COCIR

SUSTAINABLE COMPETENCE IN ADVANCING **HEALTHCARE**

European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry

THE PRECAUTIONARY PRINCIPLE

APPLIED TO MEDICAL IMAGING DEVICES

COCIR 6th ANNUAL FORUM

ON THE SELF-REGULATORY INITIATIVE FOR MEDICAL IMAGING DEVICES

PRECAUTIONARY PRINCIPLE

- The **precautionary principle** (or **precautionary approach**) to risk management states that if an action or policy has a suspected risk of causing harm to the public, or to the environment, in the absence of scientific consensus (that the action or policy is not harmful), the burden of proof that it is *not* harmful falls on those taking that action.
- The principle is used by policy makers to justify discretionary decisions in situations where there is the possibility of harm from making a certain decision (e.g. taking a particular course of action) when extensive scientific knowledge on the matter is lacking.
- The principle implies that there is a social responsibility to protect the public from exposure to harm, when scientific investigation has found a plausible risk. These protections can be relaxed only if further scientific findings emerge that provide sound evidence that no harm will result.
- The 1998 Wingspread Statement on the Precautionary Principle summarises the principle this way: "**When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically**."[I]

WHAT MEDICAL DEVICES ARE GOOD FOR

- MID are very special kinds of products, as their demand it not driven by design, fashion, habits, individual wishes, needs, desires or by convenience properties. In fact, it is determined by their ability to provide highly relevant information for the improvement of human health.
- All of its applicants and buyers come from the medical sector, who is committed to the promotion of human health as the highest value, it has to care about.
- At least within this commitment, medical personnel is obliged to undertake everything which is in its power to contribute to the best possible status of health for the patient, with economic affordability of MIP forming the lower ranking financial constraint.
- They should not be regarded so much in their contribution to economic wealth (of an individual [job], an enterprise [ROI], a region or a nation [GNP]), but in their contribution to individual and societal health.

RoHS OBJECTIVES

- Article 1 of RoHS states: “The purpose of this Directive is to approximate the laws of the Member States on the restrictions of the use of hazardous substances in electrical and electronic equipment and **to contribute to the protection of human health** and the environmentally sound recovery and disposal of waste electrical and electronic equipment.”
- We wonder whether the application of RoHS on MID can be regarded as an appropriate instrument to protect human life from health risks, or whether its application on MID “protects” human life from the exploitation of highly promising development paths, which already lead to substantial improvements regarding the prevention of serious diseases and the prolongation of human life expectancy.

IS THERE A CONFLICT? WE BELIEVE ,YES

- RoHS tries to protect health by banning hazardous substances in MDs which have minimal or no impact on human health
- RoHS reduces the ability of companies to provide better MDs, designed to improve health and life quality
- Therefore, RoHS has a negative impact on health and quality of life by delaying innovation or preventing new technologies from being discovered

PRECAUTIONARY PRINCIPLE

- Given the known limited benefits of RoHS (2,3% substitution result) for health and environment (no benefits for patients)
- Given the possible (highly likely) negative impacts of RoHS on health (delaying/negating innovation)
- Given the precautionary principle: *When an activity raises threats of harm to human health or the environment, precautionary measures should be taken even if some cause and effect relationships are not fully established scientifically*

Wouldn’t limiting the impact of RoHS on MDs be an action aligned with the precautionary principle?

STUDYING THE CONFLICT

- WE believe the conflict between RoHS objective to preserve health and the negative indirect impacts on health should be carefully assessed by the EC in the future.
- **Methodological Recommendations**
- To assess the socio-economic consequences of RoHS to MID development, a special emphasis can be placed on the gains in quality of life that could be achieved by the availability of medical imaging products and their further development within the last 20-30 years – this can be best expressed by using **QALY**.
- Nevertheless, calculations can also be based on the years of life lost (YLL) plus the years lived with disabilities (YLD) which the individuals of our society would have had to stand and endure, if RoHS had been fully applied to MIP within this period of time. In this case **DALY** should be the indicator of choice.
- It's impossible to predict what future successes might get achieved within the next 5 or 10 years by unrestricted research, development and production of MID, but we it is possible to look back on what could be achieved already by specific product generations of MID and relate our calculations to a hypothetical situation on what would have happened if Cd dependent progress in medical imaging resolution could not have been realized due to usability restrictions from RoHS, or if highly successful next product generations entered market much later.

EXAMPLES: DUCT CARCINOMA IN SITU (DCIS)

- DCIS accounts to about 25-30% of all newly detected breast cancers. 30-50% of DCIS sooner or later start to mutate to an invasive ductal carcinoma (IDC), which is the most common cause of cancer death in Europe for females, accounting to more than 131,000 deaths in 2012
- (90%) could be identified by MRI, whereas even a combination of mammography and ultrasound did not detect more than 50%
- **A delay in the introduction of high resolution MRI systems could have prevented hundreds of women to be correctly diagnosed DCIS.**

Number of new cases of invasive breast cancer expected to be detected in 2016 in US	246,660	cases/year
Number of new cases of non-invasive breast cancer expected to be detected in 2016	61,000	cases/year
Multiplication by the rate of DCIS among non-invasive forms of breast cancer (83%)	50,630	cases/year
Number of women which are expected to die from breast cancer in 2016	40,450	cases/year
Calculated percentage of DCIS of all cases	19.83%	
Calculated mortality rate of breast cancer	16.40%	
Inclusion of the information that 80% of all breast cancers are of IDC type	197,328	cases/year
Inclusion of the information that a "conservative rate" of 30% of DCIS will sooner or later mutate to IDC	15,189	cases/year
Amount of women dying from DCIS based IDC per year	2,491	cases/year
Probability of detection of DCIS by MRI (90%)	2242	cases/year
Maximum probability of detection of DCIS by other detection methods (50%)	1245	cases/year
NUMBER of saved lives from DCIS based cancer by MRI only	**996**	cases/year

EXAMPLE: DOSE REDUCTION

- Every year in US 25 million patients receive a CT scan.
- The dose range between 10mSv and 20mSv.
- Iterative image reconstruction engines (IR), introduced firstly between 2008 and 2010, allows the reduction of dose by 30% to 80%.
- 2 years of delay in the introduction of IR would have meant that 50 million patients in the US only would have received from 3 to 5 times more dose.
- Between 24000 and 1.5 million patients can be spared the possible negative consequences of being exposed to unnecessary levels of radiation.