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現代化中醫藥國際協會

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To: Panel on Commerce & Industry

Submission to the Panel on Commerce & Industry on Difficulties facing the proprietary Chinese medicine industry in moving towards Good Manufacturing Practice

The term GMP represents different levels of requirements under different jurisdictions. The levels of requirement depends on the type of goods being manufactured. It would range from intravenous injection, through oral drugs to dietary supplements and food. Hence the definition of medicine, dietary supplement or health food and food is critical when regulations are set up to protect the consumer without imposing unnecessary rules on the industry.

1. How does GMP protect the consumer? Which aspect of GMP protects the consumer over the safety aspects?

2. The HK CM industry wants to market to China and the rest of the world. Should the HK Government review its definition of the categories of products with a view to harmonize with China and major jurisdictions of the world?

3. We have compared the GMP for western medicine with that proposed for Chinese medicine (CM) to discover that in a number of clauses, the latter is more stringent than the former. Would the HKG explain the difference and assess the implications of such difference?

4. The implementation of GMP for western medicine in HK was in three phases. Please give details of the three phases and inform the industry whether they would be the same for CM with reasons to support similarity and differences.

5. GMP for CM has been implemented in Taiwan and Singapore. Is the HKG aware of the systems used and the difficulties encountered?

6. Has the HKG assessed the financial implication of GMP to the individual company and the overall social/economic implication to HK if CM GMP were implemented with demise of a substantial number of SME engaged in this industry?

7. The Food & Drug Administration (FDA) of USA has special guidance for SME. Would HKG consider such measures including official consultation, training and pilot factory services?

MODERNIZED CHINESE MEDICINE INTERNATIONAL ASSOCIATION 現代化中醫藥國際協會

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