Questionnaire for PDPs to assess their capacity and activities relating to Pharmacovigilance

1. Interviewee Information

Name of the PDP
Date
Names of the person / people interviewed
Department
Email
Phone No.
Mobile No.

1) **Products**
   a) Which products does your PDP deal with? [please send this information to us before the interview date]
   b) At what phase of development are your products? [please send this information to us before the interview date]
   c) Have you submitted marketing authorization documents for any of your products?
      i) If yes, to which NRAs?
      ii) When do you expect these products to obtain marketing authorization?
      iii) After submission of dossier, have you received any feedback related to PV from any of the NRAs?
   d) In which countries are your products registered?

2) **PDP's prior experience with National Regulatory Authority(NRAs)**
   a) In which countries are you planning to market your products?
   b) Which NRAs have you interacted with in relation to clinical trials and conducting of PV?
   c) In your opinion, do you have a sense of the technical capacity of the NRAs of these countries in relation to their PV department/activities?
   d) What actions, if any, have you taken in the case of NRAs lacking technical capacity for PV?
   e) What are the PV requirements of the concerned NRA's?
   f) Have you been asked to conduct PV activities by the NRA?

3) Overall Pharmacovigilance Strategies

a) Is PV considered to be an important area for your PDP ? [have you invested time, people in it? Have you conducted any of these activities? Haven't thought about it? Etc]

b) Which PV/Risk management strategies are you/your development partners planning to undertake—for which products—at what stage of development--in which countries?

i) Spontaneous reporting
ii) Cohort event monitoring
iii) Phase IV
iv) Demonstration studies
v) other….please specify

Product	Stage of Development	Countries in which product is/is being registered	PV strategies being implemented/explored
Product 1			
Product 2			
Etc			

c) According to you, what are the challenges in implementing these strategies?

4) Pharmacovigilance Process in the PDP

a) Reporting

i) What is your PDP philosophy of reporting ADRs/AE? Is reporting mandatory?
ii) To whom will they be reported?
iii) Under what kind of regulatory legislative mandate?
(1) What method is used for reporting
(a) Manual/Computerized / Mixed

b) Assessment

i) How will reports be analyzed and by whom?
ii) What methods or scales are used to establish causality?
iii) What methods are used for signal detection and strengthening?
iv) Do you have an efficient risk management plan for your products?

c) Communications:

i) Which strategies are in place for PV communications?
(1) With NRAs/ Health Professionals / etc.

5) PV Resources at the PDP

a) **Human resource**

i) Who are the professionals responsible for PV at the PDP?
ii) How many staff are allocated to this function (FTE?)
   (1) In house (%) / outsourced / partner org/ etc.
   (2) What is their technical knowledge or experience in the field of PV
   (3) Specify their roles and activities

b) Technology

i) What technology/software system do you have in place for PV activities?

c) Finances

i) What is the budget for PV activities by PDP / collaborating organizations (current and next fiscal year):
   (1) Overall for PV
   (2) Segment by product
ii) Who is funding the PV activities of your products?
iii) Which organizations would be interested in funding PV activities for your products ?

6) **Technical support for PV**

a) Does your PDP collaborate with any technical organization?
   i) If Yes- with whom and for what?
   ii) If not- are you interested in working with a technical organization?
      (1) Which technical organization would you like to work with?
      (2) What type of support are you looking for?

b) What are your prior experiences and future plans for capacity building;
   i) For the PDP staff?
   ii) For national regulatory staff?
   iii) For manufacturing staff and/or clinical investigators?

7) **Key challenges and gaps**

a) What are the major gaps you see in implementing PV strategies for your product(s)?
b) In conclusion…according to you what are the key challenges for your organization to develop an effective PV strategy for your products?
c) Assuming you have access to necessary technical, financial and human resources, what would you consider to be your priority needs?