Provisional/conditional approval vs full approval

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ESC
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Approval

- **Regular**
- **Conditional**
  - Risk Benefit ratio
  - Clinical urgency
  - Rare disease

  Conditions to be met Benefit risk ratio +ve

  Fulfils unmet clinical need

  Comprehensive data post authorisation

Conditional approval for Devices

- DOES NOT exist in Europe
- The closest is “Approval with Restrictions”
- A survey undertaken that this is seldom used

In the context of medical devices

Why?

Innovative Devices for Unmet needs

Early access to market

Patient perspective

- **Efficiency**
  - **Time lag to patient access**
  - **Benefit/risk ratio**
- **Innovation**
  - **Just in time testing “right test at the right time”**
- **Governance**
  - **EUDAMED**
  - **Total Life Cycle assessment (post-market surveillance)**

Breakthrough pathway

Priority review

Well defined timelines

“a reaction to delays in approval (historic)”

Concerns

Relatively early in process to note the long term implications

No clear guide on reimbursement