Saudi Food & Drug Authority
Strategic Plan 2018-2022

Protecting and promoting public health

May 2018
President’s note

Riyadh, Kingdom of Saudi Arabia
May 2018

Dear reader,

SFDA’s third annual strategic plan (2018-2022) lays out our vision and strategic priorities for addressing the challenges that we face as the regulator of the food, drugs and medical devices sectors.

We are continuing on our journey to become a leading international regulator responsible, for protecting the community and promoting access to safe products through sound regulations and effective controls.

As the Saudi economy continues to develop, we must respond to the rapid pace of innovation, the tighter integration of global supply chains, and the increasing demands of our citizens for safe and healthy products.

We expect to meet these challenges by making informed decisions based on scientific evidence and by building effective partnerships with the private sector, other government entities and our international partners.

We commit to earning the community’s trust by engaging proactively with the public and by building a high-performing, efficient and innovative organization that allows our staff to be the best in all they do.

Sincerely,

Dr. Hisham Bin Saad Al-Jadhey
CEO
In the 3rd strategic plan, SFDA will focus on achieving measurable outcomes to promote the safety and health of the community

Strategic Plan

1st Strategic Plan (2007-2011)
- Focus on building regulatory framework
- Build-up essential capabilities required to assume regulatory responsibilities

2nd Strategic Plan (2012-2016)
- Continue building-up operational capabilities
- Address gaps in SFDA mandate
- Develop organizational capabilities, policies and procedures

3rd Strategic Plan (2018-2022)
- Focus on outcomes and measurable value to stakeholders
- Efficient and effective operations utilizing existing capabilities
- Rely on scientific evidence and risk assessment
- Work with partners to effectively monitor and control different components of the value chain
The strategic plan was developed based on extensive consultations with various internal and external stakeholders.
The strategic plan presents our updated vision, mission and values, along with the strategic themes, objectives and projects that define SFDA’s path.

**Strategic Framework**

- **Vision, Mission & Values**
  - Alignment of vision, mission & values to reflect SFDA’s strategic direction

- **Strategic themes**
  - Key strategic priorities that address major challenges facing SFDA in meeting its mandate

- **Strategic objectives**
  - Cross-functional, sector-specific and enabling objectives that identify measurable outcomes

- **Performance measurement**
  - Key Performance Indicators (KPI) tied to strategic objectives

- **Projects and executive actions**
  - Projects and executive actions that provide detailed plans with milestones, owners and tasks
The updated vision and mission statements emphasize the importance of a global and scientific approach to promoting public health and protecting the community.

**Vision**

An تكون هيئة رائدة عالميا تستند إلى أسس علمية لتعزيز وحماية الصحة العامة

To be a leading international science-based regulator to protect and promote public health

**Mission**

حماية المجتمع من خلال تشريعات ومنظومة رقابية فعالة لضمان سلامة الغذاء والدواء والأجهزة الطبية ومنتجات التجميل والمبيدات والأعلاف

Protecting the community through regulations and effective controls to ensure the safety of food, drugs, medical devices, cosmetics, pesticides and feed
SFDA’s staff selected these values as most representative of their desire to serve their community by acting with integrity, aiming for excellence and thinking positively.

- **Health of the community comes first**
- **We think positively**
- **We communicate effectively and transparently**
- **We aim to be the best**
- **We are all responsible**
Five strategic themes reflect SFDA’s priorities in the coming five years

**Access to safe and effective products**
Enable access to safe and effective products on a timely basis through appropriate regulations

**Risk-based decision making**
Make decisions taking a risk-based approach, relying on scientific evidence

**Effective partnerships**
Work effectively with our public sector, private sector and international partners to achieve our mission across the value chain

**Proactive engagement with the public**
Increase transparency and proactively engage with the public

**High performing and positive culture**
Enable a high performing, efficient and innovative organization by fostering digital transformation and a collaborative culture
Strategic direction – Cross Functional Objectives

The strategic plan is built upon a number of key strategic directions:

- **Inspection:** Refrain from expanding SFDA branches across the country, and utilize current main branches to cover SFDA’s responsibilities. However, if any region has a justifiable number of manufacturers/distributors SFDA should consider some kind of representation. In addition to relying on government partners to cover various inspection components across the value chain, and outsourcing some aspects of day-to-day inspections (e.g. Warehouse inspections)

- **Laboratories:**
  - **Food:** Establish a reference and research lab in Riyadh and explore externalize routine testing labs.
  - **Drugs:** Accredit Riyadh reference and research testing lab, perform Post Market Surveillance (PMS) tests and explore externalizing local Quality Control (QC) labs.
  - **Medical Devices:** Establish a central testing lab in Riyadh, conduct research activities and externalize to local testing labs.

- **Ownership of the food chain:** Clarify roles and responsibilities of SFDA and delegated mandate to government partners across the food chain, and ensure a cross entity governance and oversight of monitoring and control activities compliance, effectiveness and efficiency.

- **Food Risk Assessment:** Establish well defined Risk Management, Risk Assessment and Risk Communication functions within SFDA’s Food sector, and redefine the Risk Assessment Executive Directorate’s operating model to be the scientific arm of SFDA’s Food sector relying on internal capabilities and external subject matter expertise when needed.

- **Drug evaluations and approvals:** Perform full assessment of new drugs and complex generics, adopting a new Committee model for registrations with expert input. Leverage the maturity effort for human drugs evaluation to build vet capabilities and adopt international best practices for cosmetics, herbal drugs & food supplements approvals.

- **Drugs access and innovation:** Improve access to registered products by exploring incentives for registrations and clarifying Marketing Authorization Holder responsibilities whilst supporting efforts to build public confidence and uptake of marketed generics. Encourage innovation by reviewing Phase 1 clinical trials and foster an environment for local R&D.

- **Medical device evaluation recognition:** Establish risk based evaluation capability for the SFDA that achieves regional and international recognition while simultaneously balancing notified body participation is core to the strategic plan for medical devices. Emphasis will be placed on ensuring equal opportunity for products manufactured by both international and domestic companies.

- **Medical device surveillance and safe use:** Enhance collaboration with healthcare providers and establishments along with comprehensive data gathering initiatives will improve adverse event reporting and ultimately lead to safer usage of medical devices. Published guidelines and best practices will provide guidance to industry, setting expectations and improving communication.
### Cross functional objectives

#### 1. Strengthen enforcement and improve resource allocation by centralizing operational activities

- **Inspection**
  - Access to safe & effective products
  - Risk based decision making
  - Effective partnerships
  - Proactive engagement with the public
  - High performing & positive culture

#### 2. Optimize SFDA lab operations by centralizing labs - acting as a reference lab for food and performing post-market surveillance testing for all three sectors, while externalizing routine QC testing

- **Labs**
  - Access to safe & effective products
  - Risk based decision making
  - Effective partnerships
  - Proactive engagement with the public
  - High performing & positive culture

#### 3. Achieve financial sustainability by increasing revenue in line with international benchmarks while increasing efficiencies and delivering better services

- **Financial sustainability**
  - Access to safe & effective products
  - Risk based decision making
  - Effective partnerships
  - Proactive engagement with the public
  - High performing & positive culture

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**The cross functional objectives address the inspection and laboratory models, as well the financial sustainability of SFDA’s operations**
Food- SFDA should introduce a modified inspection model to alleviate the need for additional inspectorate offices

Location of regulated facilities

**Current situation**

- **>80% of local sites** for inspection sit within the regions of Dammam (East), Riyadh (Central) and Makkah/Jeddah (West), where *SDFA currently has a footprint*
- **>83% of Food factories** sit within the regions of Dammam (East), Riyadh (Central) and Makkah (West), where *SDFA currently has a footprint*
- **>78%** of establishments inspected by SFDA inspectors are *Warehouses*

**Recommendations**

- **Warehouses inspections** can be *outsourced*, as warehouse inspections do not need deep subject matter expertise and specialised training
- Under this model, inspectors would typically be *site- or home-based* with the opportunity to *congregate at one of the 3 branches* at regular intervals (e.g. monthly)
Drug - Based on where local facilities are located, the Drugs sector inspectorate can cover their activities from the current 3 regional offices/branches

**Objective 1 – Inspection**

**Current situation**

- **>90% of local sites** for inspection sit within the regions of Dammam (East), Riyadh (Central) and Makkah/ Jeddah (West) where **SDFA currently has a footprint**
- **Now SFDA is physically staffed** at PoEs and manages clearance of products.

**Recommendations**

- **SFDA should delegate** would day-to-day audit and physical inspection **to Customs** at PoE.
- **Under this model, inspectors would typically be site- or home-based** with the opportunity to congregate at one of the 3 offices at regular intervals (e.g. monthly)
- **For any new regional inspector, there should be sufficient local manufacturers** to justify a regional presence; currently
- **Explore externalizing** local Quality Control (QC) labs.
Medical Devices - Based on the location of regulated facilities, the medical devices sector can cover its activities from the current regional branches

Objective 1 – Inspection

Current situation

- >93% of local sites for inspection sit within the regions of Dammam (East), Riyadh (Central) and Makkah/Jeddah (West), where SDFA currently has a footprint
- Now SFDA is physically staffed at PoEs and manages clearance of products.

Recommendations

- The need for ports inspection would be minimized if the day-to-day audit and physical inspection was delegated to customs
- Under this model, inspectors would typically be site- or home-based with the opportunity to congregate at one of the 3 branches at regular intervals (e.g. monthly)
- For any new regional inspector, there should be sufficient local manufacturers to justify a regional presence
- Explore externalizing lab activities (e.g. Research)
## Sample of Inspection KPIs for Food, Drugs & Medical Devices

<table>
<thead>
<tr>
<th>#</th>
<th>KPI</th>
<th>KPT</th>
</tr>
</thead>
</table>
| 1  | % of government food inspectors trained by the Food Inspector Development Program (FIDP) | • 2018: 30%  
• 2019: 60%  
• 2020: 100% |
| 2  | % of food establishments that are HACCP certified                    | • 2019: Baseline  
• 2020: 40%  
• 2021: 70%  
• 2022: 100% |
| 3  | % Customs clearance compliance to SFDA requirements based on SFDA audits | • 2019: 70%  
• 2020: 80%  
• 2021: 90%  
• 2022: 100% |
| 4  | % counterfeits based on PMS for human and vet drugs                 | • 2018: Baseline |
| 5  | % local drug manufacturers with critical observations during GMP inspections | • 2018: Baseline  
• 2019: 15%  
• 2020: 10%  
• 2021: 5%  
• 2022: 0% |
| 6  | % SFDA employee time spent on-site at port-of-entries (PoEs) For Drugs and Medical Devices | • 2019: 80%  
• 2020: 50%  
• 2021: 20%  
• 2022: 0% |
SFDA should establish an accredited Food Reference laboratory to perform both reference and research activates

**Proposed competencies:**
1. Residues in food & feed from Pharmaceuticals & Pesticides
2. Chemical contamination
3. Heavy metals
4. Biological toxins
5. Molecular contamination
6. Biological contaminants

- SFDA should develop its research capabilities based on inputs received from the Risk Assessment Department and the proposed Risk Assessment Advisory Committee
The Riyadh Drugs lab should be accredited as a central testing lab & as a WHO PQ lab whilst exploring externalization for local, routine QC testing

**SFDA to run**

**In- and post-market quality**
Perform full range of in-house testing\(^1\) for all relevant product types across the supply chain

**WHO accreditation**
Achieve WHO accreditation to perform tests at internationally recognized standards

**Supporting R&D within local universities**
- Explore breeding and selling animals
- Collaborating on R&D projects by making facilities available at a charge

**Explore externalization**

**Local QC**\(^{**}\) testing within private labs
1) QC test of each batch on importation for human, herbal and vet drugs
2) Rent out lab space (part of the Riyadh lab) to local private entities for QC testing
3) Repurpose the Dammam and Jeddah labs for routine imported cosmetics testing
4) For routine testing, have a separate entity so that there is no conflict of interest with PMS testing

We recommend a cost-benefit analysis be performed based on demand for work the SFDA would like to perform e.g. PMS testing and spare capacity for private lab

**International recognition**

**Business case**

\(^{1}\) PMS: Post Market Surveillance obligations of SFDA to follow up on product complaints and to test products across the value chain, potentially by following a risk-based approach.

\(^{**}\) QC testing: Quality Control testing of product before it is released to the market. SFDA would like to test each batch of product (domestic and imported) before it is released onto the market.
**Objective 2 – Laboratories**

**SFDA can improve lab utilisation by focusing on research activities, while carving out space for private laboratories to conduct routine testing**

<table>
<thead>
<tr>
<th>SFDA Medical Devices Laboratories</th>
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<tbody>
<tr>
<td><strong>Laboratory function</strong></td>
<td><strong>Capabilities</strong></td>
</tr>
<tr>
<td><strong>SFDA Central Lab</strong></td>
<td><strong>Data analytics</strong></td>
</tr>
</tbody>
</table>
| **Post-market testing**: SFDA-led testing to verify:  
  - PMS complaints  
  - Inspection of AEs/FSNs  
  - Ongoing support for Customs sampling | Data generated from laboratory to be used within SFDA to:  
  1) Inform SFDA actions including AE/FSN decisions  
  2) Act as input to risk-based decisions (e.g. increase inspection of products prone to material failure)  
  3) Create a database for future data analysis with future remote |
| **SFDA Research Laboratory** | |
| **Internal research projects**:  
  - Investigate high interest areas, including high risk/high value devices |  |
| **External research collaborations**:  
  - Joint research with Drugs Lab  
  - Leverage outsourcing |  |
| **Maintain current testing using existing equipment and staff**:  
  - Mechanical/electrical  
  - Optical |  |
| **Cooperation to obtain other services**:  
  - Collaboration with Drugs Labs  
  - Optical |  |
| **Externalized entity** |  |
| **Independent domestic testing laboratories**:  
  - Leasing laboratory space to private entities (including domestic manufacturers and CABs)  
  - Testing of products for registration submissions (pre-market)  
  - Clinical Evaluation testing (pre- and post-market) |  |
### Sample of Laboratories KPIs for Food, Drugs & Medical Devices

<table>
<thead>
<tr>
<th>#</th>
<th>KPI</th>
<th>KPT</th>
</tr>
</thead>
</table>
| 1 | Cumulative number of reference competencies developed in SFDA’s National Food Reference Laboratory | • 2019: 4  
• 2020: 6  
• 2021: 6  
• 2022: 8 |
| 2 | % tests repeated by a second lab that confirm the findings of the SFDA lab *(Drugs)* | • 2018: baseline  
• 2019-2020: 100% - adjust if baseline is much lower |
| 3 | % tests repeated by a second lab that confirm the findings of the SFDA lab *(Medical Devices)* | • 2018: baseline  
• 2019-2020: 100% - adjust if baseline is much lower |
Strategic Direction – Food

 Ownership of the food chain: Clarify roles and responsibilities of SFDA and delegated mandate to government partners across the food chain, and ensure a cross entity governance and oversight of monitoring and control activities compliance, effectiveness and efficiency.

 Food Risk Assessment: Establish well defined Risk Management, Risk Assessment and Risk Communication functions within SFDA’s Food sector, and redefine the Risk Assessment Executive Directorate’s operating model to be the scientific arm of SFDA’s Food sector relying on internal capabilities and external subject matter expertise when needed.
The food sector will focus on food safety across the value chain, while improving oversight of food imports and pesticides

Objectives for food sector

Ownership of food safety across the value chain

4. Take ownership of food safety across the value chain, by setting harmonized monitoring and control programs with our partners through effective collaboration

Risk-based decision-making

5. Reduce food hazards by applying a robust risk-based model built on scientific evidence

Clear regulatory requirements

6. Develop and apply clear regulatory requirements to ensure full compliance of domestic businesses and importers with the food and feed laws

Food imports

7. Enhance the safety of imported food through applying effective control methodologies, systems and tools

Pesticide control

8. Minimize impact of pesticides on consumers, users and the environment by introducing controls and traceability

Associated themes

Access to safe & effective products  Risk based decision making  Effective Partnerships  Proactive engagement with the public  High performing & positive culture
**Objective 4 – Ownership of food safety across the value chain**

*SFDA should take ownership of food safety across the value chain with clear roles and responsibilities for each partner...*

<table>
<thead>
<tr>
<th>Value chain Products</th>
<th>Imports</th>
<th>Primary production (Farm)</th>
<th>Factories</th>
<th>Warehouses</th>
<th>Distribution centres</th>
<th>Retail outlets</th>
<th>Exports</th>
</tr>
</thead>
<tbody>
<tr>
<td>Animal origin products</td>
<td><img src="image" alt="SFDA" /></td>
<td><img src="image" alt="SFDA" /></td>
<td><img src="image" alt="SFDA" /></td>
<td><img src="image" alt="SFDA" /></td>
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<tr>
<td>Meat</td>
<td><img src="image" alt="SFDA" /></td>
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<td><img src="image" alt="SFDA" /></td>
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<td><img src="image" alt="SFDA" /></td>
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<tr>
<td>Fruits and Vegetables</td>
<td><img src="image" alt="Quarantine" /></td>
<td><img src="image" alt="SFDA" /></td>
<td><img src="image" alt="SFDA" /></td>
<td><img src="image" alt="SFDA" /></td>
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<tr>
<td>Bottled Water</td>
<td><img src="image" alt="SFDA" /></td>
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<td><img src="image" alt="SFDA" /></td>
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<tr>
<td>Feed</td>
<td><img src="image" alt="SFDA" /></td>
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<td><img src="image" alt="SFDA" /></td>
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<tr>
<td>Pesticides</td>
<td><img src="image" alt="SFDA" /></td>
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<td><img src="image" alt="SFDA" /></td>
<td><img src="image" alt="SFDA" /></td>
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</tbody>
</table>

*To be discussed and agreed with MEWA*

- **Saudi Customs**
- **Ministry of Environment, Water and Agriculture**
- **Ministry of Municipal and Rural Affairs**
- **Saudi Food and Drug Authority**
... by positioning SFDA as the competent authority at Border Inspection Points (BIP) and delegating some monitoring and control responsibilities to its partners

1. Establish SFDA as the competent authority at BIPs
2. Cooperate with MEWA to ensure food safety requirements are met at the farm level
3. Work with MEWA and 3rd party laboratories to ensure fruits and vegetables imports are compliant with pesticides maximum residue limits
4. SFDA to take ownership of food factories, warehouses and distribution centers
5. Delegate slaughterhouse monitoring and control activities to MoMRA
6. Delegate retail outlets monitoring and control activities to MoMRA (e.g. small shops, restaurants, supermarkets)
# Sample of KPIs for Objective 4 – Ownership of food safety across the value chain

<table>
<thead>
<tr>
<th>#</th>
<th>KPI</th>
<th>KPT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>% reduction of reported food borne illness incidents</td>
<td>• 2018: baseline</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 2019: 10% of 2018</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 2020: 10% of 2019</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 2021: 15% of 2020</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 2022: 15% of 2021</td>
</tr>
<tr>
<td>2</td>
<td>% compliance of audited MEWA and MoMRA food inspectors with SFDA requirements</td>
<td>• 2021: MEWA = 50%, MoMRA = 40%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 2022: MEWA = 90%, MoMRA = 80%</td>
</tr>
<tr>
<td>3</td>
<td>% compliance of samples collected from the local market</td>
<td>• 2019: 80%</td>
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<td></td>
<td></td>
<td>• 2020: 85%</td>
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<tr>
<td></td>
<td></td>
<td>• 2021: 90%</td>
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<td></td>
<td></td>
<td>• 2022: 95%</td>
</tr>
</tbody>
</table>
### Sample of KPIs for Objective 6, 7 & 8 – Ownership of food safety across the value chain

<table>
<thead>
<tr>
<th>#</th>
<th>KPI</th>
<th>KPT</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>% compliance of inspected domestic food establishments (food factories, warehouses and distribution centres)</td>
<td>• 2018: baseline</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 2019: 75%</td>
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<tr>
<td></td>
<td></td>
<td>• 2020: 80%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 2021: 85%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 2022: 90%</td>
</tr>
<tr>
<td>2</td>
<td>% compliance of imported food samples collected from BIPs</td>
<td>• 2019: 90%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 2020: 92%</td>
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<tr>
<td></td>
<td></td>
<td>• 2021: 95%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 2022: 98%</td>
</tr>
<tr>
<td>3</td>
<td>% of imported food samples collected from BIPs exceeding pesticide maximum residue limits</td>
<td>• 2019: 2%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 2020: 2%</td>
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<tr>
<td></td>
<td></td>
<td>• 2021: 2%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 2022: 2%</td>
</tr>
<tr>
<td>4</td>
<td>% of food samples collected from the local market exceeding pesticide maximum residue limits</td>
<td>• 2019: 2%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 2020: 2%</td>
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<tr>
<td></td>
<td></td>
<td>• 2021: 2%</td>
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<tr>
<td></td>
<td></td>
<td>• 2022: 2%</td>
</tr>
</tbody>
</table>
To support the proposed Risk Analysis Model, the Risk Assessment Department should establish a Risk Assessment Advisory Committee to provide scientific advice.
**Strategic Direction – Drug**

**Drug evaluations and approvals:** Perform full assessment of new drugs and complex generics, adopting a new Committee model for registrations with expert input. Leverage the maturity effort for human drugs evaluation to build vet capabilities and adopt international best practices for cosmetics, herbal drugs & food supplements approvals.

**Drugs access and innovation:** Improve access to registered products by exploring incentives for registrations and clarifying Marketing Authorization Holder responsibilities whilst supporting efforts to build public confidence and uptake of marketed generics. Encourage innovation by reviewing Phase 1 clinical trials and foster an environment for local R&D.
The drug sector will focus on improving drug approvals, safety and access, as well as regulating cosmetics, herbal drugs and food supplements.

### Objectives for drug sector

<table>
<thead>
<tr>
<th>Objective</th>
<th>Associated themes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Drug approvals</strong></td>
<td></td>
</tr>
<tr>
<td>9. Build trust and achieve recognition for SFDA’s approval process for human and veterinary drugs by enhancing capabilities and simplifying evaluation pathways</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Drug safety</strong></td>
<td></td>
</tr>
<tr>
<td>10. Safeguard public and animal health by strengthening detection, surveillance and response to identified risks</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Drug access</strong></td>
<td></td>
</tr>
<tr>
<td>11. Increase access of human and veterinary drugs by collaborating with other government entities to adapt relevant policies and by supporting a vibrant pharmaceutical sector in the Kingdom</td>
<td>✓</td>
</tr>
<tr>
<td><strong>Cosmetics, herbal drugs &amp; food supplements</strong></td>
<td></td>
</tr>
<tr>
<td>12. Reduce the regulatory burden for cosmetics, herbal drugs and food supplements by aligning their regulatory framework with international best practices</td>
<td>✓</td>
</tr>
</tbody>
</table>

Associated themes:

- Access to safe & effective products
- Risk based decision making
- Effective Partnerships
- Proactive engagement with the public
- High performing & positive culture
Objective 9 – Drug approvals

**SFDA should fast track pathways for products with shortage issues or unmet needs when prior approval exists**

- **Fast Track:**
  - A) Prior approval from EU/US FDA
  - Advanced Medicinal Therapies e.g. gene, cell therapy

- **Assessment:**
  - Only review topics relevant to the Saudi Context M1, 3 & 5

- **Focus Area:**
  - Perform parallel assessments

1. **Request COPP (not at submission) for first three years where SFDA does full assessment**

2. **Full and independent assessment & evaluation for products which are not approved by EU/US regulators**

3. **Key Principles & building capabilities for generics**
   - Bioequivivalence of generics
   - Build up capability
   - Leverage current single department for Human & Vet drugs to learn about human drugs maturity

4. **Product registration**
   - Use of expert panel

- **Objective 3 – Drug approvals**
  - Fast Track Assessment Focus Area
  - Only review topics relevant to the Saudi Context M1, 3 & 5
  - Perform parallel assessments
  - Improved internal coordination to streamline company interactions
  - Fast track approval process for products with prior approval
  - Additional accelerated pathways should also be available for high priority products

Note: 1) Prior approval from a stringent regulatory authority, including: EMA; US FDA and other EU Regulators
## Sample of KPIs for Objective 9 – Drug approvals

<table>
<thead>
<tr>
<th>#</th>
<th>KPI</th>
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<tbody>
<tr>
<td>1</td>
<td>Score positively across SFDA customer service, evaluation process, systems, scientific rationale and timelines during a survey conducted by the Quality team in 2020</td>
<td>• Score an average of 4 out of 5 across each parameter</td>
</tr>
</tbody>
</table>
SFDA should leverage its pharmacovigilance (PV) framework for human drugs to improve the process for veterinary and herbal drugs

**Establish active surveillance**
- Access and evaluate pharmacoepidemiological data collected via drug registries

**Create PV regional centers**
- Establish a regional PV network in hospitals that will provide support to the national PV center

---

**PV framework for Human drugs and Vet drugs**

**Human drugs: Enhancing PV framework**
- Increased capabilities to evaluate signals from clinical trials (SUSARs) and measure effectiveness of risk minimization measures
- Performing GPV inspections of all Scientific Offices and Marketing Authorization Holders
- Fining companies who fail to report AEs to SFDA

**Vet drugs**: Establishing PV framework
- Years 1-4: PV department built up capabilities and freed up capacity to start to establish vet PV framework
- Year 5: Established PV framework for vet drugs in line with international standards

**PV interface system**
- Interface for AE reporting for human drugs, vet drugs and herbal drugs
- Interface for collecting complaints on cosmetics and food supplements and passing on to departments
- Collaboration with external stakeholders to improve signal evaluation and management
**Objective 10 – Drug safety**

*Sample of KPIs for Objective 10 – Drug safety*

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<thead>
<tr>
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</table>
| 1  | % increase in Adverse Events reports submitted by practitioners and companies based on level in 2017 | • 2018: 1000% increase from baseline  
• 2019: 50% increase from 2018  
• 2020: 50% increase from 2019  
• 2021: 50% increase from 2020  
• 2022: 50% increase from 2021 |
SFDA should consider a number of access and pricing strategies to address shortages and incentivize registration within the Kingdom

- Initial pricing at registration to control ceiling price
- Regulating Profits
- Making products available to the market
- Support access to medicines in hospitals & via retail pharmacies
- Address long-term drug shortages

Objective 11 – Drug access
## Sample of KPIs for Objective 11 – Drug access

<table>
<thead>
<tr>
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</table>
| 1 | % increase in basic human drug availability in the local market (addressing drug shortages) based on 2017 baseline | • 2018: 10%  
• 2019: 15%  
• 2020: 20%  
• 2021: 25%  
• 2022: 30% |
**Strategic Direction – Medical Devices**

*Medical device evaluation recognition:* Establish risk based evaluation capability for the SFDA that achieves regional and international recognition while simultaneously balancing notified body participation is core to the strategic plan for medical devices. Emphasis will be placed on ensuring equal opportunity for products manufactured by both international and domestic companies.

*Medical device surveillance and safe use:* Enhance collaboration with healthcare providers and establishments along with comprehensive data gathering initiatives will improve adverse event reporting and ultimately lead to safer usage of medical devices. Published guidelines and best practices will provide guidance to industry, setting expectations and improving communication.
The medical devices sector will strengthen evaluation capabilities and adverse event reporting, while promoting the safe use of medical devices

### Objectives for medical devices sector

#### Medical device approvals

- **13** Become an internationally-recognized reference Regulatory Authority by building capabilities to perform independent evaluation within a flexible, risk-based, harmonized evaluation model

#### Proactive surveillance

- **14** Enhance medical device safety and performance by improving adverse event reporting and by collaborating with international Regulators in order to take proactive action against identified issues

#### Safe use of medical devices

- **15** Protect patients and medical device operators by developing guidance and monitoring for safe use of medical devices in healthcare and non-healthcare facilities

### Associated themes

- [ ] Access to safe & effective products
- [ ] Risk based decision making
- [ ] Effective Partnerships
- [ ] Proactive engagement with the public
- [ ] High performing & positive culture
**Objective 13 - Medical device approvals**

*SFDA should up its evaluation capabilities and better manage internal capacity by splitting submission categories between SFDA and CABs*

**Low Risk**
- **Class A** (listing only)
- **Class 2A** (sterile/measurable)
- **Class B**

**High Risk**
- **Class C**
- **Class D**
- **New technology**
- **IVD**

*While New technology and IVD may be part of other product classifications (Class A, B, C, D), SFDA may want to consider evaluation capabilities for these device types separately from the parent classification group.*

**Evaluation capacity**
- **Year 0**
  - Class A: SFDA
  - Class B: SFDA
  - Class C: SFDA
  - Class D: SFDA
  - New technology: SFDA
  - IVD: SFDA

- **Year 5**
  - Class A: SFDA
  - Class B: SFDA
  - Class C: SFDA
  - Class D: SFDA
  - New technology: SFDA
  - IVD: SFDA

**Class A products are MDNR listing-only, and do not require SFDA evaluation**

SFDA will start building capabilities in low-risk devices (Class 2A and B) to support both domestic and international submissions.

At the end of 5 years, SFDA will only review 10% of Class 2A and 50% of Class B submissions in order to allow for fluctuating volumes and to enable training of junior evaluators.

**Class C**
- **SFDA will begin to transition to higher-risk product evaluation once the by-law has been amended**

**Class D**
- **SFDA should start preparing for evaluation of class D devices because the by-law can be amended in 3-6 months**
  - CAB begins with 100% evaluation of Class D and New technology while SFDA builds capabilities and takes over 20% of both classes by Year 5

**New technology**
- SFDA has the 3 year goal of evaluating 100% of IVD submissions

*SFDA will continue to evaluate all clinical investigation/performance evaluation (clinical trials)*
## Sample of KPIs for Objective 13 – Medical device approvals

<table>
<thead>
<tr>
<th>#</th>
<th>KPI</th>
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<tbody>
<tr>
<td>1</td>
<td>% submissions independently reviewed by SFDA on-time and against the target plan, annually (for SFDA evaluated products only, not including CAB evaluations)</td>
<td>• 2020: 60%&lt;br&gt;• 2021: 80%&lt;br&gt;• 2022: 100%</td>
</tr>
<tr>
<td>2</td>
<td>% company satisfaction on timeliness and quality of evaluation</td>
<td>• 2020: &gt; 70%&lt;br&gt;• 2022: &gt; 80%</td>
</tr>
</tbody>
</table>
SFDA should improve Post Market Surveillance (PMS) through better reporting of adverse events and thorough evaluation and enforcement

**Objective 14 - Proactive surveillance**

SFDA collected PMS

- **Manufacturers/ARs**
  - Patient adverse event
  - Field Safety Notice
  - Correction & recalls
  - FSCAs

- **Distributors**
  - Logistical incidents

- **Healthcare Providers**
  - Adverse Event Reporting

- **Consumer/Patients**
  - Voluntary reporting

**PMS data input**

**PMS evaluation & enforcement**

- **Mandatory reporting**
  - In the event the manufacturer is not notified directly

- **Voluntary reporting**

- **Notification**

- **Adverse event/FSN/FSCA/data signal assessment**

- **Conduct data analytics & signal detection**

- **Risk-based filtering of adverse events**

SFDA domestic post-market surveillance database

Domestic market

Voluntary reporting

Two-way interface
Sample of KPIs for Objective 14 & 15 – Surveillance and Safe use of Medical Devices

<table>
<thead>
<tr>
<th>#</th>
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<tbody>
<tr>
<td>1</td>
<td>% increase in adverse events (AEs) reported from healthcare providers</td>
<td>• 2017: baseline</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 2018: 1000%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 2019: 50%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 2020: 50%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 2021: 50%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 2022: 50%</td>
</tr>
<tr>
<td>2</td>
<td>% of Adverse Events reported by healthcare providers and Authorized Representatives with root cause of improper calibration or maintenance</td>
<td>• 2018: baseline</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 2019: 10% decrease from 2018</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 2020: 10% decrease from 2019</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 2021: 10% decrease from 2020</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 2022: 10% decrease from 2021</td>
</tr>
</tbody>
</table>
The enabling objectives are designed to provide the environment and capabilities that are necessary for SFDA to achieve its objectives.

<table>
<thead>
<tr>
<th>Enabling objectives</th>
<th>Associated themes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>People, Culture &amp; Organization</strong></td>
<td></td>
</tr>
<tr>
<td>Increase organizational performance by fostering a collaborative and accountable culture, attracting and retaining talent, and clarifying responsibilities</td>
<td>✔ ✔ ✔</td>
</tr>
<tr>
<td><strong>Technology</strong></td>
<td></td>
</tr>
<tr>
<td>Design an IT strategy that is aligned with SFDA’s business requirements and improves decision-making and operational effectiveness by deploying innovative systems</td>
<td>✔ ✔ ✔</td>
</tr>
<tr>
<td><strong>Awareness</strong></td>
<td></td>
</tr>
<tr>
<td>Engage proactively with the public and other external stakeholders to promote safe and informed use of products and foster trust in SFDA</td>
<td>✔ ✔ ✔</td>
</tr>
<tr>
<td><strong>International presence</strong></td>
<td></td>
</tr>
<tr>
<td>Increase SFDA’s role in the international community through effective collaboration, scientific contributions and mutual exchange of know-how</td>
<td>✔ ✔ ✔</td>
</tr>
</tbody>
</table>
**Sample of KPIs for Objective 16 – People, Culture & Organization**

<table>
<thead>
<tr>
<th>#</th>
<th>KPI</th>
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<tbody>
<tr>
<td></td>
<td>Employee satisfaction rate (%)</td>
<td>• 2018: Baseline</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 2019: Baseline + 5%</td>
</tr>
<tr>
<td>1</td>
<td></td>
<td>• 2020: 2019 + 5%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 2021: 2020 + 3%</td>
</tr>
<tr>
<td></td>
<td></td>
<td>• 2022: 2021 + 2%</td>
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</tbody>
</table>

Note: 1) Raw data for number, location and type of site (manufacturers and distributors) was provided by the sectors
### Sample of KPIs for Objective 18 – Awareness

<table>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>User satisfaction rating of interaction with SFDA’s Business Support Centres (%)</td>
<td>• 2018: baseline&lt;br&gt;• 2019: 2018 + 10%&lt;br&gt;• 2020: 2019 + 5%&lt;br&gt;• 2021: 2020 + 5%&lt;br&gt;• 2022: 2021 + 3%</td>
</tr>
<tr>
<td>2</td>
<td>Percentage of consumers who are aware of SFDA services and awareness campaigns (%)</td>
<td>• 2017: 61%&lt;br&gt;• 2018: 68%&lt;br&gt;• 2019: 74%&lt;br&gt;• 2020: 80%</td>
</tr>
<tr>
<td>3</td>
<td>Public trust in SFDA (Food, Drugs and MD) (%)</td>
<td>• 2018: baseline&lt;br&gt;• 2019: 2018 + 10%&lt;br&gt;• 2020: 2019 + 5%&lt;br&gt;• 2021: 2020 + 5%&lt;br&gt;• 2022: 2021 + 3%</td>
</tr>
<tr>
<td>4</td>
<td>Number of followers on SFDA social media channels (#)</td>
<td>• 2018: baseline&lt;br&gt;• 2019: 2018 + 10%&lt;br&gt;• 2020: 2019 + 5%&lt;br&gt;• 2021: 2020 + 5%&lt;br&gt;• 2022: 2021 + 3%</td>
</tr>
</tbody>
</table>