

Comments on TGA Review of the regulation of certain self-testing IVDs in Australia

Self-testing devices for some common infectious diseases such as influenza and hepatitis would allow for earlier identification of cases and treatment or intervention if required. It would allow more individuals to be tested and would allow people who cannot or will not access current health services or live in remote regions to perform their own testing. In periods of strong demand for health care such as with seasonal influenza it can be difficult to access required care through ED or GP's and so treatment may be delayed or not provided at all. In the event of an influenza pandemic this delay is likely to be substantially amplified. There is little downside to allowing self-testing if TGA oversees the performance of the tests to ensure they reach a suitable standard. False negatives and false positives occur in even the most sophisticated laboratories! I agree completely with your statement "Earlier use of rapid screening for influenza could also reduce the severity of the disease by allowing for earlier treatment with antiviral drugs" as clinical trials have proven that the neuraminidase inhibitors (Relenza or Tamiflu) are most effective if taken within 48 hours of symptom onset.