

# Agenda

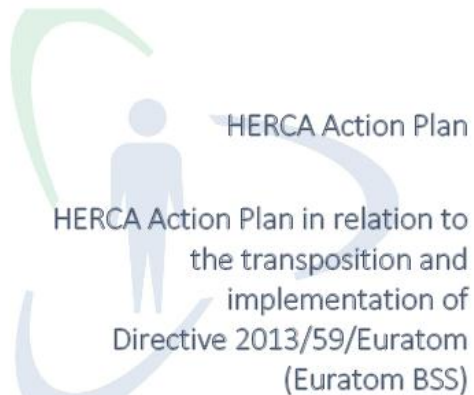


## I. Setting the Scene

- ▶ What is so Special about Medical Exposure?
- ▶ Principle of Justification in the Medical Field
- ▶ Art. 55.2 (a) EU-BSS Directive

## II. Some Infos about the Multi-Stakeholder Workshop on „Generic Justification“ → [Jean-Luc Godet](#)

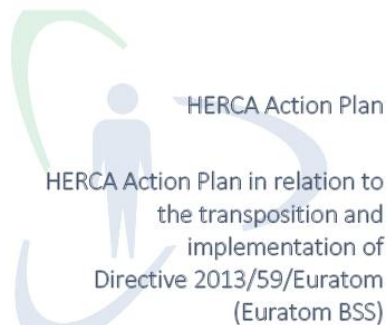
# MSW Generic Justification: Background



October 2014

- ▶ In 2014, the HERCA Board of Heads approved an **Action Plan** in support of the transposition of the new **Council Directive 2013/59/Euratom**.

# MSW Generic Justification: Background



October 2014

In relation to medical exposures, the Action Plan identified

- ▶ the **justification of new types or classes of practices** and
- ▶ the **interrelation with bio-medical research** as **key topics** where HERCA could add value to the transposition process.

Council Directive 2013/59/Euratom:

- ▶ Article 19 and 55.2 (a),
- ▶ Article 55.2 (c),
- ▶ Article 55.2 (e)

# MSW Generic Justification: Background

- ▶ To further explore the transposition process of the EU-BSS Directive on the justification of new types of practices, HERCA organised today's

**HERCA Multi-Stakeholder Workshop on  
"Generic Justification", Paris, 24-26 October 2016**

# MSW Generic Justification: Agenda



The **Agenda** of the workshop includes **three parts**:

**1. Introductory Session** → to develop a common understanding concerning the *Justification of New Types of Practices* for the MSW

- ▶ Legal Basis
- ▶ Conceptual Considerations & Regulatory Requirements
- ▶ Existing Challenges in the Member States
- ▶ Views of International Organisations

# MSW Generic Justification: Agenda

**Agenda** of the workshop includes **three parts (cont.)**:

## **2. Plenary Session 1 – 6 → to discuss various transposition approaches within Member States**

- ▶ Health Technology Assessment
- ▶ CE Marking
- ▶ “Standard Medical Practice List”
- ▶ Authorization Process
- ▶ Further Approches in MS
- ▶ New Types of Practices versus
- ▶ Biomedical Research

### **→ Stakeholder's Platform:**

- Feedback from *European Medical Associations & Manufacturers*
- Round Table Discussion

# MSW Generic Justification: Agenda

**Agenda** of the workshop includes **three parts (cont.)**:

## **3. Towards a Framework for Good Governance**

- ▶ Perspectives from Manufacturers  
→ *COCIR Position Paper*
- ▶ Perspectives from Medical Associations  
→ *ESR, EANM, ESTRO, EFRS*
- ▶ General Discussion  
→ *All participants*



- **here, HERCA expects an active role of the Stakeholders:**
  - to raise concerns
  - to support / to criticise approaches
- **all this will have an important input on the outcome of the *MSW on Generic Justification***

# MSW Generic Justification: Objectives



The **objectives** of the workshop are:

- ▶ to **explore a common understanding** of the **new requirements**;
- ▶ to **exchange information on national approaches** relating to the transposition and implementation of these new requirements;
- ▶ to **collect the opinion** of **important European stakeholders**, particularly the European medical societies and manufacturers;
- ▶ to **assist in the development** of a **HERCA Position Paper** intended to facilitate the transposition and implementation of the Council Directive 2013/59/Euratom.



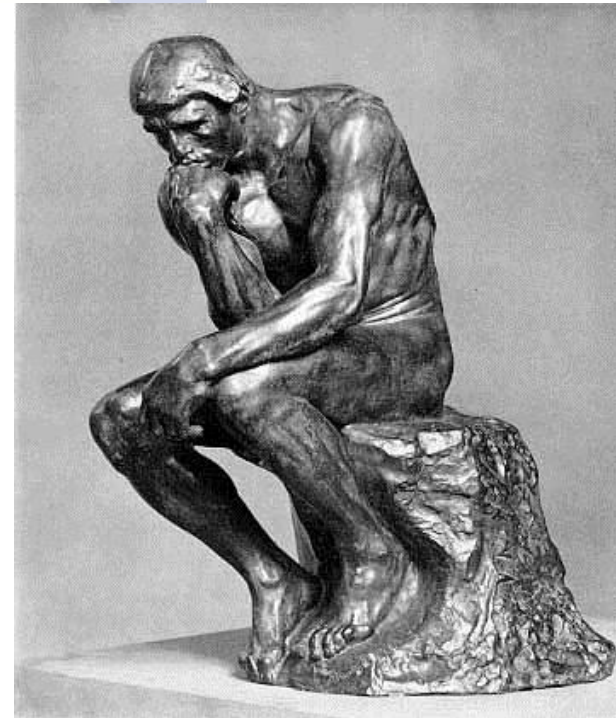
# MSW Generic Justification: Objectives

Transposition and Implementation  
of  
Council Directive 2013/59/Euratom  
laying down Basic Safety Standards for Protection  
against the Dangers arising from Exposure to Ionising Radiation:

**Justification of Types or Classes of Practices  
Resulting in Medical Exposures**

**– Discussion Paper –**

*HERCA-Working Group „Medical Applications“*



In view of **today's workshop** and as a first step towards the **HERCA Position Paper**,

- ▶ the *HERCA-Working Group „Medical Applications“* (WGMA) prepared a **discussion paper**.

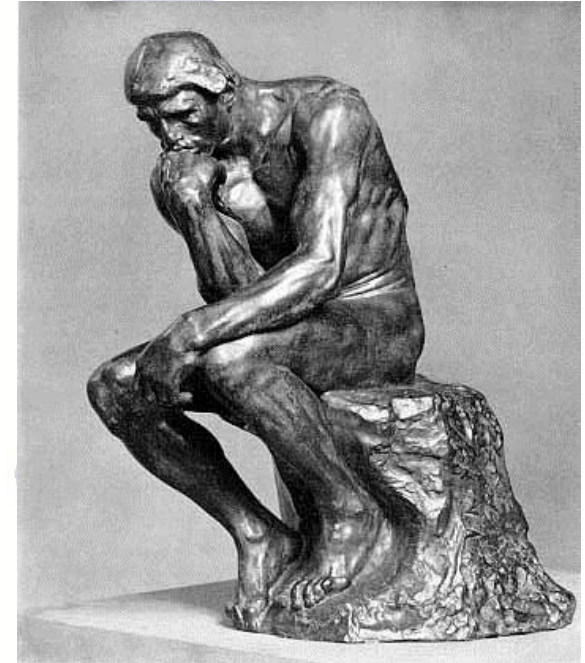
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**– Discussion Paper –**

*HERCA-Working Group „Medical Applications“*



The **aim** of the discussion paper is:

- ▶ **to set the scene** - following the discussions within the WGMA,
- ▶ **to serve as starting point** for the discussions at the MSW  
→ **“Questions / Issues to be discussed”** with respect to the  
**Plenary and Introductory Sessions**
- ▶ **to initiate** the development of the **HERCA Position Paper** – after today’s workshop.

# Thank You for Your Attention!



[www.herca.org](http://www.herca.org) | [secretariat@herca.org](mailto:secretariat@herca.org)