

Do-and-Tell MIV-2 Quick guide.

1. What is a 'Do-and-Tell' variation?

An administrative change that may be implemented without prior approval from HSA. However, HSA needs to be notified of the change/s via a MIV-2 Do-and-Tell submission. Please refer to Appendix 13B and 14B for the list of Do-and-tell changes.

2. When do I submit 'Do-and-Tell' changes?

Option 1: 6-monthly notification

You may consolidate all "Do-and-Tell" changes that have been implemented within a 6-month timeframe of the scheduled submission periods of January (changes made from July to December of the preceding year) and July (January to June of the present year).

Option 2: Flexible notification

You may submit a Do-and-Tell change anytime as a MIV-2 submission, or together with other standard MIV-2 changes, according to your business needs, provided that the change was implemented within the preceding 6 months.

Please note that at any one time, there can only be one MIV-2 application per product registration, with a turn-around-time of 40 working days excluding stop-clock.

3. The same Do-and-Tell change was amended and re-implemented during the 6-month timeframe, do I submit this as 2 Do-and-Tell changes?

Only the latest version of the change should be submitted to HSA.

4. Can I submit the Do-and-Tell MIV-2 changes together with other MIV-1 applications?

You may submit the Do-and-Tell MIV-2 changes in an MIV-1 application provided that these changes are consequential to the proposed MIV-1 changes.

5. Given the limit of one MIV-2 submission at any given time, how do I plan my Do-and-Tell submissions?

Please refer to some examples below:

	Scenario	What you should do
1	You have 3 Do-and-Tell changes implemented in March, May and June 2019.	Combine the changes in one MIV-2 and submit by the end of July 2019.
2	You have implemented a Do-and-Tell change in March 2019, but omitted this in your July 2019 submission package.	You may submit the omitted change as a standalone or combined MIV-2 application after the submission period, latest by September 2019 (6 months from implementation).

3	Your MIV-2 is still pending notification by HSA in January 2020 and you need to submit a Do-and-Tell variation.	You may submit the Do-and-Tell variation after the pending MIV-2 application has been processed (within 6 months of implementation), or make a written request to include the Do-and-Tell change in the pending MIV-2 application.
4	You have prepared one Do-and-Tell MIV-2 submission package scheduled for July 2019, however you need to also submit an urgent MIV-2 variation at the same time.	You may combine both changes in the same MIV-2 application.