SG1 – Practical Implementation of Harmonised Guidelines

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Health Sciences Authority • To be the leading innovative authority protecting and advancing national health and safety

Centre for Medical Device Regulation
Health Products Regulation Group
Health Sciences Authority

SG1 Guidances

SG1 Guidances: finalised guidances
draft guidances

Examples: Definition of medical devices
Classification rules
Essential principles
Conformity assessment

Guidance – Is it the Solution?

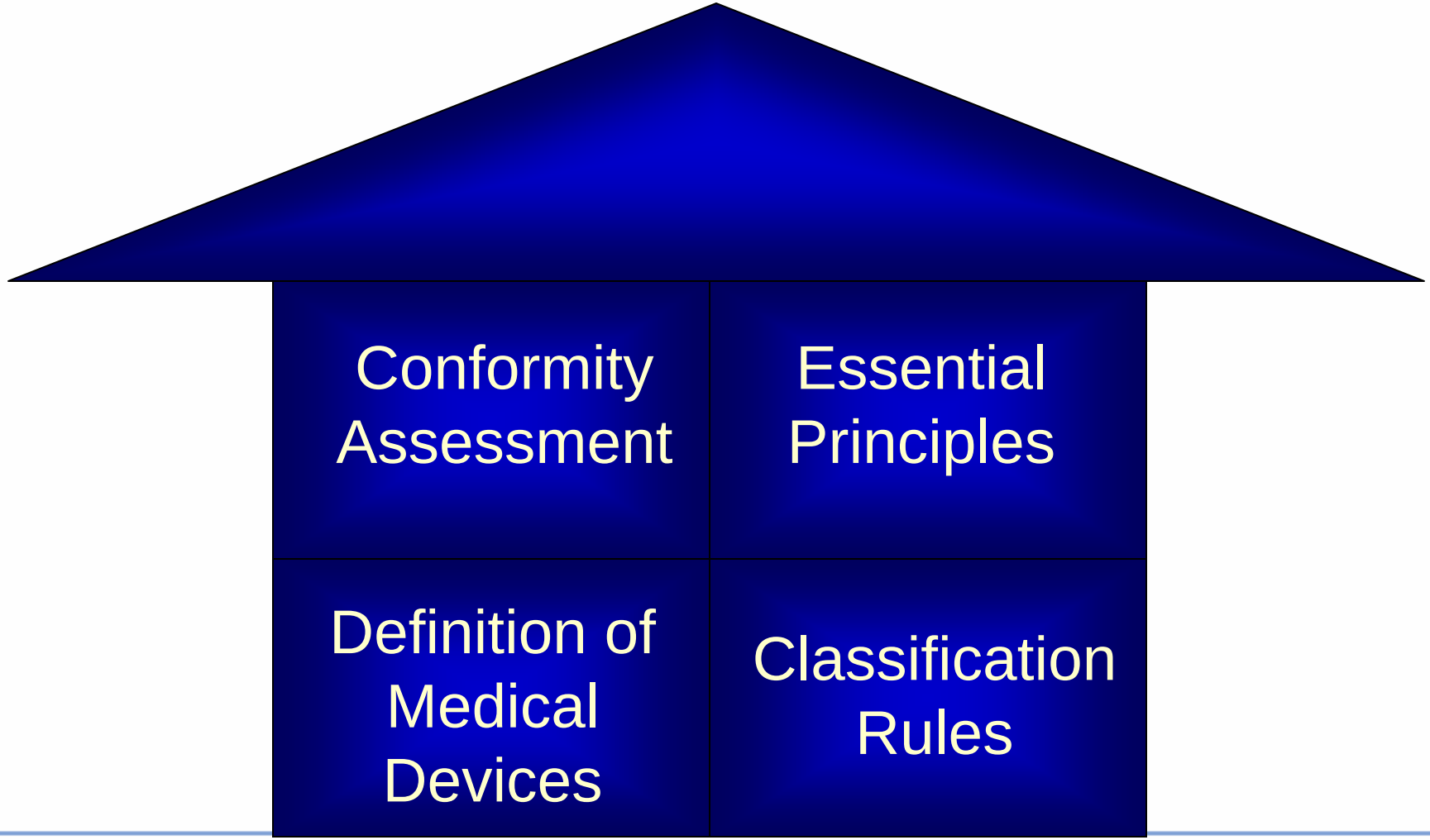
Panacea (cure-all / universal remedy)

OR

Pandora's Box

How do we make sure it becomes the **solution?**

Making Sense of Guidances – Piecing the Pieces Together



Legal Status of Guidances

	Enforceable?	Non-Enforceable?
Definition of medical device	Adopt entire document? Redraft?	Can you include it in your regulations?
Classification rules	Adopt entire document? Redraft? (difficult task)	Can you include it without redrafting by your lawyers into your regulations?
Essential Principles	Is it written in the language and style that your population understands?	Can you include it without redrafting by your lawyers into your regulations?

Elements Of Conformity Assessment

Elements regulatory authorities may include in a conformity assessment system are:-

(A) Conformity assessment of the quality management system:

1. a quality management system;
2. a system for post-market surveillance;

(B) Conformity assessment of device safety and performance:

3. summary technical documentation;
4. a declaration of conformity;

(C) Registration:

5. the registration of manufacturers and their medical devices by the regulatory authority.

Elements Of Conformity Assessment

Element	Description	Benefits
1	A quality management system	Emphasises that quality must be built into the device during the design and the production stage, as well as maintaining it throughout the entire product life cycle.

Elements Of Conformity Assessment

Element	Description	Benefits
2	A system for post-market surveillance	To ensure the continued safety and performance of a device after it is placed on the local market. The obligation is on the manufacturers and its local authorised representative to have an effective post market surveillance system in place

Elements Of Conformity Assessment

Element	Description	Benefits
3	Summary Technical Documentation	Provides summarised technical data

Elements Of Conformity Assessment

Element	Description	Benefits
4	A Declaration of Conformity	Provides a legal basis and assurance when the manufacturer, or its local authorised representative, makes a declaration (for eg. that a device product is tested to an international standard) that it meets the local regulatory requirements.

Elements Of Conformity Assessment

Elemt	Description	Benefits
5	The registration of manufacturers and their Medical Devices by the regulatory authority	In essence, to allow regulatory authorities to know “who” is selling “what” in their local markets. This is especially important for effective enforcement of local medical device regulations.

Risk Management

- What is your risk management framework?
- What are the obligations of the manufacturers, importers, distributors, 3rd party certification bodies, 3rd party conformity assessment bodies, 3rd party logistics companies, clinical trial organisations?

Local Requirements

- Understanding local and international obligations (e.g. WTO obligations)
- Local trading models and scenarios
- Understanding local requirements (risk appetite)
- Adaptation to local requirements
- Industry feedback
- Avoiding past mistakes of others through sharing

Conclusion

- SG1 guidances
- Are they the cure-all / universal remedy?
- Legal status of guidances
- Risk management framework
- Local requirements

- **Many questions seeking answers**
- **They must be answered before effective and practical**

IMPLEMENTATION

Thank You

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