Explanation for queries on registration of Covid-19 rapid antigen test devices

Procedure for Medical Device Registration

local agent profile creation → Approval of the manufacturing site → Sample import license → Application for the product registration → Preliminary evaluation for the mandatory documents → Clinical evaluation of the product → Pharmaceutical evaluation → MDEC (Medical Device Evaluation Sub Committee) approval → CEO, NMRA approval → Issue Registration certificate and Import license

1. **How George Steuart Health (Pvt) Ltd submitted the application manually on 19th October 2020 while it was allowed only through the automated system?**

Process of registration of Covid-19 rapid antigen tests

1. Due to the Covid-19 crisis NMRA decided to process sample import licence and accepting registration dossiers manually for **ALL**Covid related products to expedite the registration. (eg: PCR test kits, Rapid antigen test kits, masks, hand sanitizers etc).But the applicant should complete first two steps (Local agent profile creation and foreign manufacturing site registration via e-nmra online system)
2. This decision was taken as the automation system was implemented recently and some of the steps are still under development stage.
3. After completing profile creation the local agent applied for registration of two foreign manufacturing sites (Manufacturer:Abbott Rapid Diagnostics Jena GmbH, Germany formerly known as Standard Diagnostics Inc., Korea and SD Biosensor, Korea) on 20th April 2020 and 05th May 2020 respectively as existing manufacturers.(Both manufacturers **are already registered with NMRA** since 2016 under the same local agent George Steuart Health (Pvt) Ltd)
4. NMRA received two application files for registration of Covid-19 Rapid antigen test on 19th October 2020 and 20th October 2020.
   File No:i.D/3690 (Panbio Covid-19 rapid antigen test device)
   ii. D/3691(Standard Q Ag Test)
5. Both of these products have been tested, validated and recommended for procurement by the WHO and these are included in the WHO emergency use list.
6. In addition to this Panbio Covid-19 rapid device are approved by HealthCanada and TGA, Australiaand Standard Q Covid-19 Ag test is approved by HSA , Singapore , Ministry of Health & Prevention, UAE and Saudi Food and Drug Authority.
7. After receiving the application NMRA followed the routine evaluation procedure. Accordingly, information was sent to an expert who has been appointed by the College of Microbiologist. Based on the recommendation by the expert NMRA completed the evaluation process.

2. **How is the registration granted while the technical evaluation shows 6 points to be corrected?**

   NMRA has granted only provisional registration for these products. This is standard regulatory practice. In the meantime the NMRA has requested for some additional data

where necessary, which registration holder is expected to submit in due course. These are not considered critical to withhold registration. Accordingly, NMRA granted one-year **provisional registration**(NOT full registration) as the products are new to the country, they are both pre-qualified and listed by the WHO and are needed urgently.

3. **Was there an assessment done by MDEC on rapid antigen tests? If so, who were the members of that panel? When was the meeting held?**

1. The Medical Device Evaluation Committee (MDEC) assesses the reports submitted by the external experts as well as the pharmacist evaluation reports at monthly meetings.
2. All main committee meetings of NMRA including MDEC are scheduled to be held once a month. However, NMRA has requested to appoint a subcommittee within MDEC to assess evaluation reports as a solution to grant registration without delay. The main committee of MDEC was held on 07th October 2020 and evaluation reports of these products were tabled at the meeting of MDEC sub-committee held on 21st October 2020. The same procedure is followed for medicines as well to ensure products used against COVID 19 are available without any delay.

4. **How was the pricing done on 20th October 2020?**

Technical evaluation was started on 20th October. On the same day NMRA requested pricing details from the local agent. And they have submitted their price on the same day. All were coordinated through emails. The initial price quoted was successfully negotiated to a lower price by the NMRA before registration.

Rapid antigen test for COVID 19

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1. With the current epidemiological situation in the country with COVID 19 the expert opinion is to use rapid antigen tests (RAT) to perform contact tracing and optimize PCR testing.
2. Although PCR is the gold standard, RATs are known to be useful to trace 1st or 2nd level contacts. They are especially useful when large numbers of positive cases are reported (e.g. factory). RATs cannot replace PCR, but by using RAT the country can optimize use of PCR tests, for which we have a limited capacity. These are considered most useful in manufacturing zones from where significant numbers of the cases are reported to trace contacts and isolate. The BOI and EDB hope careful use of RATs will help them to keep manufacturing sites open to ensure country's economy does not crash.
3. RATs are efficient for contact tracing because it is a point of care test and does not need laboratory facilities for analysis. The RAT is a much cheaper test that could be performed more frequently and takes only 15 minutes to read. MOST importantly it picks up the INFECTIOUS people compared to the PCR that also picks up pre-infectious, infectious and post-infectious people without any discrimination. It must be noted majority of the PCR-positive cases are non-infectious. This will allow efficient trace and isolate activities in high incidence areas.
4. The clinical application of RAT has become a game changer in the battle against COVID 19. It is needed urgently in the country to face the 2nd wave we are facing now. [Copies of scientific paper & letter issued by Professors of Medicine in Sri Lanka attached].
5. Two such RATs have been validated by the WHO and are listed on their website (Emergency User Listing) and are eligible for procurement. The WHO recommends their use in countries as they have reviewed these carefully and provides an assurance about their quality. When the WHO pre-qualifies a product regulators do not need to expend valuable and limited resources to do further validation. This in regulatory terminology is known as 'reliance'. The two WHO certificates are attached. [Copies of WHO listing and approval letters attached].
6. The two listed products are manufactured by two manufacturers (SD Diagnostics & Abbott Diagnostics) who are registered with the NMRA since 2008 and 2018. These are NOT new manufacturers for Sri Lanka.

7. The NMRA provides priority review for products that are used against COVID 19. The NMRA has done this for PCR kits, medical masks, sanitizers and other product to ensure timely and continued availability of these products in the country.
8. The NMRA has registered the two RATs approved for procurement by the WHO after priority internal review considering the urgent need in the country. However, ONLY provisional registration has been granted on the condition that they will be used ONLY under expert review UNDER guidelines on their use that are developed by relevant experts in the Ministry of Health. Until then, the two RATs are not allowed to be used. These instructions have been given clearly by the CEO, NMRA, who is authorized to take decisions on matters related to priority review and registration.
9. As a further precaution samples of these RATs were sent to IDH for local validation. All these steps have been taken by the CEO, NMRA, with an abundance of caution.

The WHO has procured 120 million RATs (two products listed by the WHO) to be distributed to LMICs. Sri Lanka has already received 100,000 kits as a donation. A further donation of 100,000 kits is expected next week. The RATs so donated are from one of the brands registered by the NMRA.