Questionnaire for interviews with stakeholders

Introduction:
NIVEL (Netherlands institute for health services research), RIVM (National Institute for Public Health and the Environment) and EPHA (European Public Health Alliance) are conducting a study for the European Commission on off-label use of medicinal products in the European Union. The general objective of this study is to provide the EC with a clear overview of existing and foreseen practices of off-label use across Member States and a factual analysis of all parties' positions towards the existing measures and possible future tools to regulate off-label medicine use. Hereto we are conducting an extensive literature study and complement this by interviewing relevant stakeholders. In this interview we will be asking you about existing and foreseen policy measures or tools, the extent of off-label use as well as drivers of off-label use and your view on the pros and cons of off-label use.

We use a structured questionnaire for this interview and will follow this closely. You will be given room at the end of the interview to add information on topics that you missed during the interview. With your permission we would like to record the interview. This recording will only be used for the purpose of this project and will be destroyed afterwards.

Section 1: Background information

We would like to start by asking you some background information. What is your:

Organization	
Department	
Position in the organization	
Educational and professional background	
Relation/expertise to the subject of off-label use	

Section 2: Off-label use: existing measures and policy tools

1. Can you describe and provide us with the existing measures or policy tools to handle off-label use at European level? Are these measures and tools implemented or only available on paper?

2. What is your opinion on these existing measures or tools with regard to sufficiency and suitability? (i.e. how adequate and appropriate are they in regulating off-label use?)

3. Are you aware of any new measures or policy tools to address off-label use that are currently being developed/considered at European level? If yes, can you describe (and if possible provide) these new measures or tools?

4. Are off-label safety and/or efficacy monitored on a European level? Are there any European databases to monitor this? Are adverse drug reactions linked to off-label use (i.e. is it known when an adverse drug reaction is the result of off-label use)?

Section 3: Extent and practices of off-label use

We would now like to ask you some questions about the extent and practices of off-label use.

5. Are there any figures available on the extent of off-label use at European level? Where can we find these figures / can you provide us with these figures?

6. Are you familiar with studies on off-label prescribing at European level? If yes, can you provide us with these studies, or tell us where we can find these studies?

7. How do you perceive the extent and practice of off-label use, with regard to:
   a) Children

   b) Orphan diseases

   c) Elderly

   d) Pregnant women

   e) Therapeutic areas (e.g. oncology, psychiatry)

8. Are there any other particular areas or specific patient groups in which off-label use occurs, besides the before mentioned areas?

9. In your opinion, what areas need special attention in existing regulation? And why?

Section 4: Drivers of off-label use

10. What are the major drivers for off-label use? Can you motivate your answer?
    a) regarding the healthcare system

    Motivation for each mentioned driver:

    b) regarding professional drivers

    Motivation for each mentioned driver:

    c) regarding patient drivers

    Motivation for each mentioned driver:

Section 5: Off-label use: pros and cons

We are interested in your opinion on the advantages and disadvantages of off-label use. Similar to the previous questions, we distinguish three levels: healthcare system, professional and patient level.

11. What are advantages of off-label use? Can you motivate your answers?
    a) at the healthcare system level

    Motivation for each mentioned advantage:

    b) at the professional level

    Motivation for each mentioned advantage:

    c) at the patient level

    Motivation for each mentioned advantage:

12. What are disadvantages of off-label use? Can you motivate your answers?
    a) at the healthcare system level

    Motivation for each mentioned disadvantage:

    b) at the professional level

    Motivation for each mentioned disadvantage:

c) at the patient level

Motivation for each mentioned disadvantage:

Section 6: Policy tools and/or measures - what is needed

13. In your opinion, what is needed with regard to policy measures or tools, to further address the issue of off-label use at a national level?

14. In your opinion, what is needed with regard to policy measures or tools, to further address the issue of off-label use at European level?

Section 7: Court cases

15. Do you know of any court cases on off-label prescribing at European level? If yes, can you provide us with an analysis of the court cases, or tell us where to find this information? (e.g. website/experts)

Finally, do you have any additional information that you would like to share with us that has not come up during the interview?