

## Plenary Session 4

Shall the regulator link the justification of new types of practices to the authorisation process?

Co-chairs

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MSM Generic Justification  
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# Questions and issues to be discussed according to the discussion paper

- How to ensure – by this approach – an adequate execution of Art. 55.2 (a) in a MS with the respect to the claim that new practices involving medical exposure are justified in advance before being generally adopted?
- How to ensure – by this approach – a harmonised execution of Art. 55.2 (a) in a MS