• Does your market have country-specific guidance? Do you leverage ICH or WHO? If not are there any plans to move in that direction?

• Do your agency complete a full review of a submission or do you leverage reviews and approvals from other markets (reference market) to make your review more efficient? And if so, which markets do you reference? If you do a full review is there anything being planned to work with other markets, or request more information from sponsors on the status of reviews and approvals globally?

• How does your agency use Science and/or Risk based approaches in your reviews?
• How are CPP's or approval letters from other markets leveraged by your agency? Is there a shorter review period if those documents are provided?

• Is there is an established way of interacting with and leveraging information from other regulatory agencies? If so, what worked well in developing that process? If not, considering the information you would need from other agencies, what are the roadblocks in preventing you from doing that - with the understanding that sovereignty and the final approval/rejection decision lies with your country.
• Understanding ancillary documentation requirements – how do these documents contribute to the overall review and approval process? What assurances do they provide and is there potentially an easier way to provide the same assurances, perhaps in the data already submitted? (is the submitted dossier/variation not considered a legal document so the additional documents are needed?) Are these requirements part of the law? Or historical requirements? Examples of ancillary documents include: Wet signatures on some documents, pagination, batch records, CoA, apostilled or legalized documents.

• If not currently accepting electronic submissions, are there plans or interest in moving towards their use such as submissions on a CD (compact disk) to make reviews more efficient by making it easier to find data and sections of the submission?