External Stakeholder Engagement Plan

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1. Introduction

IPRP is an international platform for its regulatory members and observers with the objectives of
- Identifying and addressing emerging issues of shared interest and discussing approaches;
- Establishing a collaborative environment to share regulatory perspectives on ICH work, discuss challenges and promote consistent implementation of ICH guidelines;
- Promoting greater convergence in regulatory approaches based on international standards and best practices;
- Creating conditions to facilitate greater inter-agency collaboration, enhance communications and support capacity building (e.g. training).

While maintaining its focus as a forum for regulators to share best practices and experiences, IPRP is also committed to engage with its external stakeholders where needed.
The Terms of Reference (http://www.iprp.global/page/procedures) identify external engagements and communications as one of the key IPRP objectives.

This document identifies target IPRP external stakeholders, lays down the engagement objectives, specifies IPRP's principles of engagement and outlines proposed activities of outreach and involvement.

2. Target Stakeholders

The following matrix identifies a number of external stakeholder groups for IPRP and categorizes them according to their interest and power/influence.

IPRP engages with its external stakeholders on the level of organizations/associations, not on the individual level.

	Low Interest	High Interest
High Power	***'Consider needs'*** • Academic research organizations • Patient organisations • Public health NGOs	***'Key players'*** • ICH Industry Members and Observers • Other Industry Associations • ICMRA • PIC/S • Other Pharmaceutical Regulatory Authorities
Low Power	***'Minimal effort'*** • General public • Student organisations	***'Keep informed'*** • Other standards/harmonisation forums and initiatives • Conference organizers, professional societies, e.g. DIA, TOPRA, RAPS

3. Stakeholder Engagement Objectives

The IPRP provides members and observers a unique opportunity to leverage expert scientific knowledge, regulatory and operational experience, on-going technical harmonization activities, and information exchange from a broad range of regulatory bodies.

To raise awareness of its activities and work products, engagement with external stakeholders and an open, transparent communication is of particular importance to the IPRP Management Committee.

By engaging with its stakeholders, the following overall objectives should be reached:

1. Raising awareness and providing information on what IPRP is and what its objectives are;
2. Ensuring input from external stakeholders is received on IPRP work products during development, if needed.

4. Level of Engagement

Interaction with external stakeholders can occur on different levels and to a varying degree of profoundness:

Level of Engagement
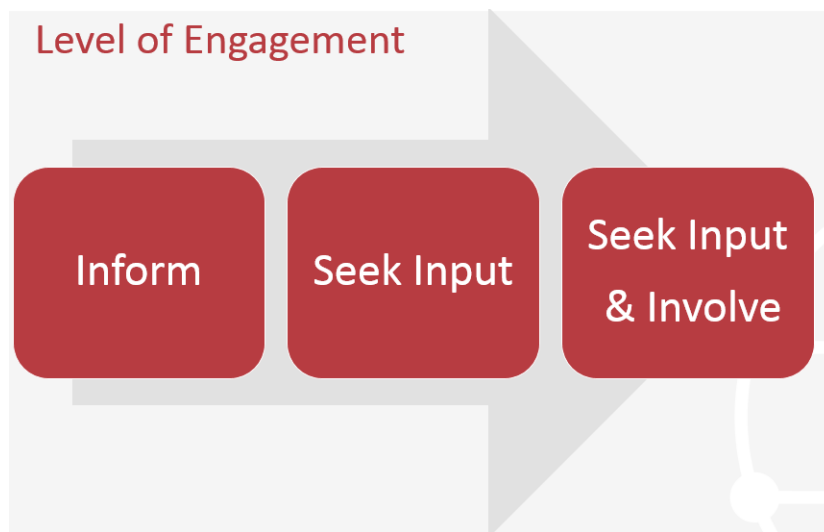
1. **Inform** – about IPRP MC meetings and work products, about what IPRP is and what its objectives are

2. **Seek input** - on IPRP draft work products

3. **Seek input & involve** - direct interactions, e.g. stakeholder event

At this stage, IPRP focuses its engagement with external stakeholders on the first and second level.

5. Guiding Principles

The IPRP MC is committed to an open, proactive and meaningful dialogue with its external stakeholders.

It is acknowledged that the level of interaction may vary; however, irrespective of the level of engagement, the following guiding principles shall apply:

- **Transparency**
Communication and dialogue with external stakeholders should be open and transparent (when and as appropriate according to the topics being discussed).

- **Independence and integrity**
IPRP engages collaboratively with its external stakeholders. Yet, it retains its ability to assess advice independent of influence and expectations.

- **Accountability**
For all its external engagements, IPRP needs to assign accountability appropriately.

- **Appropriate interaction**
Identifying the right level of interaction which is adapted to each external stakeholder group is essential to enable adequate, timely and pro-active communication with all relevant stakeholders.

- **Respect and trust**

IPRP's external stakeholder engagement activities are based on mutual respect for each other's interests and views thereby enabling the building of confidence and establishing of trust.

6. Stakeholder Engagement Activities

The overview table below provides information on how the objectives will be addressed and what kind of activity is proposed.

#	How	Activity
Raising awareness and providing information on what IPRP is and what its objectives are		
1	Provide up-to-date information on what IPRP is and what its activities are	• Keep IPRP website up-to-date, especially with regard to IPRP work products • Issue Press Release shortly after each IPRP Management Committee Meeting • Present IPRP at international/regional conferences
2	Establish and maintain a Communication Activities Register	• Establish and maintain a list of potential activities for IPRP members to undertake to promote IPRP and its work products, e.g. presentations about IPRP at external conferences, symposia etc., social media
Ensuring input from external stakeholders is received – where appropriate - on IPRP work products during development		
3	Seek public input on draft IPRP work products (if external input is needed according to Working Group recommendation)	• Publish draft IPRP work products on website to gain stakeholder input/feedback
4	Consider organising dedicated stakeholder event after a Working Group meeting where deemed of value by the group	• Present and discuss activities of IPRP working groups to/with external stakeholders with special focus on (draft) work products

7. Resources and Responsibilities

The below table specifies the lead for each activity and defines additional resources and support needed.
The activities are rated according to their priority: 1 High, 2 Middle, 3 Low.

Activity	Lead	Resources and support needed	Priority
Raising awareness and providing information on what IPRP is and what its objectives are			
Keep IPRP website up-to-date, especially with regard to IPRP work products	IPRP Secretariat	▪ IPRP WG Chair to closely liaise with IPRP Secretariat	1
Issue Press Release after each IPRP Management Committee Meeting	IPRP Secretariat	▪ Chair and Vice Chair of IPRP MC with the support of the IPRP Secretariat	1
Establish and maintain a Communication Activities Register	IPRP Secretariat	▪ Input from all Members needed	2
Present IPRP at international/regional/local conferences	All Members	▪ Commitment and support from all members needed	2
Ensuring input from external stakeholders is received – where appropriate - on IPRP work products during development			
Publish draft IPRP work products on website to gain stakeholder input/feedback	IPRP Secretariat	▪ IPRP Secretariat to closely liaise with WG Chair	1
Present and discuss activities of IPRP working groups to/with external stakeholders with special focus on (draft) work products (external stakeholder event)	IPRP WG Chair/Vice Chair	▪ IPRP WG Chair to seek prior IPRP MC approval	2

IPRP Working Groups are addressing a variety of complex regulatory topics, especially with regard to new technologies and regulatory advances. At some point or the other, it might be of value for the group to seek a broader view and exchange experience with multiple disciplines. A dedicated stakeholder event could help in gaining this insight and get involved with the respective stakeholder group(s).
In-line with the above-mentioned stakeholder engagement objectives and principles, each IPRP WG can propose a dedicated stakeholder event if deemed of value. The WG Chair/Vice-Chair shall inform the IPRP MC at least 3 months prior to the event for MC endorsement (ideally this is done with the

working group activities update at an IPRP MC meeting). All presentations should be shared with the IPRP MC prior to the event. Administration and organization is with the Working Group Chair/Vice-Chair; there is no IPRP budget allocated to the event.

In case external stakeholder groups are approaching IPRP for engagement, these inquiries shall be forwarded to the IPRP Secretariat.

8. Monitoring and Reporting

The outlined activities shall be monitored by the IPRP Secretariat and reported back to the IPRP MC at their face-to-face meetings in form of a short status report.
Two years after endorsement of this paper, an analysis shall be undertaken to assess to what extent the objectives have been achieved and where adjustments or additional measures are needed. This analysis could take the form of a survey among IPRP's stakeholder groups.