

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

**Plenary Session 6:
Justification of New Types of Practices
versus Biomedical Research**

Introduction

Jürgen Griebel

Art 55.2 (a) EU-BSS Directive:

**new types of practices
involving
medical exposure**

**are justified
in advance
before**

**being generally
adopted**

principle of justification

benefit versus risk analysis

**Art. 55.2 (e) EU-BSS Directive:
bio-medical research**

**What level
of evidence
is needed for
the benefit
versus
risk analysis?**

**model, which may be helpful for a first common understanding, but
which needs to be refined during the workshop**

Re-Formulation of the Problem: What is the Way to Healthcare for a New Type of Practice?

New Type of
Practice



Biomedical /
Clinical Research

shortcuts



conservative way



Healthcare Scenario

Circle of Action: EU-BSS Directive

Art. 55.2 (a):

new types of practices are **justified in advance** before being **generally adopted**



Art. 55.2 (e):

medical exposure for **medical or biomedical research** are examined by an **ethics committee**, set up in accordance with **national procedures**, and/or by the **competent authority**

complicates conservative way



Art. 55.2 (b): Healthcare Scenario

all individual medical exposures are **justified in advance** taking into account the **specific objectives of the exposure** and the **characteristics of the individual involved**



ICRP Level 2

ICRP Level 3

Questions to be discussed: Art. 55.2 (a + e)

- When a new type of practice is not – yet – justified in general according to Art. 55.2 (a), is it then to be handled under the provisions of bio-medical research according to Art. 55.2 (e)?
- How to progress from the status of research according to Art. 55.2 (e) to the status of a generally accepted new type of practice according to Art. 55.2 (a)?

**New Type of
Practice**



**Biomedical
Research**



Healthcare Scenario

Another Provision: EU-BSS Directive

Art 55.2 (c):

If a **type of practice** involving medical exposure is **not justified in general**, a **specific individual exposure** of this type **can be justified**, where appropriate, in **special circumstances**, to be evaluated on a **case-by-case basis** and **documented**.

- The scope of Art. 55.2 (c) is limited to *special circumstances* that have *to be evaluated on a case-by-case basis and documented*.
- The term “*special circumstances*” seems to be closely related to the terms “*off-label use of drugs*” or “*compassionate use of drugs*”.
- Both cases refer to situations where a drug is provided to a patient – on humanitarian grounds – prior to a drug's receiving regulatory approval for a clinical indication.
 - The first case refers to an already established drug used for a new clinical indication.
 - The second case refers to a newly developed drug.

Questions to be discussed: Art 55.2 (c)

- How broad is the scope of application of Art. 55.2 (c)?
- How to regulate the interrelation of Art. 55.2 (c) with
 - Art 55.2 (a) addressing new types of practices and
 - Art 55.2 (e) addressing bio-medical research?



Questions to be discussed: Art 55.2 (c)

- Does Art. 55.2 (c) establish a further way to the healthcare scenario, i.e. to the individual application of medical exposures, which is not a shortcut, but a way consistent with the EU-BSS Directive?

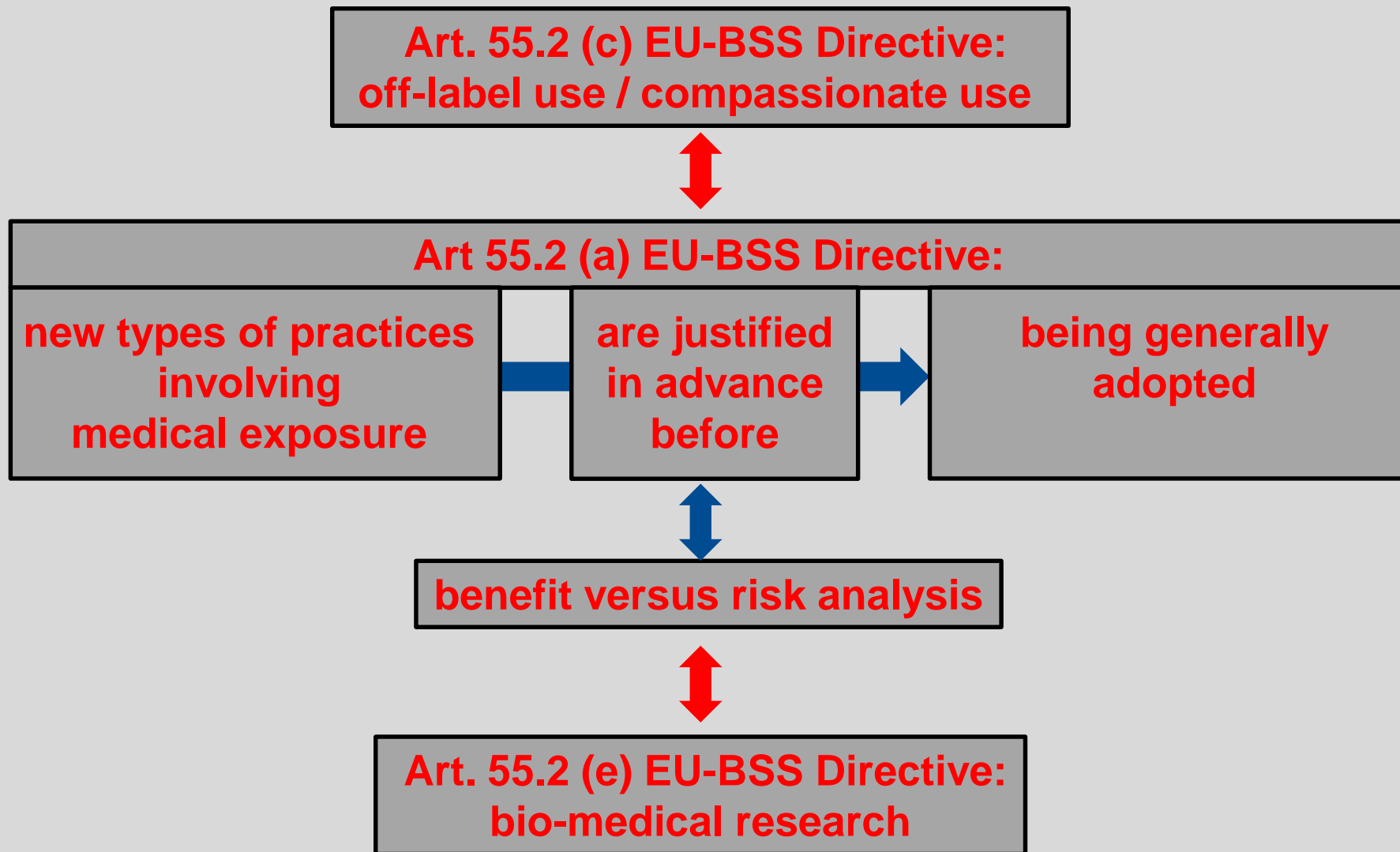


Off-Label / Compassionate Use

Healthcare Scenario

individual application of medical exposures

The Way to the Healthcare Scenario



Thank You for Your Attention!



Hheads of the European Radiological
protection Competent Authorities

www.herca.org | secretariat@herca.org

**Art. 55.1 EU-BSS Directive, 2014
- Principle of Justification -**

Medical exposures shall show a sufficient net benefit



Benefit versus Risk Analysis



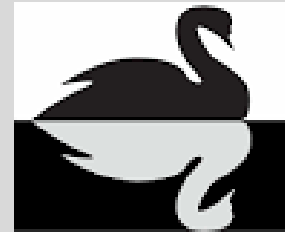
**What level of evidence is needed for
the benefit versus risk analysis?**

The Way to the Healthcare Scenario

Black Swan Metaphor:

- The metaphor is based on an ancient saying which presumed black swans did not exist.
- But the saying was rewritten after black swans were discovered in the wild.

Wikipedia, the free encyclopedia



The Way to the Healthcare Scenario

Black Swan Metaphor - extended:

Rumsfeld distinguished 3 epistemic cases:

- there are **known knowns** \Leftrightarrow
we know there are things we know
- there are **known unknowns** \Leftrightarrow
we know there are things we don't know
- there are **unknown unknowns** \Leftrightarrow
we don't know there are things we don't know

But there is a 4th epistemic case:

- there are **unknown knowns** \Leftrightarrow
we don't know there are things we know



US Secretary of Defense Donald Rumsfeld at a briefing on February 12, 2002 about the lack of evidence linking the government of Iraq with the supply of weapons of mass destruction to terrorist groups.

Prof. Michael Flentje: 2016 Annual Meeting of the German Radiation Protection Commission