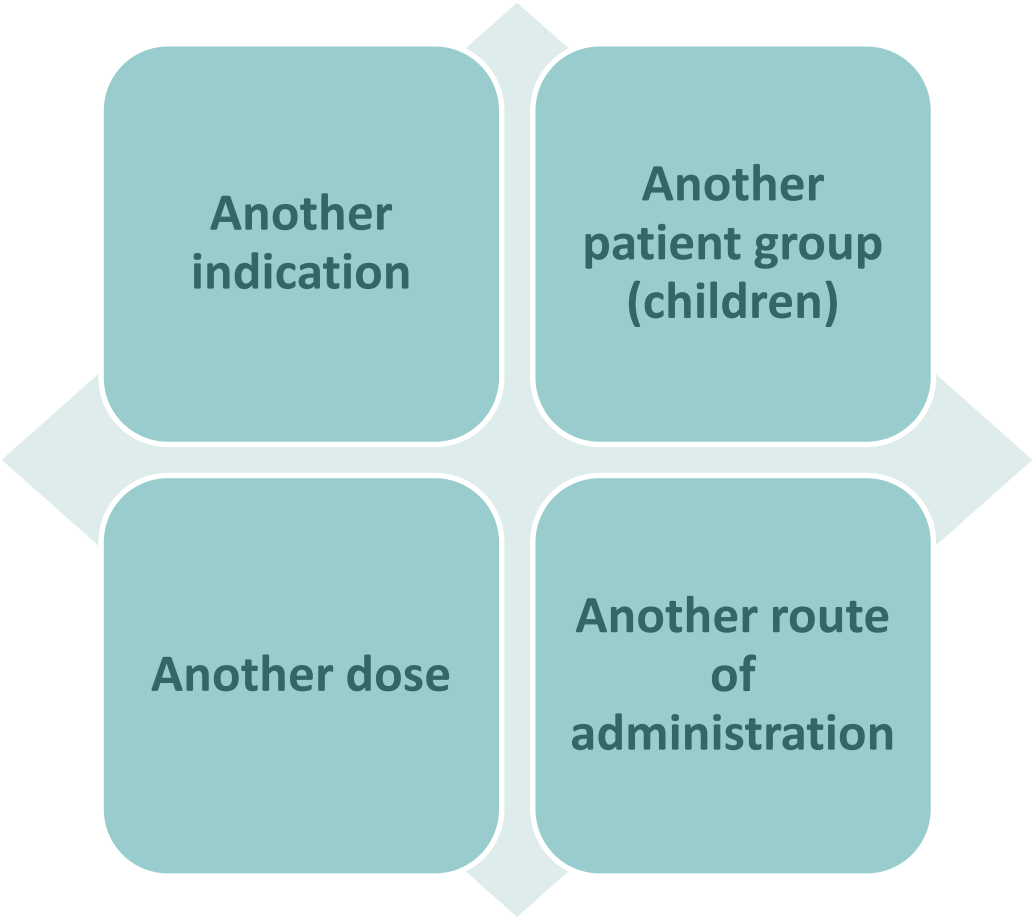
Good Off-Label Use Practices (GOLUP)

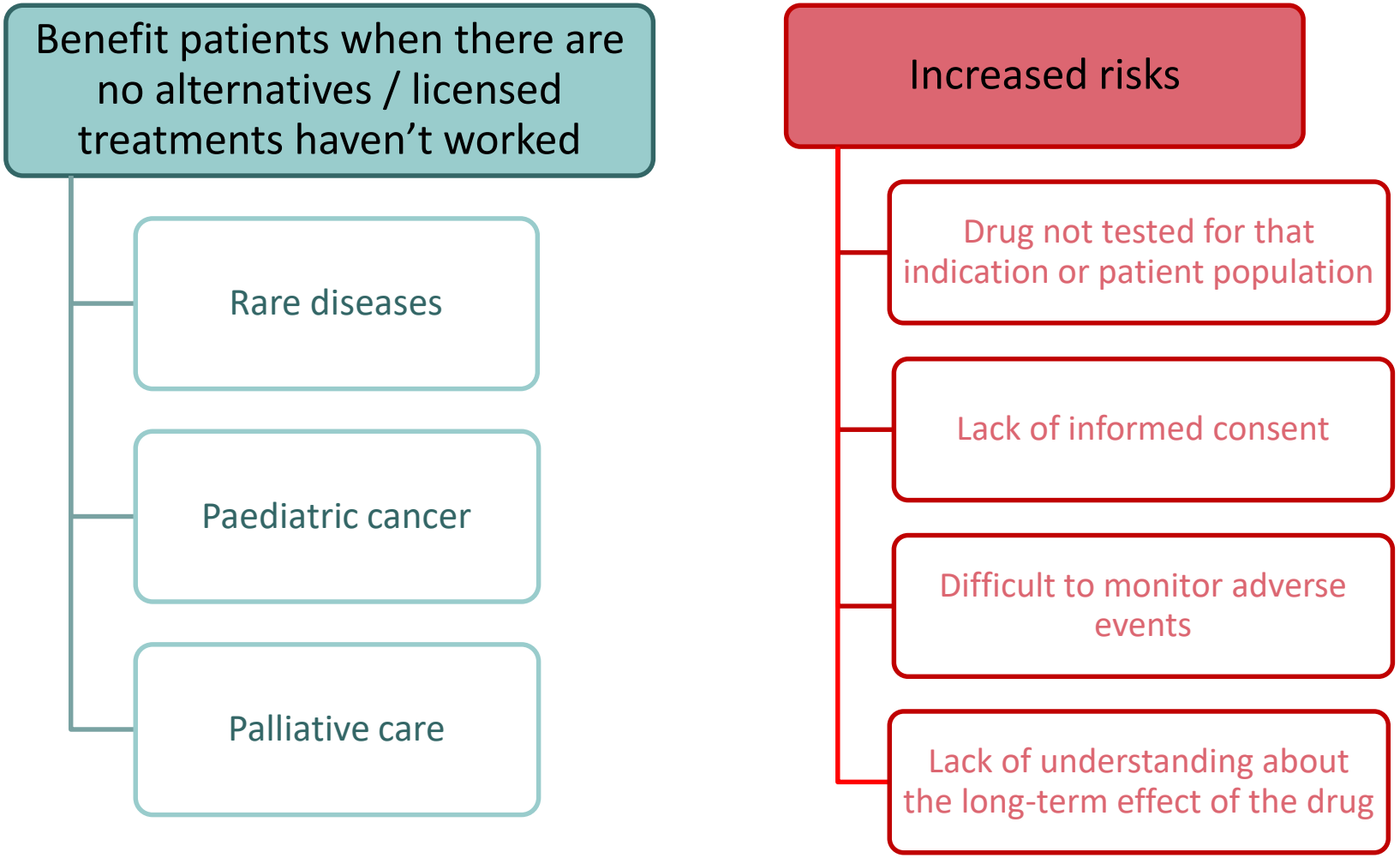
Product labelling

- A label (or Summary of Product Characteristics) explains how, by whom and when the medicine should be taken
- **How?** Based on extensive testing on quality, efficacy and safety
- **Objective**: ensuring effective benefit-risk balance and maintaining the highest levels of patient safety while minimising adverse events

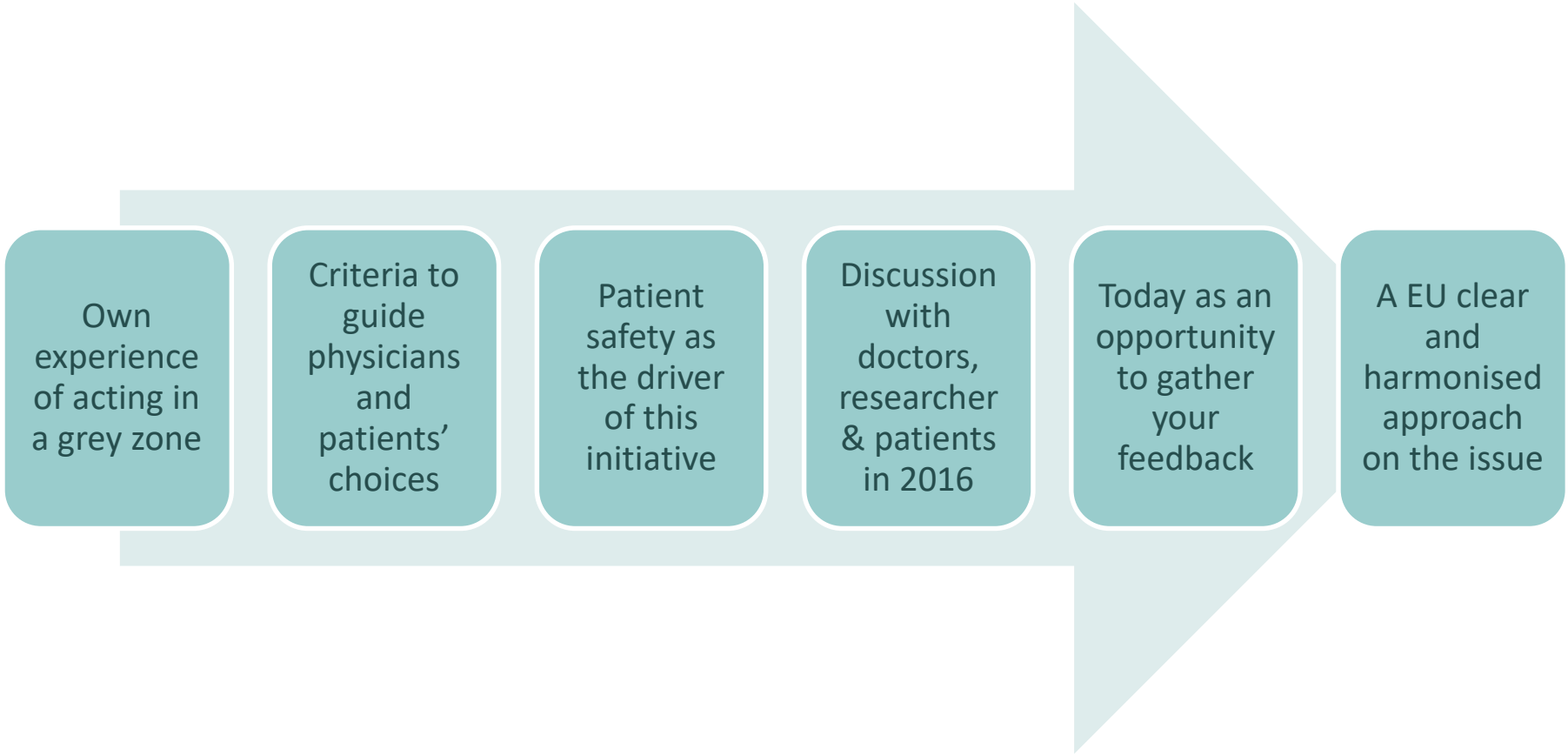
What is off-label use (OLU)?



Benefit and risks of OLU



Introduction to the GOLUP



Launching the GOLUP

- The GOLUP Declaration was officially launched in September 2016 in the European Parliament
- Following the event, the criteria were reworked to take into account some of the concerns expressed by stakeholders, in particular the paediatric community that considered some criteria too restrictive
- The new, improved declaration allows for more flexibility for doctors and patients without compromising on the key principle of ensuring patient safety

The GOLUP Declaration

1. **Presence of a medical therapeutic need based on a current examination of the patient by a suitably qualified health care professional;**

2. **Absence of authorised treatment and licensed alternatives tolerated by the patient or repeated treatment failure;**

3. **A documented review and critical appraisal of available scientific evidence favours off-label use to respond to the unmet medical need of the individual patient;**

4. **Patients (or their legal representative) must be given sufficient information about the medicines that are prescribed to allow them to make an informed decision;**

5. **Presence of established reporting routes for outcomes and adverse events linked to off-label use.**

Roundtable

Ensuring the safe prescription of medicines off-label in Europe:

What role for the European Union?

European Brain Council
Rue d'Egmont 11, Brussels