الهيئة العامة للغذاء والدواء
Saudi Food & Drug Authority

COVID-19 Pandemic: SFDA Medical Devices Regulatory Updates

SFDA-Medical Devices efforts to manage the outbreak of COVID-19

Aim

Due to the outbreak of COVID-19, The Saudi Food and Drug Authority (SFDA) has taken steps to:

- Ease importing restrictions, accelerate registration processes
- Provide all support for local manufacturers and distributing companies
- Ensure regulations do not block the development or supply of devices

SFDA-Medical Devices efforts to manage the outbreak of COVID-19

Regulatory actions

1. **Expedite the Approval Process for Personal Protective Equipment (PPE).**
    - SFDA expedited the evaluation process and issuing the medical devices marketing authorization (MDMA) for the medical Personal Protective Equipment (PPE) such as medical masks, medical gloves, gowns and single-use protective clothing to be within two working days after ensuring their safety.

2. **Reduce SFDA technical documentations required for the approval of COVID-19 test Kits and PPE.**
    - In the normal situation, Saudi FDA require the technical file and all supported documents in order to proceed the applications
    - As the current outbreak of COVID-19, Saudi FDA requires the following documents to issue EUA with the following:
        - Quality Management System (ISO 13485:2016)
        - Performance Evaluation report
        - Labelling samples
        - Testing reports
        - Attestation letter

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Regulatory actions

3. **Supporting unauthorized local factories**
    - Organizing an audit visit by SFDA representative team to ensure safety and quality of raw materials and overall manufacturing processes.
    - If the safety and quality of the manufacturing processes were accepted, a temporary permission will be provided during the urgent crisis period.
    - The manufacturers shall register later with SFDA and fulfill all manufacturing requirements including ISO 13485 from accredited organizations.

4. **Granting Emergency Use authorization (EUA) for IVD tests for COVID-19**
    - To expedite the approval process for IVD test
    - Applicants must provide the minimal documentations to ensure safety and effectiveness of tests
        - Previous approval from other international regulatory bodies (If possible)
        - The manufacturer of the IVD test must have (ISO 13485:2016) from accredited organizations
        - International factories must have registered SFDA Authorized representative For
        - Applicant or importer most have valid SFDA importing license
        - Stating that the minimal required documentations will be provided and registration for Marketing authorization will be completed within 60 days)

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Regulatory actions

5. **List of SFDA emergency Use authorization (EUA) and Medical Devices Marketing Authorization (MDMA) for COVID-19**

- SFDA Internal list:
  - Include SFDA approved IVD tests (EUA and MDMA)
  - IVD Tests available in the market (Newly developed and approved by other regulatory bodies)
  - Updated regularly

- SFDA external list:
  - Include SFDA approved IVD tests (EUA and MDMA)
  - Shared via a link in SFDA website
  - Updated regularly
  - Ensure healthcare providers are aware of SFDA approved tests

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Regulatory actions

6. Updating Medical Devices regulation and legislations by:

- Develop and publish the standard SFDA.MD/GSO EN 14683:2020 for medical masks requirements
- Develop and publish the guidance documents:
  - ✓ Guidance on General Requirements for Medical Device Manufacturing
  - ✓ Guidance on Requirements for Medical Masks - Recognized Standards
  - ✓ Guidance on Requirements for Ventilators, Ventilator Tubing Connectors, and Ventilator Accessories – Recognized Standards
  - ✓ Temporary guidance for Emergency Use Authorization (EUA)
  - ✓ Guidance for Protective Medical Goggles and Face Shields – Recognized Standards
- Distribute guidance to Healthcare Providers on safe use of medical devices inside radiology, nuclear medicine and radiotherapy department during the pandemic to prevent the spread of Coronavirus.

SFDA-Medical Devices efforts to manage the outbreak of COVID-19

Regulatory actions

7. Strengthening the proactive and reactive activities of Post-market surveillance

- Reporting:
  - ✓ Masks (66 reports)
  - ✓ Isolation Gown (10 reports)
  - ✓ COVID-19 Swap (5 reports)
  - ✓ Thermometer (25 reports)
- Field Safety Corrective Actions (FSCA):
  - ✓ 11 Field safety corrective actions were gathered and followed up with AR in Saudi to confirm the implementation of Corrective actions
- Studies:
  - ✓ Issues to be considered to avoid the transmission of COVID-19 through MD
  - ✓ An evaluation for the reliability of rapid-diagnostic testing for COVID-19

SFDA-Medical Devices efforts to manage the outbreak of COVID-19

Regulatory actions

7. **Strengthening the proactive and reactive activities of Post-market surveillance**
    - Awareness:
        - 3 Workshops on Safe use of medical devices at healthcare facilities
    - Recommendations on the use of MASKS in the context of COVID-19
    - Effective Communication By SFDA with Healthcare Professionals and Public
    - Warning of IVDs unauthorized test kits fro diagnose Covid-19
8. **Conduct a remote assessment to evaluate the safe use of (ionizing and non-ionizing) emitting medical devices in healthcare facilities.**
9. **Evaluate the effectiveness of UV gates used for sterilization against COVID -19.**
10. **Study the different types of medical infrared thermometers that been used commonly during the COVID -19 pandemic.**
11. **Study the association between the COVID-19 and the use of ionizing emitting medical devices in health care facilities.**

SFDA-Medical Devices efforts to manage the outbreak of COVID-19

Regulatory actions

12. Engage with global changes in medical devices regulation

- Communication with the medical devices regulators
- Publish the list of EUA devices on the GHWP webpage
- Regular meetings with GHWP and IMDRF

13. Support countries in Medical Devices Regulation through Saudi FDA WHO Collaboration Centre

- SFDA participated in many sessions remotely with attendance of WHOEMERO with WHO to discuss the potential opportunities of supporting the African medical devices forum (AMDF) and provide expertise in the medical devices area during this pandemic.
- Saudi FDA participated in 4 working groups (WG1: COVID-19 IVDD tests (Mainly NAT assays), WG2 (Medical devices required during the COVID-19 outbreak including (PPE and ventilators)), WG3 (Medical devices Adverse events reports- Post-market Surveillance) and WG4 (Guidance document in assessing MD and IVD tests donations during emergencies

14. SFDA Participated in the WHO/TAG/PPE to develop documents related to covid-19

- The Rational use of personal protective equipment for COVID-19 and considerations during severe shortages: interim guidance.
- Technical specifications of personal protective equipment for COVID-19

SFDA-Medical Devices efforts to manage the mutation of COVID-19

Regulatory actions

15. Collaboration and conducting regular meetings with Saudi CDC

- Mentor the changes of the COVID-19 genomic changes and variation (including UK variants)
- Creating a special team from SFDA and Saudi CDC staff members to conduct Inspection visits
  - ✓ Check the performance and safety of COVID-19 PCR-based diagnostic kits, which are used within the licensed governmental and private clinical laborites to conduct the diagnostic testing of COVID-19.
  - ✓ Ensure all the kits and analyzers used in these Labs obtained SFDA MDMA.
  - ✓ Ensure that the kits and analyzers are used for their authorized purposes.
- Send a precaution safety instruction for all licensed governmental and private clinical laboratories to stop using COVID-19 PCR-based diagnostic kits that relay on detection of S-gene only for diagnostic outcome.

16. Contacting all Authorized representatives (AR) of all COVID-19 PCR-based diagnostic kits that obtained SFDA marketing authorization to provide proof/ justifications of the accuracy of the performance of the kits toward the possibility of the presence of the UK the variants.

- SFDA received reports from AR and manufacturing companies of the COVID-19 PCR-based diagnostic kits with verification and validation testing and/ or justifications to proof no effect of the UK variants on the performance of COVID-19 PCR-based diagnostic kits.

Thanks