



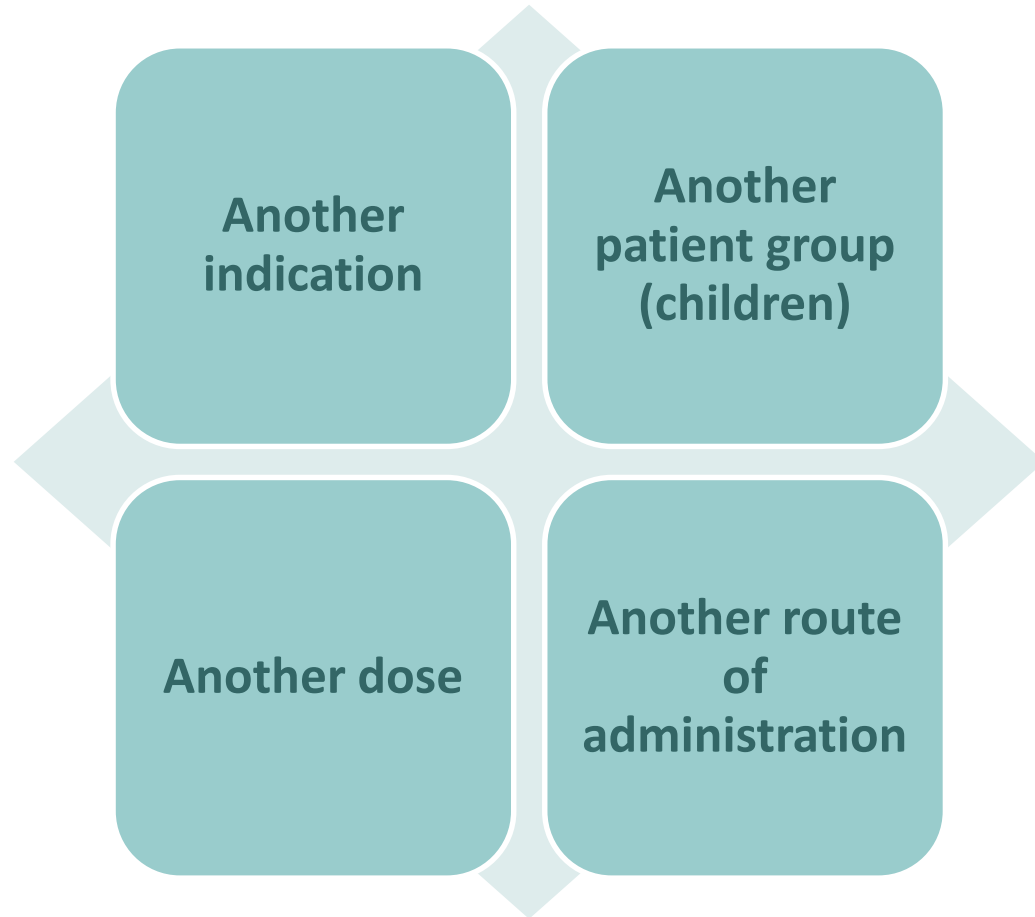
Good Off-Label Use Practices (GOLUP)



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

Benefit patients when there are no alternatives / licensed treatments haven't worked

Rare diseases

Paediatric cancer

Palliative care

Increased risks

Drug not tested for that indication or patient population

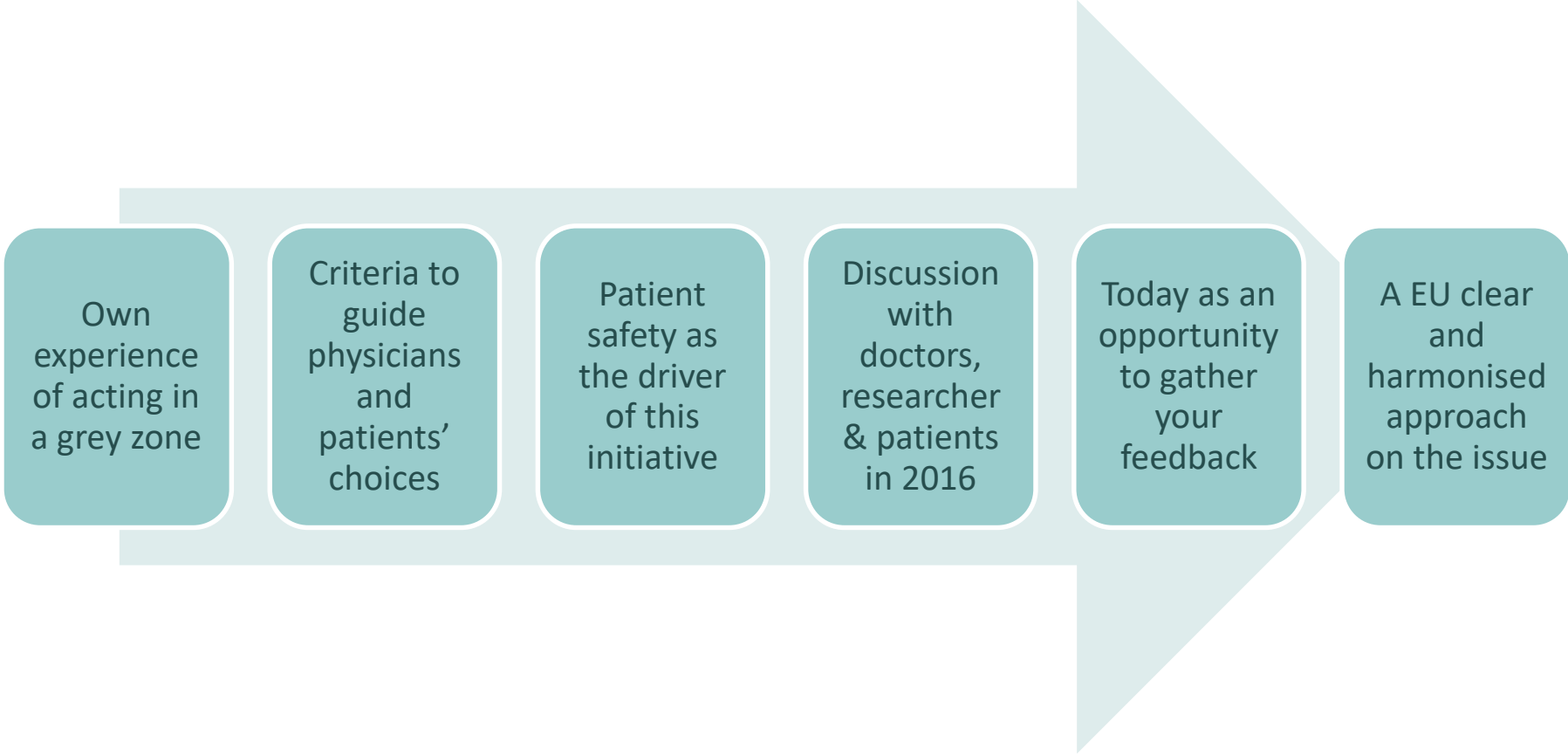
Lack of informed consent

Difficult to monitor adverse events

Lack of understanding about the long-term effect of the drug



Introduction to the GOLUP



Own
experience
of acting in
a grey zone

Criteria to
guide
physicians
and
patients'
choices

Patient
safety as
the driver
of this
initiative

Discussion
with
doctors,
researcher
& patients
in 2016

Today as an
opportunity
to gather
your
feedback

A EU clear
and
harmonised
approach
on the issue



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



ROUNDTABLE DISCUSSION:
Monday, 10th July 2017
11:00 am – 13:00 pm

Ensuring the safe prescription of medicines off-label in Europe: *What role for the European Union?*

European Brain Council
Rue d'Egmont 11, Brussels