair and clear to all.

Policies and regulations should be reviewed periodically to respond to changes in technologies by incorporating appropriate amendments.

Shared Responsibility

The ideal conditions that will ensure the safety and performance of medical devices require **shared responsibility** by all stakeholders.

This requires continuous good **communication** and **cooperation** symbolized in the picture.



Shared Responsibility

The most important factor that ensures the cooperation of all these stakeholders is an **informed and common understanding of the issues**.

Shared understanding and responsibility are achieved through **communication and mutual education**, which can be effectively achieved by having all stakeholders participate in establishing the process that ensures safety and performance of medical devices.

END

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