MARKET SURVEILLANCE OF MEDICAL DEVICES

Uganda Experiences

Post Market Surveillance

Elijah Kirabira

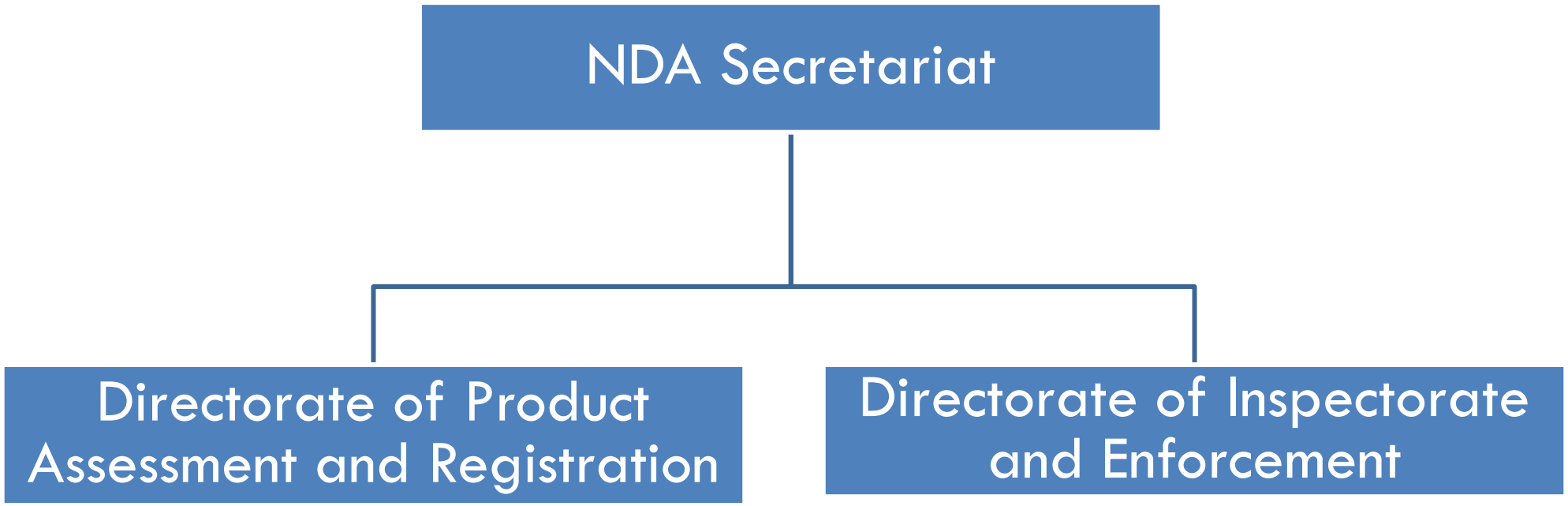
Policy

- NDA regulates the import, manufacture, export and supply of medical devices in Uganda to safeguard public health.

- Medical devices are regulated under a ministerial decree ADM.140/323/01 of 20th July 2020 and statutory Instrument no 77 of the Surgical Instruments and appliances Regulation 2019.

- NDA requires companies to acquire licenses before manufacturing domestically, importing or supplying medical devices. All medical devices will require registration with us before they can be supplied in Uganda.

Medical device regulation



Proactive Market Surveillance

1. **Mandatory testing**
   - Gloves
   - Condoms
   - Long lasting insecticidal nets

2. **Post Market quality Monitoring**
   - Sutures
   - Needles and Syringes
   - Malaria RDTs
   - HIV RDTs
   - Medical Masks

Reporting

Complainant details

Product Details

Complaint description

National Drug Authority
Plot No. 19 Buruna Towers
Lumumba Avenue, Kampala, Uganda.
email: ndaug@nda.or.ug; website: www.nda.or.ug
+256-791415555; Uganda National Drug Authority

The Republic of Uganda
Ministry of Health

Doc. No.: QMS/FOM/013
Revision No.: 4
Effective Date: 12 Nov 2020

Market Complaint Report Form – Part 1

Page 1 of 1

Complaint Number *(To be inserted by NDA)*	Date complaint received at NDA *(To be inserted by NDA)*

1.0	**LOGGING IN OF THE COMPLAINT** *(To be completed by client/customer/stakeholder/interested party/anybody)*
1.1	**Name of complainant** — **1.2 Designation / Occupation**
1.3	**Name of institution:**
1.4	**Location address:**
1.5	**Tel. No.:** **Email address:**
1.6	**Type of Complaint:** *(Check whichever is applicable by double clicking on the box)* **Drug Product Complaint** ☐ **Complaint about NDA** ☐ **Other** ☐ *(Please Specify)*
1.7	**Nature of product complaint** *(Check whichever is applicable)* Quality ☐ Suspected Counterfeit ☐ Efficacy ☐ Expired ☐ Labelling ☐ Packaging ☐ Other ☐ *(Please Specify):*_____
1.8	**Product Category** (Check whichever is applicable) Drug ☐ Herbal Medicine ☐ Sundries ☐ Medical Device ☐ Other ☐ *(Please Specify)*
1.9	**Product Details** *(Please fill whichever applies)* Name of Product: — Batch/Lot No: Manufacturing Date: — Expiry date: — Dosage Form: Name of manufacturer: Address:
1.10	**Name & Address where product was obtained or bought**
1.11	**Description of the complaint** *a) Provide as much information as possible about the complaint and attach any available relevant information.* *b) Continue to the back of this page if you need more space.* *c) If complaint is about a product, provide a sample of the product or send a photograph on the WhatsApp number shown above.*
1.12	**Complaint Delivered to NDA Offices via** *(Check whichever is applicable)* Hand ☐ Email ☐ Telephone ☐ WhatsApp ☐ NDA Staff ☐ Feedback box ☐
1.13	**Have you logged a complaint about this issue before**: YES ☐ NO ☐
1.14	**If YES, when?**

Note: This form is also available online at: https://www.nda.or.ug/?ddownload=5172

How to report

1. What's Up: +256- 791-415-555
2. Toll free 0800 101 999
3. Tel: 0414-255655/347391/2
4. Email address. druginfo@nda.or.ug

   pms@nda.or.ug

1. NDA website: www.nda.or.ug
2. Market Complaint can be obtained online at: https://www.nda.or.ug/?ddownload=1062

REQUIREMENTS FOR MEDICAL DEVICE COMPLAINTS REPORTING

1. Manufacturers and/or LTRs are required to investigate all complaints related to their products and provide CAPA.

2. Should have a complaint register, complaint procedures and persons qualified to investigate such complaints.

INVESTIGATION OF MEDICAL DEVICE RELATED COMPLAINTS

1. NDA is responsible for reviewing the investigation conducted by the manufacturer to establishment of root cause of complaints
2. The timelines depend on the **risk classification** of the complaint as per the *Guideline for investigation of product related complaints*
3. Complaints received include,
   - Needles and syringes
   - HIV RDTs
   - Sutures
   - Medical Masks
   - Gloves
   - Infusion sets
   - Detox machine

Industry Guidance arising from complaints investigation

DRUG NATIONAL AUTHORITY

Safe Drugs Save Lives

2300/ID/NDA/10/2021

7th October 2021

Attention: Manufacturers and Importers

CIRCULAR NO. 004/DIE/2021

LABELLING REQUIREMENTS FOR SURGICAL SUTURES

National Drug Authority has noted with concern the importation of Absorbable and Non-absorbable Surgical Sutures which fail to meet the labelling requirements as per the Uganda Standard US1958-1, First Edition specifically with regards to the composition of the packaging fluid.

Section 8.2 of the standard states that, "if the sachets of sutures (packets or containers) are packaged in boxes, the boxes shall be labelled with the following:

- Name and address of the manufacturer/packer/distributor
- Name of the product
- Type of suture (Absorbable and Non-absorbable)
- Structure (Microfilament or Multifilament)
- Composition of any packaging fluid, if used;
- Batch Number; and
- "Sterile"

Therefore, manufacturers and importers of Absorbable and Non-absorbable Surgical Sutures are hereby notified to comply with the above labelling requirements on the primary and secondary packaging.

All consignments imported into the country without fulfilling the same will not be authorized effective 1st January 2022.

David Nahamya
SECRETARY TO THE AUTHORITY

OFFICE OF THE SECRETARY TO THE AUTHORITY

HEAD OFFICE
Plot 19 Lumumba Avenue P.O. Box 23096, Kampala, Uganda
Tel: (+256) 417 788 100/1 (+256) 417 788 124/417 788 129
Toll Free: 0800 101 999, 0791 415 555
Website: www.nda.or.ug, Email: ndaug@nda.or ug
Facebook: Uganda National Drug Authority
Twitter: @UNDAuthority
NATIONAL DRUG QUALITY CONTROL LABORATORY
Tel: (+256) 414 540 067 / (+256) 414 583 095

OUR MISSION
Promoting and protecting public health through the effective regulation of human and animal medicines and healthcare products

REGIONAL OFFICES
Central Region, Nakawa- Tel: +256 393 261 548,
Western Nile Region, Arua - Tel: +256 414 671 033,
South Western Region, Mbarara- Tel: +256 414 671 034,
South Eastern Region, Jinja - Tel/ Fax: +256 434 122 176,
Eastern Region, Tororo - Tel: +256 454 445 195,
Western Region, Hoima- Tel:/Fax +256 465 440 688,
Northen Region, Lira- Tel/Fax +256 414 671 032

DRUG NATIONAL AUTHORITY

Safe Drugs Save Lives

2455/ID/NDA/10/2021

28th October 2021

Attention: Manufacturers and Importers

CIRCULAR NO. 006/DIE/2021

RE: LABELLING REQUIREMENTS FOR MEDICAL FACE MASKS

National Drug Authority has noted with concern the failure to meet the labelling requirements for medical/surgical face masks and surgical respirators which poses a risk to the health workers in the wake of the COVID-19 pandemic.

Medical/Surgical masks intended for medical purposes cover the user's nose and mouth and provides a physical barrier to fluids and particulate materials. Surgical masks have to meet certain fluid barrier protection standards and flammability requirements and are also tested for particulate and bacterial filtration efficiencies and biocompatibility. Medical face masks protect both the health worker and the patient.

The labelling of medical face masks shall include but not limited to the following information;

1) Name and address of the manufacturer/packer/distributor
2) Name/Brand of the product including the term "Medical Mask"
3) Lot/Batch identification number
4) Type of medical face mask- Type I, Type II and Type IIR
5) Type of material/fabric used
6) Date of manufacture and Expiry date by month and year
7) Manufacturer's Instructions for Use
8) Recommended storage conditions
9) Precautions to include warnings like "for single use" and "dispose after use".

National Drug Authority further requires compliance to the labelling requirements for surgical instruments and appliances as per Statutory Instrument No. 29; National Drug Policy and Authority (Registration) Regulations, 2014.

Therefore, any consignments of medical face masks imported into the country or manufactured locally without fulfilling the above stated requirements will not be authorized effective 31st January 2022.

David Nahamya
SECRETARY TO THE AUTHORITY

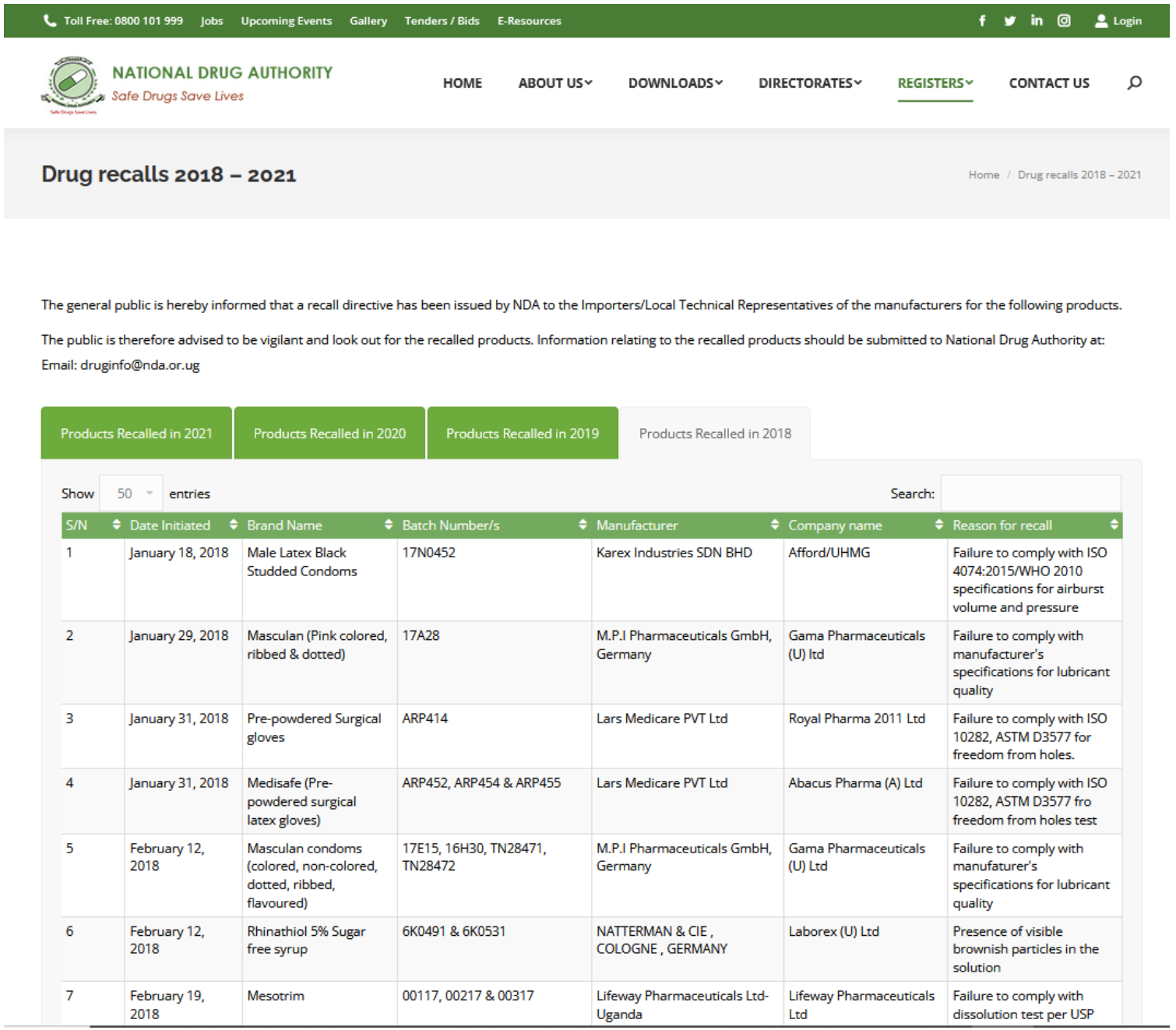
OFFICE OF THE SECRETARY TO THE AUTHORITY

HEAD OFFICE
Plot 19 Lumumba Avenue P.O. Box 23096, Kampala, Uganda
Tel: (+256) 417 788 100/1 (+256) 417 788 124/417 788 129
Toll Free: 0800 101 999, 0791 415 555
Website: www.nda.or.ug, Email: ndaug@nda.or ug
Facebook: Uganda National Drug Authority
Twitter: @UNDAuthority
NATIONAL DRUG QUALITY CONTROL LABORATORY
Tel: (+256) 414 540 067 / (+256) 414 583 095

OUR MISSION
Promoting and protecting public health through the effective regulation of human and animal medicines and healthcare products

REGIONAL OFFICES
Central Region, Nakawa- Tel: +256 393 261 548,
Western Nile Region, Arua - Tel: +256 414 671 033,
South Western Region, Mbarara- Tel: +256 414 671 034,
South Eastern Region, Jinja - Tel/ Fax: +256 434 122 176,
Eastern Region, Tororo - Tel: +256 454 445 195,
Western Region, Hoima- Tel:/Fax +256 465 440 688,
Northen Region, Lira- Tel/Fax +256 414 671 032

Regulatory action



Toll Free: 0800 101 999 Jobs Upcoming Events Gallery Tenders / Bids E-Resources Login

NATIONAL DRUG AUTHORITY
Safe Drugs Save Lives

HOME ABOUT US DOWNLOADS DIRECTORATES REGISTERS CONTACT US

Drug recalls 2018 – 2021

Home / Drug recalls 2018 – 2021

The general public is hereby informed that a recall directive has been issued by NDA to the Importers/Local Technical Representatives of the manufacturers for the following products.

The public is therefore advised to be vigilant and look out for the recalled products. Information relating to the recalled products should be submitted to National Drug Authority at:
Email: druginfo@nda.or.ug

Products Recalled in 2021 | Products Recalled in 2020 | Products Recalled in 2019 | Products Recalled in 2018

Show 50 entries Search:

S/N	Date Initiated	Brand Name	Batch Number/s	Manufacturer	Company name	Reason for recall
1	January 18, 2018	Male Latex Black Studded Condoms	17N0452	Karex Industries SDN BHD	Afford/UHMG	Failure to comply with ISO 4074:2015/WHO 2010 specifications for airburst volume and pressure
2	January 29, 2018	Masculan (Pink colored, ribbed & dotted)	17A28	M.P.I Pharmaceuticals GmbH, Germany	Gama Pharmaceuticals (U) ltd	Failure to comply with manufacturer's specifications for lubricant quality
3	January 31, 2018	Pre-powdered Surgical gloves	ARP414	Lars Medicare PVT Ltd	Royal Pharma 2011 Ltd	Failure to comply with ISO 10282, ASTM D3577 for freedom from holes.
4	January 31, 2018	Medisafe (Pre-powdered surgical latex gloves)	ARP452, ARP454 & ARP455	Lars Medicare PVT Ltd	Abacus Pharma (A) Ltd	Failure to comply with ISO 10282, ASTM D3577 fro freedom from holes test
5	February 12, 2018	Masculan condoms (colored, non-colored, dotted, ribbed, flavoured)	17E15, 16H30, TN28471, TN28472	M.P.I Pharmaceuticals GmbH, Germany	Gama Pharmaceuticals (U) Ltd	Failure to comply with manufaturer's specifications for lubricant quality
6	February 12, 2018	Rhinathiol 5% Sugar free syrup	6K0491 & 6K0531	NATTERMAN & CIE , COLOGNE , GERMANY	Laborex (U) Ltd	Presence of visible brownish particles in the solution
7	February 19, 2018	Mesotrim	00117, 00217 & 00317	Lifeway Pharmaceuticals Ltd-Uganda	Lifeway Pharmaceuticals Ltd	Failure to comply with dissolution test per USP

In summary

"At some point in every person's life, you will need an assisted medical device - whether it's your glasses, your contacts, or as you age and you have a hip replacement or a knee replacement or a pacemaker. The prosthetic generation is all around us. -."

Aimee Mullins