

Supplementary material 1: Interview Topic Guide – Industry

Briefing

The purpose of briefing in the interview is to inform the interviewee about:

- The interviewer's background
- The purpose of the master thesis
- The interviewee's anonymity
- Recording of the interview and that the recording will be used for data analysis
- That the interviewee can at any time choose not to answer a question

Interview questions

Theme	Question
Interviewee's background <i>The interviewee works either in regulatory affairs or pharmacovigilance</i>	Thank you for your willingness to participate today
	Can you start by telling me about your educational background?
	Can you tell me about your job, what are your main focus areas?
	Can you tell me about your experience within regulatory affairs/PV? <ul style="list-style-type: none"> - How many years have you worked with regulatory affairs/PV?
	In your own words what is the responsibility of the MAH in pharmacovigilance and regulatory affairs? In risk minimization? Is it perceived differently in the different departments in the company?
	How many DHPCs have you been involved during your time in (company)?
Preparation of DHPCs	How do you prepare DHPCs? <ul style="list-style-type: none"> - How many people are involved? - How many departments and teams are involved? - Are healthcare professionals' organizations or other societies involved in the preparation process and why?
	How are you informed that a safety concern is identified and that a DHPC should be prepared?
	Follow-up: Does the level of commitment of employees depend on the seriousness of the safety concern?
	What do you give consideration to when preparing DHPCs? (compliance to regulation vs. HCP change in behavior)
	When preparing a DHPC, which general issues do you find yourself discussing with your colleagues?
	What is the process for disseminating a DHPC in this company?
	Follow-up: Have your company ever used patient and healthcare professionals' organizations to disseminate DHPCs and what was the rationale behind this choice?

	What happens if your company fails to disseminate a DHPC?
Template and content of DHPCs	<p>What do you think about the template?</p> <p>Follow-up: Do you think the template, format and structure could be optimized and why?</p> <p>In your opinion, would you prefer if the structure was more open?</p> <p>Have you ever felt that your morality was compromised in the process of preparing a DHPC?</p> <p>Do you feel your rational considerations are compromised when following a template?</p>
Collaboration with regulator	<p>How does the collaboration between the NCA, EMA and you work?</p> <p>How would you describe the distribution of work; would you say that it is a joint effort or does the involvement in the process differ between you and the EMA/NCA?</p> <p>What arguments do you use in the collaboration in relation to the content and wording and what arguments does the EMA/NCA use?</p> <p>Follow-up: Do you put emphasis in different sections/issues on content/wording?</p> <p>Does the DHPC process affect the relationship between regulator and your company – and how?</p>
Effectiveness of DHCPs	<p>What is your general opinion about DHPCs as a risk minimization measure?</p> <p>Follow-up: Do you find DHPCs as an effective risk minimization measure?</p> <p>How does your company measure effectiveness of DHPCs?</p>
Regulation perspective	<p>The 2012 PV legislation lead to increased focus on risk communication. How would you say the DHPC process has changed?</p> <p>Follow-up: How has the increased focus on risk communication changed your behavior in relation to DHPCs?</p> <p>Can you name other changes in regulation that affects your behavior?</p>
Society perspective	How does your behavior towards DHPCs change if a safety concern has gotten media attention?
Personal morality	<p>What do you think are the challenges of the current DHPC setup in regards to public health? In regards to industry-society relations? In regards to industry-HCP relations?</p> <p>Follow-up: Do you think DHPCs are able to change the behavior of physicians in the current format?</p>

	The literature states that healthcare professionals find the MAHs an unreliable sender source and that DHCPs are not always read.
	Does or how does this influence your opinion of DHCPs and does it influence how you act in the process and why?
	In your opinion, could or should the process (in terms of preparation, collaboration with EMA/NCA and dissemination) be done differently?
	Follow-up: Have you ever felt that you would have done it differently?

Debriefing

I have no further questions; do you have anything else to add that hasn't been brought up?

- Can I contact you in the future if I find something from the transcription that I need you to clarify?

Do you think that from what we have talked about, that I should speak to someone else in this company?

Supplementary material 2: Interview Topic Guide – EMA

Briefing

The purpose of briefing in the interview is to inform the interviewee about:

- The interviewer's background
- The purpose of the master thesis
- The interviewee's anonymity (although interviewee can agree not to be anonymous)
- Recording of the interview and that the recording will be used for data analysis
- That the interviewee can at any time choose not to answer a question

Interview questions

Theme	Question
Interviewee's background	Can you start by telling me about your educational background?
	Can you tell me about your job, what are your main focus areas?
	How many DHPCs have you been involved during your time at EMA?
	What is the responsibility of EMA in terms of risk minimization activities?
Preparation of DHPCs	What is the responsibility of EMA in terms of preparation of DHPCs?
	How are you informed that a safety concern is identified and that a DHPC should be prepared?
	Follow-up: Does the level of commitment of employees depend on the seriousness of the safety concern?
	Which general issues do you find yourself discussing with your colleagues in terms of DHPCs?

Template and content of DHPCs	What do you think about the template? Follow-up: Do you think the template, format and structure could be optimized and why?
	In your opinion, would you prefer if the structure was more open?
	Have you ever felt that your morality was compromised in the process of preparing a DHPC?
	Do you feel your rational considerations are compromised when following a template?
Collaboration with Industry	How does the collaboration between the companies and EMA work?
	How would you describe the distribution of work; would you say that it is a joint effort or does the involvement in the process differ between EMA and the companies?
	What arguments do you use in the collaboration in relation to the content and wording and what arguments do the companies use? Is there a difference between companies in terms of the collaboration?
	Follow-up: Do you put emphasis in different sections/issues on content/wording?
	Does the DHPC process affect the relationship between EMA and the companies – and how?
Effectiveness of DHCPs	What is your general opinion about DHPCs as a risk minimization measure?
	Follow-up: Do you find DHPCs as an effective risk minimization measure?
	Do you feel that companies are good in measuring effectiveness of DHPCs and why/why not? What could be done differently?
Regulation perspective	The 2012 PV legislation lead to increased focus on risk communication. How would you say the DHPC process has changed?
	Follow-up: How has the increased focus on risk communication changed your behavior in relation to DHPCs?
Personal morality	What do you think are the challenges of the current DHPC setup in regards to public health? In regards to industry-authority relations? In regards to authority-HCP relations?
	Follow-up: Do you think DHPCs are able to change the behavior of physicians in the current format?
	The literature states that healthcare professionals do not always read DHPCs.
	Does or how does this influence your opinion of DHPCs and does it influence how you act in the process and why?

	<p>In your opinion, could or should the process (in terms of preparation, collaboration with the companies and dissemination) be done differently?</p> <p>Follow-up: Have you ever felt that you would have done it differently?</p>
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Debriefing

I have no further questions; do you have anything else to add that hasn't been brought up?

- Can I contact you in the future if I find something from the transcription that I need you to clarify?