

SG2**Study
Group 2**

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DG ENTR.F A/5804	
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RE: Application from The Medical Devices Control Office of Hong Kong to Join the National Competent Authority Report (NCAR) Program.

Dear Mrs Lalís

The SG2 has received an application for the Medical Devices Control Office of Hong Kong (MDCO) to join the NCAR program that is run by the SG2 on behalf of the GHTF. As you may be aware the requirements for joining the NCAR Program are set down in GHTF SG2 N38 R14 which can be downloaded from the GHTF website, but I have attached it to this letter for convenience. SG2 N38 R14 stipulates that the applicant must apply to the SG2 Chairman and meet several conditions before being eligible to join the NCAR program. Upon demonstrating that the conditions are met the SG2 Chairman writes a letter of recommendation to the Steering Committee of the GHTF who has the final decision. In this letter I will summarise the claims that the MDCO has against each of the conditions stipulated in GHTF SG2 N38, and outline the special circumstances surrounding that agencies status as a "National Competent Authority". The latter may need some special consideration before you make a final decision.

Claims against the conditions set down in GHTF SG2 N38

1. Existence of a National Adverse Event Reporting Program:

This pre-requisite is fully met. The MDCO runs a user reporting system with direct links to Hong Kong hospitals. They hope to implement a compulsory manufacturers reporting system as their national registration system for medical devices matures (registration is currently voluntary in Hong Kong).