Reducing Unnecessary Regulatory Burdens (RURB) in Pharmaceutical Industry:
Engagement with Pharmaceutical Association of Malaysia (PhaMA)
30 October 2020, 3.30pm, ZOOM Meeting

Attended by:

Mr. Mohd Hilmi Mohd Idris	MPC
Mrs. Anis Marina Abd Wahab	MPC
Mr. Ahmad Zaidi Abd. Wahab	MPC Associate
Dr. Yogesvari Sambasevam	MPC Associate
Ms. Alice Chee Seat Mee	PhaMA
Ms. Janice Tan	Novartis Corporation (M) Sdn. Bhd.
Ms. Ta Su May	DKSH Malaysia
Ms. Stephanie Ong	Sanofi-Aventis (Malaysia) Sdn. Bhd.
Ms. Long Siew Mei	Merck Sharp & Dohme (MSD) Malaysia
Ms. Nesha Armo	Merck Sharp & Dohme (MSD) Malaysia
Ms. Sebrina Su	AstraZeneca Sdn. Bhd.

Salient points:-

1. The members of meeting mentioned that the issues collected previously does not relevant to them since they had not been a local manufacturer.

2. Mr. Zaidi mentioned that for issue on multiple agency approval (MDA – NPRA), there had been discussions between MDA and NPRA (on behalf of DCA). The meeting had concluded a new guideline (3rd Ed. 15th Sep 2020) for the Medical Device-Drug interphase product registrations. Under the new guidance, the registration will only be handled by one agency with an endorsement letter from the other agency.

3. Following that, Ms. Stephanie further mentioned that even though there had been new guideline impose to register pharmaceutical products, there still need to submit substantial documents to MDA on the device section. The requirements to submit documents (such as EPSP list) to MDA happened to be extensive as well.

4. Ms. Janice further added that Malaysia had been the only country that imposes the unique requirements pertaining to registration of pharmaceutical products. Some of the documents had to be obtained from other companies which had been quite troublesome if the company had been not cooperative.

5. Ms. Siew Mei expressed her frustration towards the issue on multiple agency approval. Her company has been dealing with vaccines and comes with pre-filled sterile diluent syringes. Sterile diluent is not a drug, however, the diluent

available in prefilled syringes and packed together in the vaccines. So, there has been requirement to submit information on the prefilled syringe containing the diluent to MDA. There have been cases where the syringes have been manufactured by third parties/vendor. She further added that in major countries such as EU, this has been not regulated for combination products, unlike Malaysia. She suggested that MDA and NPRA should work together to impose flexibility on the registration of combination products. At some cases, the vaccines were not able to renew due to extensive requirements.

6. Other concerns may be related to import and export of products. One of the member from DKSH (directly involved in distribution), highlighted on Poison Act 1952 regulation on the requirement of original document. It was proposed to revise to accept electronic documents in conjunction to digital transformation. Example of regulations; Sales of Poisons, Poisons sign order. The digital transformation was expected to speed up the process as well.

7. Ms. Stephanie added on the digital transformation. She mentioned that there had been duplication at administration level. The company need to apply for import license with related documents. The import license requirements have been tedious and troublesome. It was suggested that MOH and Customs to work together in terms of electronic documentations and data sharing.

8. Ms. Siew Mei mentioned that as part of ministries initiatives on digital transformation, e-labelling and ECTD can promote more work efficiency and regulatory convergence.

9. Ms. Janice spoke about reliance approach which means relying on reference countries evaluation report, and then health authorities in Malaysia would make decision based on assessment done by other countries such as EU. The program was started by NPRA in Malaysia via reference countries such EU and US at the moment. She proposed to expand further as the approach can reduce the redundancy workload and help in simplifying work.

10. Ms. Janice requested if more reference countries (Australia, NZ, Canada, etc.) to be added in the list, new indication for new products and expand to variation as well to be considered reliance approach program.

11. Ms. Siew Mei mentioned that the full assessment reports / un-reducted reports are not available in the reference countries' public domain. Thus, it was suggested to make available the full report for the companies that requesting.

12. Ms. Stephanie mentioned about having to have access to innovative medicine to Malaysia. There has been a need of reference country approval prior to

registration and the approval time taken has been much longer (2 years). It was suggested that NPRA to accept full registration without reference country approval and their capacity building for innovative medicine into Malaysia (eg. COVID vaccines).