

## Newsletter

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## Singapore Association of Pharmaceutical Industries ("SAPI") Code's Guidance on Sponsorship of Third Party Events Effective from January 2019

The Singapore Association of Pharmaceutical Industries Code of Conduct (the "**SAPI Code**") has been amended to provide clearer guidelines on the sponsorship of healthcare professionals to attend third party educational events. SAPI is an organisation that represents the interests of 42 pharmaceutical companies ("**Member Companies**"), and the code provides guidance for these Member Companies in efforts to promote a high standard of ethical conduct.

While the 2018 version of the code was published in January 2018, the particular guidelines regarding third party educational events (covered in article 7.2.4) only came into effect on 1 January 2019, so as to give companies time to adapt to the changes.

Third party educational events are defined in the SAPI Code as any scientific conference, professional programme, or event sponsored or conducted by a third party or independent professional association, such as events of an educational, scientific or policy-making nature or events for the purpose of promoting medical advancement or delivery of effective healthcare.

Member Companies may support a healthcare professional ("**HCP**") to attend such third party events, through providing sponsorships to hospitals, medical associations and independent medical associations (referred to in the SAPI Code as "**Organisers**"). However, such sponsorship must be provided in accordance with certain requirements. Some of the key requirements are as follows:

- a. The support provided to the HCP must preserve the independence of medical education. Sponsorship must not be conditional upon any obligation by the HCP to recommend, prescribe, dispense, purchase, supply, administer or promote Member Companies' products.
- b. Sponsorship funding provided must be proportionate to the overall costs of the event.
- c. The event agenda must not include standalone entertainment, side trips, or other inappropriate activities, and the venue must be appropriate and conducive to the scientific and educational objectives of the event.
- d. Organisers must independently control and take responsibility for the selection of programme content, faculty, educational methods and materials.
- e. Member Companies must not offer or directly pay for, or reimburse, the expenses of any HCP to attend the event. Sponsorship must not inappropriately benefit any HCP or provide for any private side trips, recreation, entertainment or lavish meals and accommodation.



- f. Member Companies must not select or influence the selection of any HCPs to attend the event, be it directly or indirectly. All HCPs should be independently selected by a decision making committee, professional body or medical association whereby selection criteria and processes are legitimate.
- g. Member Companies cannot make registration, accommodation and/or travel arrangements for any attending HCP. Payment of any sponsorship must be paid only to the Organisers.

Sponsorships can be made through a written offer by Member Companies or a request for support by the Organisers. In the case of the latter, sufficient information must be given to allow Member Companies to evaluate the scientific and educational merit of the event and the appropriateness of the venue and agenda.

While the SAPI Code does not have the force of law, acceptance and active observance of the SAPI code is considered mandatory for all Member Companies.

More information about the revisions made to the SAPI code can be found [here](#), and the SAPI Code in full can be found [here](#).

## Health Sciences Authority ("**HSA**") Introduces "Do-and-Tell" Approach for Minor Variations of Therapeutic Products

The Health Sciences Authority ("**HSA**") has introduced a new "Do-and-Tell" option for a list of specified post-approval minor variations ("**MIV-2**") to enable timely implementation of changes by companies and enhance regulatory efficiency.

Under this option, companies can implement certain minor administrative changes without needing to obtain prior approval from the HSA. There are two ways in which this may be done:

1. Companies may consolidate all of their "Do-and-Tell" changes and submit them during the scheduled submission periods of January or July, as long as the changes were effected within a 6 month timeframe of the submission period.
2. Alternatively, companies may submit a "Do-and-Tell" change at any point in time as a MIV-2 submission, or together with other standard MIV-2 changes, as long as the "Do-and-Tell" change was implemented within the preceding 6 months.

If a scenario arises where the same "Do-and-Tell" change was further amended and thereafter effected once more during the 6 months timeframe, only the latest version of the change should be submitted. Should the need arise, companies can also submit their "Do-and-Tell" MIV-2 changes in an MIV-1 application (for



minor variations relating to quality aspects), if the "Do-and-Tell" changes are consequential to the proposed MIV-1 changes.

More information about the approach can be found [here](#) and a quick guide can be found [here](#). The full list of specified MIV-2 applicable for the "Do-and-Tell" variations can be found at Appendices 13C and 14C of the Guidance on Therapeutic Product Registration of Singapore, found [here](#) and [here](#) respectively.

## HSA Makes Amendments to Categorisation of Post-Approval Variations (MAV-1 and MIV)

The HSA has re-categorised the inclusion of clinical information on concomitant administration of vaccines in the product label from MAV-1 to MIV-1. MAV-1 refers to any variation to the indications, dosing regimens, patient population and/or inclusion of clinical information for extending the use of a registered product, while MIV-1 refers to a minor variation to the quality aspects and/or labelling of a therapeutic product.

These changes take into consideration the fact that updates relating to the potential interference between co-administered vaccines do not entail extension of the use of the product.

The HSA has also announced that certain MIV-1s will be re-categorised to MIV-2s. MIV-2 refers to a minor variation or an administrative change. The relevant MIV-1s that will be re-categorised are as follows:

- Alignment of the Package Insert/Patient Information Leaflet of generic drugs with the corresponding current labels of the Singapore Reference Product;
- Addition or amendment of information on "Instructions for Use" for products with special delivery system/device (e.g. transdermal patches, inhalers, prefilled syringes, etc.); and
- Addition or amendment to the Drug interactions and overdose sections that result in strengthening of safety information or restriction of use.

The HSA elaborates these re-categorisation changes seek to refine their regulatory approach and to simplify the regulatory filing process for safety and administrative changes.

More information about the approach can be found [here](#).

## HSA Makes Amendments to Guidance on Therapeutic Product Registration

The Health Sciences Authority ("HSA") has revised the Guidance on Therapeutic Product Registration in Singapore (the "**Guidance**"). The revised Guidance was



published on 15 January 2019 and came into force on the same date. The key changes are as follows:

1. Site-specific stability data requirement streamlined

Changes have been made to the requirements for registration of multiple primary packagers of therapeutic products. Primary packagers refer to primary packaging sites in which therapeutic products are packaged after manufacture.

Prior to the revision, in order to register multiple primary packagers, companies had to include in their dataset a minimum of one set of 12 months stability data from one of the primary packaging sites, transport validation of the bulk product to the other proposed primary packaging site(s), and a minimum of one set of 6 months of stability data from the other primary packaging site(s) with a commitment to provide the data upon completion of the stability study.

The stability data requirement has now been streamlined to remove the need for any site-specific data. Applicants would only have to submit transport validation of the bulk product. However, this only applies if the same container closure system is used for all sites, and to new drug applications, generic drug applications and post-approval variations.

This change further aligns the stability data requirements with that of chemical and biological therapeutic products.

2. Guidelines on Minor Variation Applications for Chemical Therapeutic Products Revised

Changes have been made to Appendix 13 of the Guidance, which contains guidelines on minor variation applications ("**MIV**") for chemical therapeutic products. Some of the key changes highlighted by the HSA are as follows:

- a. An addition or replacement of an alternative site for primary packaging for a non-sterile product may be submitted as a MIV-2 application.
- b. A new checklist for "Change of Specification of Drug Product" has been added. This change was previously included under "Change of Specification of Drug Substance (where CEP is not available)".
- c. A MIV-1 submission will be required for the deletion of a specification parameter which may have a significant effect on the quality of the drug substance or drug product.



- d. No variation application will be required for changes in the supplier of the primary packaging material, provided that the type of primary packaging material and specification remain unchanged.
- e. Two MIV-2 checklists have been added, namely, the “Submission of CEP for an approved drug substance manufacturer” and the “Change of Specification of starting material”.
- f. Any “Change in Name and/or address of Product Registrant” should be submitted via Transfer@PRISM instead.

Other changes have also been made to streamline submission requirements (e.g. checklists B8, C6, C12, C16, C22), enhance certain checklists (e.g. checklist B5, B7, B15, C27), and clarify conditions and/or documentation requirements.

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3. Creation of e-forms for Patent Declaration Forms and Drug Master File (“DMF”) Submission Forms

The HSA has also converted the existing Word document format of Patent Declaration Forms and DMF Submission Forms into an electronic PDF format. With the digitised forms, applicants will no longer have to print, sign and scan the hardcopy forms.

More information about the changes can be found [here](#) and the revised Guidance can be found [here](#).