GÜNEY AFRİKA SAĞLIK SEKTÖRÜ ONLINE BİLGİLENDİRME SEMİNERİ İKMİB SUNUMU

GÜNEY AFRİKA

Sağlık Sektörü Online Bilgilendirme Semineri

İKMİB İstanbul Kimyevi Maddeler ve Mamulleri İhracatçıları Birliği

Turkish Healthcare

İÇERİK

- İKMİB Hakkında
- İKMİB – Sağlık Sektörü Faaliyetleri

İKMİB İstanbul Kimyevi Maddeler ve Mamulleri İhracatçıları Birliği

Turkish Healthcare

İKMİB HAKKINDA

İKMİB İstanbul Kimyevi Maddeler ve Mamulleri İhracatçıları Birliği

Turkish Healthcare

İKMİB HAKKINDA

İstanbul Kimyevi Maddeler ve Mamulleri İhracatçıları Birliği (İKMİB) 1991 yılında Türk ihracatçısının kimya ve mamulleri sektöründeki lider temsilcisi olarak kurulmuştur.

Birlik, ulusal ölçekte kimya endüstrisinde resmi olarak 18.000 den fazla ihracatçıyı kapsamaktadır ve bunların yaklaşık 8.500'ü aktif üye ve dünya çapında ihracatçıdır.

Birliğimiz, Türkiye İhracatçılar Meclisi (TİM) bünyesindeki İstanbul Maden ve Metaller İhracatçı Birlikleri (İMMİB) Genel Sekreterliği ile bağlı ve nihai olarak Türkiye Cumhuriyeti Ticaret Bakanlığı'na bağlı olarak hizmet vermektedir.

İKMİB
Sağlık Sektörü Faaliyetleri

İKMİB İstanbul Kimyevi Maddeler ve Mamulleri İhracatçıları Birliği

Turkish Healthcare

İKMİB- SAĞLIK SEKTÖRÜ FAALİYETLERİ

- MİLLİ KATILIM ORGANİZASYONU
- TİCARET HEYETLERİ
- KOMİTE TOPLANTILARI
- URGE PROJELERİ

Milli Katılım Organizasyonlarımız

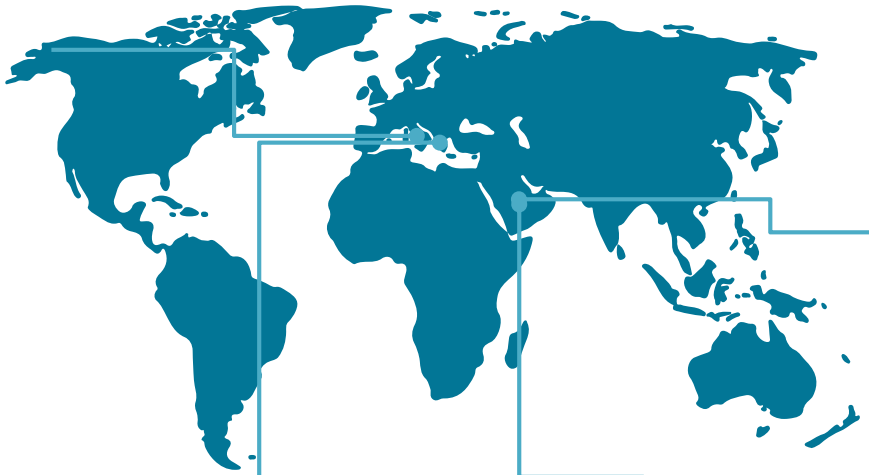
İKMİB İstanbul Kimyevi Maddeler ve Mamulleri İhracatçıları Birliği

Turkish Healthcare

PLANLANAN MİLLİ KATILIM ORGANİZASYONLARIMIZ

Medica

13-16 Kasım 2023
Düsseldorf/ Almanya
Nakliye Dahil : 880 € /m2
Nakliye Hariç : 850 € /m2



Arab Health

29 Ocak-1 Şubat 2024
Dubai- BAE
Nakliye Dahil: 1.865 $/m2
Nakliye Hariç: 1.815 $/m2
2023 Milli Kat Firma S.:45 -666 m2 Bireysel :136

IDS

25-29 Mart 2025
Köln/ Almanya
Duyuruya çıkılacaktır.

AEEDC

6-8 Şubat 2024
Dubai- BAE
Duyuruya çıkılacaktır.

MİLLİ KATILIM ORGANİZASYONLARIMIZ

Medica 2022
Medikal Sektörü
12. Milli Katılım Organizasyonu
Milli Katılımcı Sayısı 34

Arab Health 2023
Medikal - OTC Sektörü
4. Milli Katılım Organizasyonu
Milli Katılımcı Sayısı 45

İKMİB İstanbul Kimyevi Maddeler ve Mamulleri İhracatçıları Birliği

Turkish Healthcare

MİLLİ KATILIM ORGANİZASYONLARIMIZ

AEEDC 2023
Dental Sektörü
4. Milli Katılım Organizasyonu
Milli Katılımcı Sayısı :25

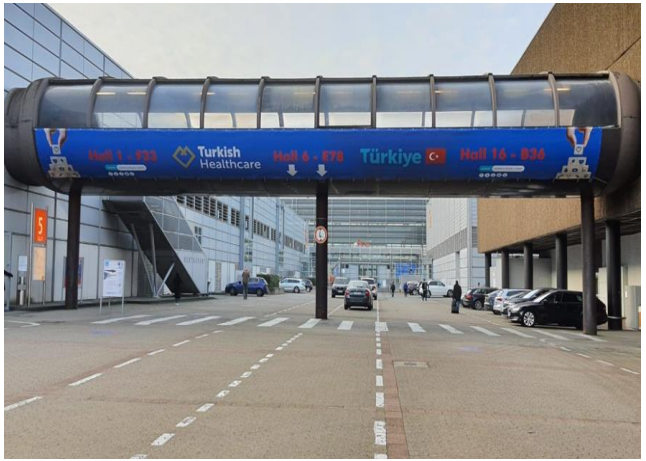
IDS 2023
Dental Sektörü
2. Milli Katılım Organizasyonu
Milli Katılımcı Sayısı 10

İKMİB İstanbul Kimyevi Maddeler ve Mamulleri İhracatçıları Birliği

Turkish Healthcare

MİLLİ KATILIM ORGANİZASYONLARIMIZ

FUARLARA YÖNELİK TANITIMLARIMIZ



TİCARET HEYETLERİMİZ

KENYA İLAÇ MEDİKAL SEKT. TİCARET HEYETİ 2018

Katılımcı firma sayısı 16

Yabancı firma sayısı 92

VİETNAM İLAÇ MEDİKAL SEKT. TİCARET HEYETİ 2019

Katılımcı firma sayısı 14

Toplam Görüşme Sayısı 121

SEKTÖREL KOMİTE TOPLANTILARI

Tıbbi Cihaz Sektörü Komite Toplantısı

İlaç Sektörü Komite Toplantısı

ALIM HEYETLERİMİZ

EXPOMED 2022

Katılımcı firma sayısı: 6
Yapılan görüşme sayısı :11
Bahreyn, Kırgızistan, Moritanya, Svaziland
Tunus ve Yunanistan

IDEX 2022

Katılımcı firma sayısı: 12
Yapılan görüşme sayısı : 4
Azerbaycan, Bosna-Hersek, Kosova
Moğolistan, Kosova ve Sudan

UR-GE PROJELERİMİZ

DEVAM EDEN PROJELER

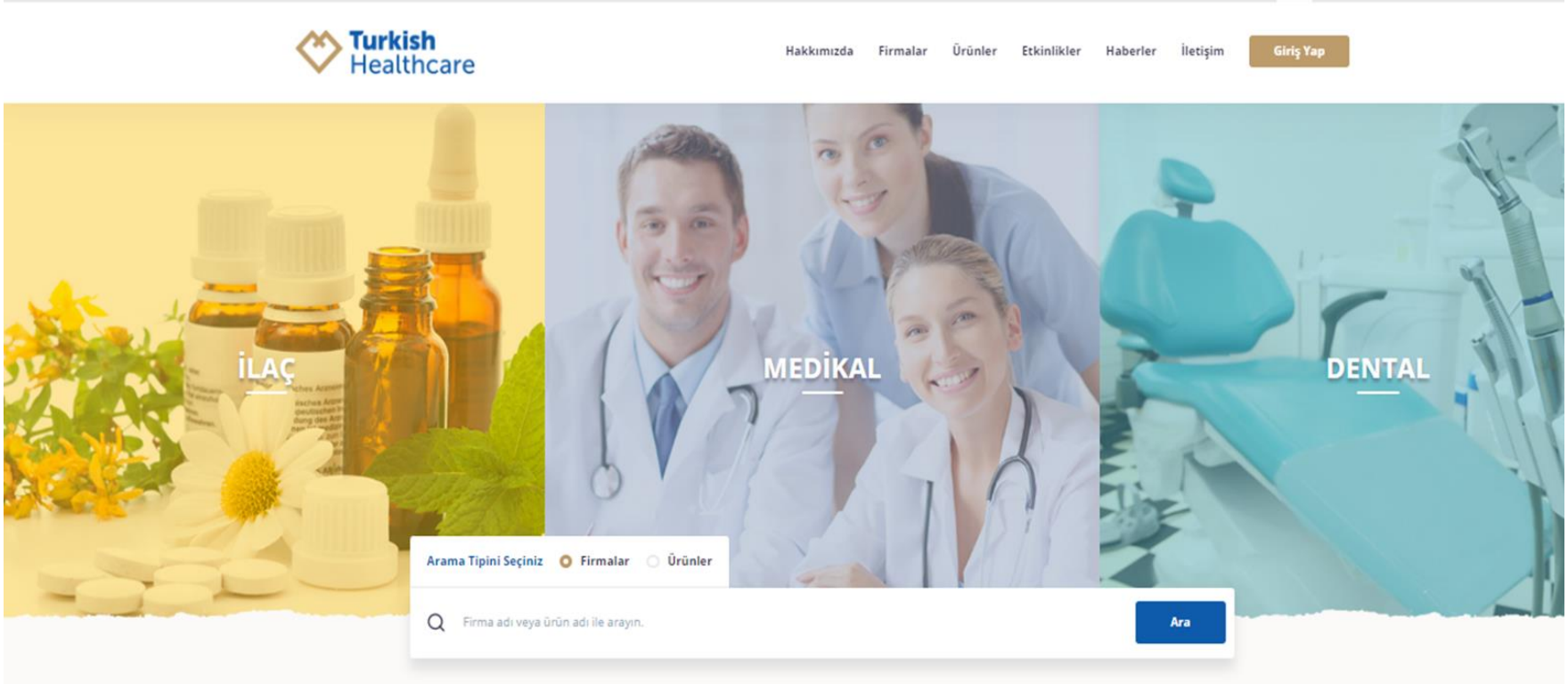
1. *HealthTech Start-Up UR-GE Projesi*
2. *In-Vitro Diagnostic Industries Cluster*

BAŞVURUSU ALINAN PROJEMİZ

Tıbbi Cihaz - İlaç - Dental Sektörleri UR-GE Projesi

MUHTELİF TANITIM FAALİYETLERİMİZ

WEB SİTEMİZ



İKMİB İstanbul Kimyevi Maddeler ve Mamulleri İhracatçıları Birliği

Turkish Healthcare

İKMİB SAĞLIK EKİBİ İLETİŞİM BİLGİSİ

turkishhealthcare@ikmib.org.tr

Adresinden bize ulaşabilirsiniz.

İKMİB İstanbul Kimyevi Maddeler ve Mamulleri İhracatçıları Birliği

Turkish Healthcare


Teşekkürler!

GÜNEY AFRİKA SAĞLIK SEKTÖRÜ ONLINE BİLGİLENDİRME SEMİNERİ
GÜNEY AFRİKA TİCARET MÜŞAVİRLİĞİ SUNUMU

TÜRKİYE CUMHURİYETİ
TİCARET BAKANLIĞI

GÜNEY AFRİKA CUMHURİYETİ

Ülke Sunumu

Pretoria Ticaret Müşavirliği

İlker Eralp & Bengü Okur Erdoğan

24 Mayıs 2023

Nüfus:
60,6 milyon (2022-StatsSA)
- %80,2 Siyahi Afrika kökenli;
- % 8,8 melez;
- % 8,4 beyaz;
-%2,5 Hint/Asya kökenli

Dil:
(11) İngilizce, Afrikaans, Zulu, Spedi, Swati ..

9 Eyalet:
Guateng (%24), Kwazulu-Natal (%20), Limpopo, Mpumalanga, Norht-West, Free State, Nothern Cape, Eastern Cape (%12), Western Cape (%11)

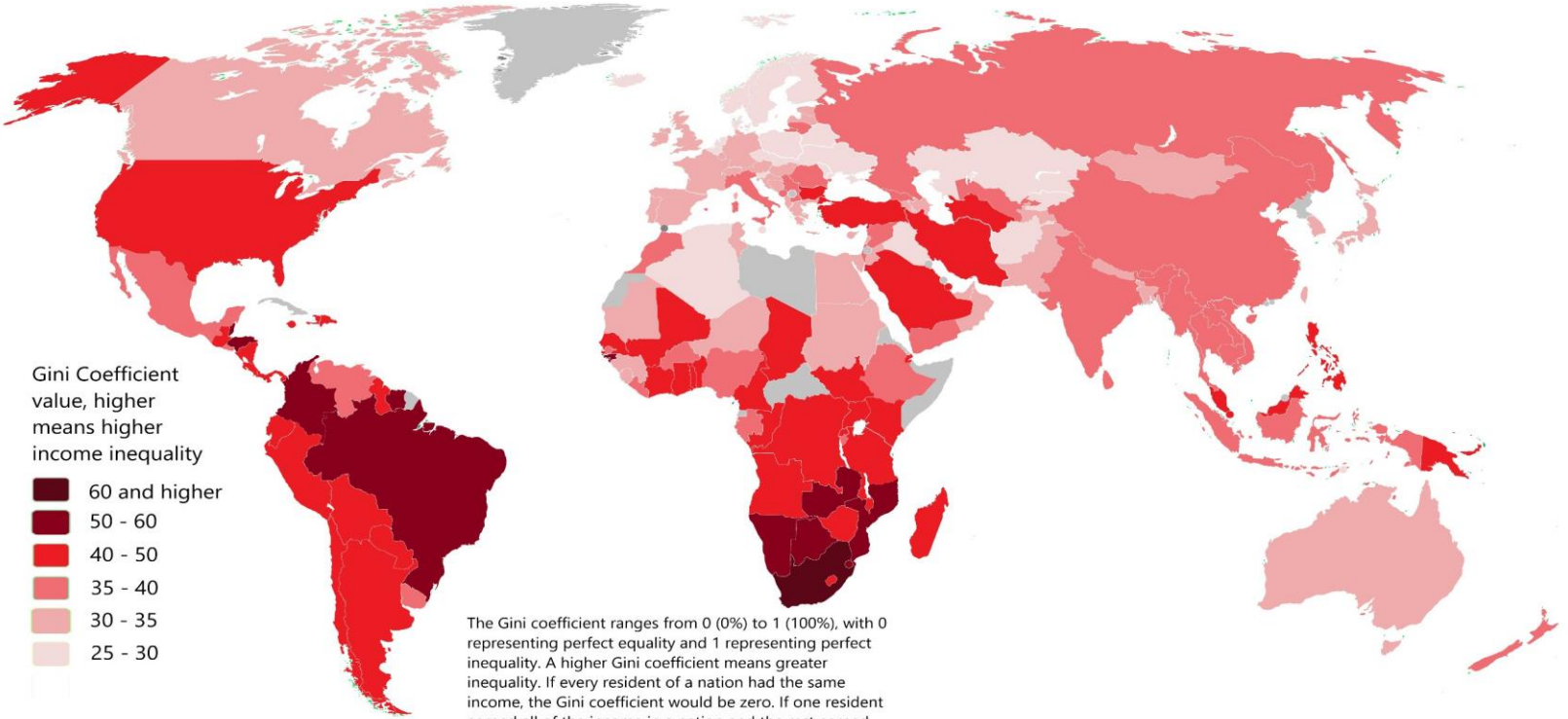
Başkentler:
- Pretoria (yürütme),
- Cape Town (yasama),
- Bloemfontein (yargı)

Önemli Ticari Merkezler:
- Johannesburg, Durban, Cape Town (Başkosolosluk), Port Elizabeth, Pretoria (BE, Ticaret Müşavirliği)

Güney Afrika Cumhuriyeti

Townships

Güney Afrika Cumhuriyeti – Gini Katsayısı



The Gini coefficient ranges from 0 (0%) to 1 (100%), with 0 representing perfect equality and 1 representing perfect inequality. A higher Gini coefficient means greater inequality. If every resident of a nation had the same income, the Gini coefficient would be zero. If one resident earned all of the income in a nation and the rest earned zero, the Gini coefficient would be 1.

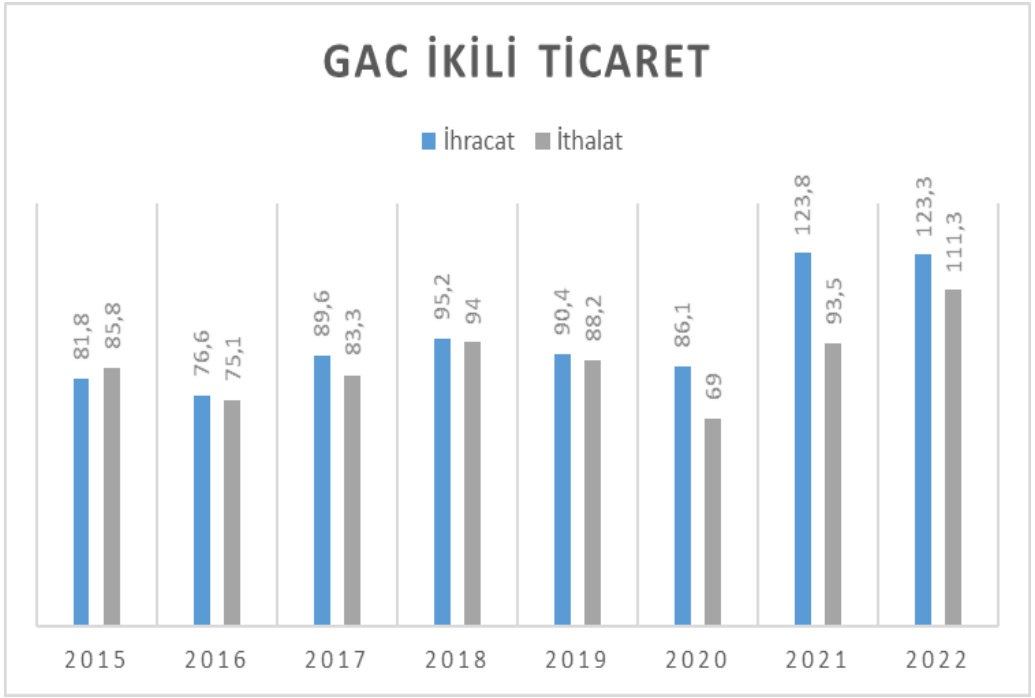
Temel Ekonomik Göstergeler (2022)

GSYİH (Nominal) (2022-IMF)	405 milyar $ **/W 31./AF 2. /NIJ.**
KİŞİ BAŞINA GSYİH (2022-IMF)	6,694 **$;** 13.200 $ (SAGP**-2022**)
GSYİH BÜYÜME HIZI (Reel-IMF)	**2022: %2, 2021: %5 2023 Tahmin (%0,5-1), (2024: 0,7; 2025: %1**
İHRACAT (2021)	123,3 milyar $ (2022 123,8 milyar **$**)
İTHALAT (2021)	111,3 milyar $ (**2022 93,5 milyar $)**
Dış Ticaret Dengesi (2021)	+ 12 milyar $ **(2022 + 30,3 milyar $)**
Cari İşlemler Dengesi/ GSYH (%)	% 0,5 (2022 - % 3,7)

Temel Ekonomik Göstergeler (2022)

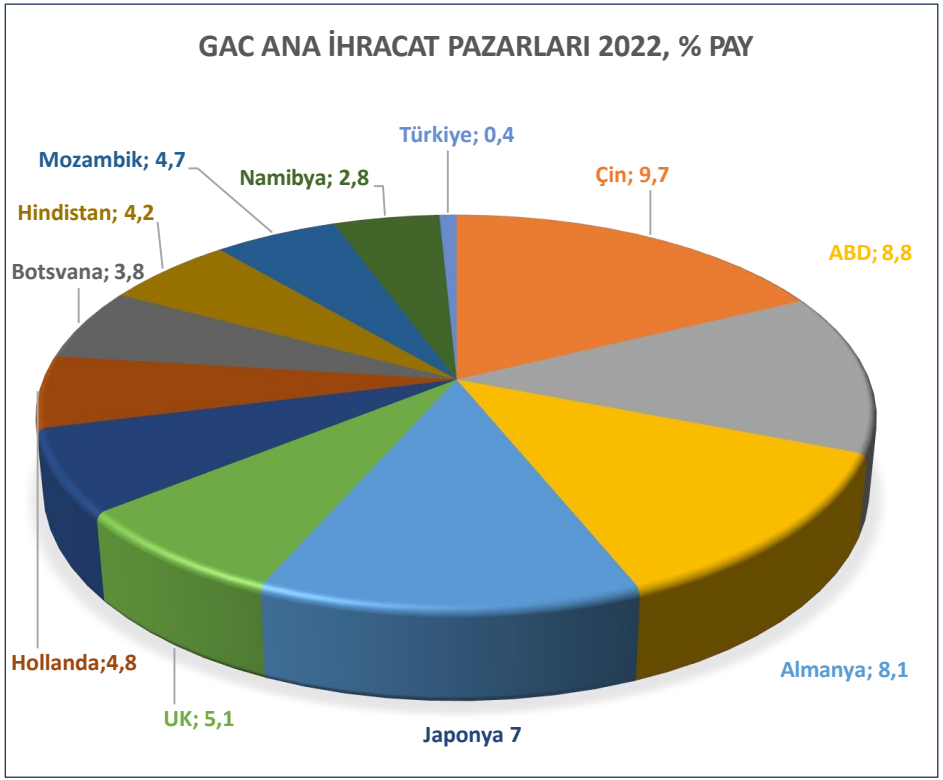
İŞSİZLİK ORANI (2022 2. çeyrek)	%32,7 (2022) (Genişletilmiş tanımla %41,1; Genç işsizlik %59,6)
ENFLASYON ORANI (2022 Aralık)	%7
Asgari Ücret	2023: 25.5 Rand (2022: 23.19 Rand)
Döviz Kuru (24 Mayıs 2023)	Rand/TL – 1,03 USD/Rand – 19,23
DÜNYA BANKASI İŞ YAPMA KOLAYLIĞI SIRALAMASI (2020)	84/190
GSYİH'NİN SEKTÖREL DAĞILIMI	Tarım: %2,5 Sanayi: %24 Hizmetler: %64,5 (2022)
BAŞLICA SANAYİ DALLARI	Madencilik (Dünyanın en büyük platin, altın ve krom üreticisi), motorlu taşıt üretimi ve montajı, makine-teçhizat, çelik ve demir-dışı metaller, gemi bakım-onarımı, kimyasallar, gübre ve işlenmiş gıda

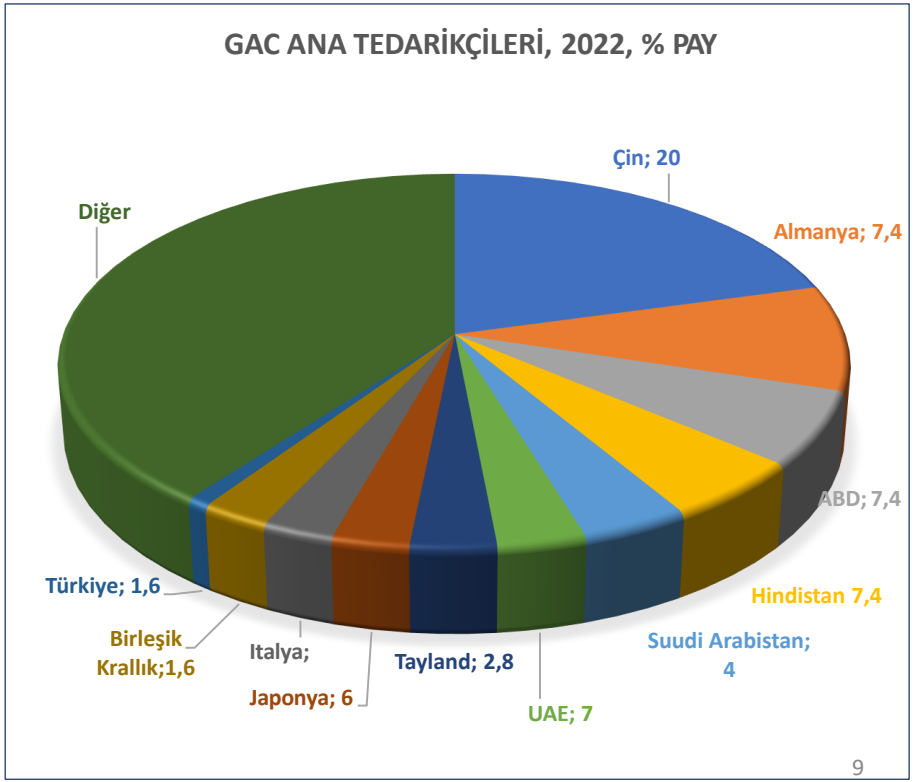
Dış Ticaret (2022) – Ürün Grupları



BAŞLICA İHRAÇ ÜRÜNLERİ (2022)	**PLATIINUM, PALADYUM, RODYUM, KÖMÜR, MANGAL KÖMÜRÜ, DEMİR, CEVHERİ, ALTIN, DİĞER KIYMETLİ METAL VE TAŞLAR, MANGANEZ, FERRO-KROM, KROM, ALUMİNYUM GİBİ MADEN CEVHERLERİ, MOTORLU KARA YOLU TAŞITLARI, MİNERAL YAKIT VE YAĞLAR, ELMAS, ŞARAP** **TARIM: NARENCİYE, MISIR, ÜZÜM**
BAŞLICA İTHALAT ÜRÜNLERİ (2022)	**PETROL ÜRÜNLERİ, MİNERAL YAKIT VE YAĞLAR, MAKİNE VE AKSAMLARI, CEP TELEFONLARI VE BİLGİSAYARLAR, MOTORLU KARAYOLU TAŞITLARI VE PARÇALARI, ÜRE, TRAKTÖRLER VE PARÇALARI, PİRİNÇ, BUĞDAY, PALMİYE YAĞI, TEKSTİL ÜRÜNLERİ, , İLAÇ-**

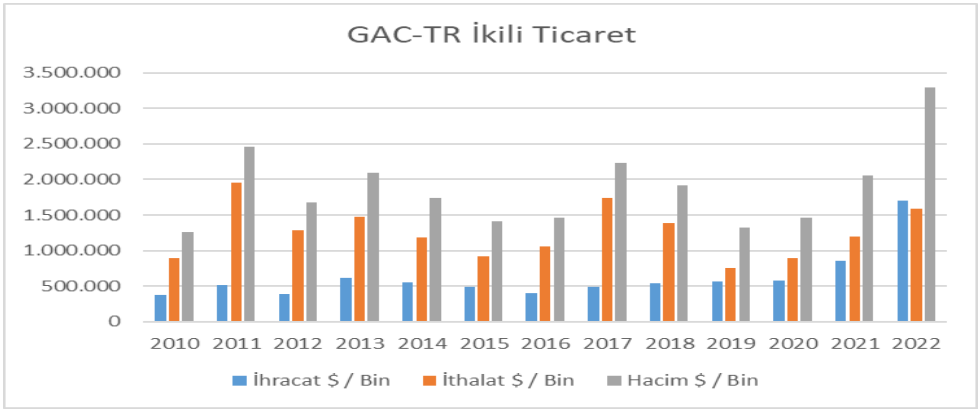
Dış Ticaret (2022) - Paydaşlar





TR-GAC İkili Ticari İlişkiler

Yıl	İhracat $ / Bin	İhracat Değişim %	Genel İhracata Oranı %	İthalat $ / Bin	İthalat Değişim %	Genel İthalata Oranı %	Hacim $ / Bin	Denge $ / Bin
2011	510.523	38,3	0,38	1.954.586	119,7	0,81	2.465.109	-1.444.063
2012	381.772	-25,2	0,25	1.289.821	-34,0	0,55	1.671.593	-908.049
2013	619.718	62,3	0,41	1.479.338	14,7	0,59	2.099.056	-859.621
2014	545.232	-12,0	0,35	1.189.352	-19,6	0,49	1.734.584	-644.120
2015	489.162	-10,3	0,34	918.541	-22,8	0,44	1.407.703	-429.379
2016	405.943	-17,0	0,28	1.058.114	15,2	0,53	1.464.057	-652.170
2017	485.070	19,5	0,31	1.744.438	64,9	0,75	2.229.508	-1.259.368
2018	534.231	10,1	0,32	1.381.537	-20,8	0,62	1.915.767	-847.306
2019	569.560	6,6	0,31	754.214	-45,4	0,36	1.323.774	-184.654
2020	574.029	0,8	0,34	887.896	17,7	0,40	1.461.925	-313.867
2021	861.263	50,0	0,38	1.192.742	34,3	0,44	2.054.004	-331.479
2022	1.706.159	98,1	0,67	1.585.297	32,9	0,44	3.291.456	120.862



BAŞLICA İHRAÇ ÜRÜNLERİ (2022)	Mineral yakıt ve yağlar, motorlu kara taşıtları, çamaşır, bulaşık ve kurutma makinaları, traktör ve traktör parçaları, tekstil ürünleri, demir-çelik ürünleri, kakao içeren ve içermeyen şekerlemeler, kauçuk (oto lastikleri), plastikler, elektrikli su ısıtıcıları, halılar, bakır teller, makineler ve aksamı
BAŞLICA İTHAL ÜRÜNLERİ (2022)	Altın, taşkömürü, santrifüjler, motorlu taşıtlar, demir, krom vb. maden cevherleri, alüminyum, demir-çelik ürünleri, motorlu taşıtlar, lazerler, sakatat ve kabuklu deniz hayvanı, balık unu/yemi

TR-GAC İkili Ticari İlişkiler - Şirketlerimiz

Türk Şirketleri
- **DEFY**
- **ASELSAN**
- **THY**
- **AKSA**
- **SAMPA**

Sektörler
- Otomotive yedek parça
- Tekstil, hazır giyim
- Restaurant
- Turizm
- Kuru gıda, şekerleme
- Mobilya
- Halı, ev tekstili
- Plastik
- Kablo

Diğer
50-70 Türk Şirketi

TURKISH AIRLINES
A STAR ALLIANCE MEMBER

aksa POWER GENERATION

Yatırımlar (2002 – 2022)
- TR'nin GAC'taki yatırımları : 30 Milyon USD
- GAC'nin TR'deki Yatırımları: 270 Milyon USD

aselsan

DEFY

SAMPA


makro


WOOLWORTHS


Pick n Pay


SHOPRITE


THE
CRAZY
STORE


PEPKOR


Checkers


Mr Price


Dis-Chem
PHARMACIES


SPAR


game


CLICKS

TÜRKİYE CUMHURİYETİ
TİCARET BAKANLIĞI

SAĞLIK SEKTÖRÜ

Genel Bilgiler -1

En fazla görülen hastalıklar: - HIV/AIDS/TB

- Diyabet, Kardiyovasküler hastalık, hipertansiyon, kanser
- Travma (kurşun, bıçak yaralanmaları, kişiler arası şiddet)

Sağlık Sistemi: 1) Kamu : Nüfusun % 85'ine hitap ediyor.

Ulusal Sağlık Sigortası Programı (NHI)

GSYİH'ın % 9'u, Toplam sağlık harcamalarının % 49'u.

2) Özel: **Nüfusun % 15'ine hitap ediyor.**

Özel Sağlık Sigortası

Gelişmiş yüksel teknolojili ürünlerle tedavi

Genel Bilgiler-2

4 Büyük Hastane Grubu:

1 Netcare Limited,
https://www.netcare.co.za/

2 Life Healthcare Group,
https://www.lifehealthcare.co.za/

3 Mediclinic Southern Africa,
https://www.mediclinic.co.za/

4 LenMed Private Hospitals,
https://www.lenmed.co.za/

Pazara Giriş Bilgileri

- **Tabi olduğu Teknik Kurallar:** South Africa Health Products Regulatory Authority

  https://www.sahpra.org.za/acts-and-regulations/

  (GAC'da yerleşik yetkili temsilci*)

- **Tabi olduğu Gümrük Vergisi:** % 0-3 (30 ve 90. fasılların ilgili GTIP'leri, tıbbi cihaz, eczacılık ürünleri)

- **Sektörel Birlikler:** The South African Medical Technology Industry Association (SAMED), https://samed.org.za/

  Medical Device Manufacturers of South Africa, https://mdmsa.org.za/

  Hospital Associations South Africa, https://hasa.co.za/

  The Innovative Pharmaceutical Association of South Africa, https://ipasa.co.za/

- **Önemli Fuarlar:** Africa Health, 17-19 Ekim 2023, Johannesburg (Uzak Ülkeler Stratejisi)

  https://www.africahealthexhibition.com/en/home.html

Tıbbi Cihaz Sektörü Market Büyüklüğü

Tablo: Tıbbi Cihaz Sektörü 2020-2023				
	2020	**2021**	**2022 (tahmin)**	**2023 (tahmin)**
Toplam	1.07	1.021	1.068	1.118
İthalat	0.963	0.918	0.96	1.0
İhracat	0.107	0.102	0.112	0.162

Fitch, Milyar dolar

İlaç Sektörü Market Büyüklüğü

Tablo: İlaç Sektörü; 2020-2023					
		2020	**2021**	**2022 (tahmini)**	**2023(tahmini)**
Reçeteli Satış		2.57	2.70	2.84	2.97
Innovator Drugs		1.45	1.50	1.53	1.56
Generics		1.12	1.20	1.31	1,40
OTC (Reçetesiz)		0.32	0.33	0.33	0.34

TÜRKİYE CUMHURİYETİ
TİCARET BAKANLIĞI

TEŞEKKÜRLER!

İlker ERALP Tica
ret Müşaviri
Tel (Voip): 0312 204 8343

Bengü Okur Erdoğan
Ticaret Müşaviri
Tel (Voip): 0312 204 8292

T.C. Pretoria Büyükelçiliği Ticaret Müşavirliği
Tel: + 27 12 342 6051
E-posta: pretoria@ticaret.gov.tr

dtpre@global.co.za

GÜNEY AFRİKA SAĞLIK SEKTÖRÜ ONLINE BİLGİLENDİRME SEMİNERİ
SAHPRA SUNUMU

SAHPRA
South African
Health Products
Regulatory Authority

Medical Devices Unit

Candidate info

- Oneaho Monyileote holds a B. Sc honours in Medical Sciences, from the University of Limpopo. She has technical experience in various molecular biology techniques, Quality control and Quality Assurance including developing and implementing quality management systems for ISO 9001, 17025 and 13485. One joined SAHPRA in Dec 2022 as a Medicine Registration Officer under the Licencing subdivision.

- Puseletso Mogano holds a MSc(Med) in Pharmacy, from the University of Limpopo. Apart from regulatory environment, having worked for SAPC for over 5 years, and now with SAHPRA, she has more than 10 years experience in public, private, academic, pharmaceutical industry, Managed Healthcare, and non-governmental environment. She joined SAHPRA in September 2022 as the Medical Devices Manager, responsible for Licencing, Vigilance and Compliance.

- About SAHPRA
- Vision, Mission and Values
- Legislative framework
- Background
- Medical Devices (IVDs)
- Application process
- Non- compliance

- An entity of the National Department of Health
- Pillars: Safety, Efficacy & Quality
- Tasked : regulating (monitoring, evaluating, investigating, inspecting and registering) all health products.
  - clinical trials, complementary medicines, medical devices and in vitro diagnostics (IVDs)
- Medicines and Related Substances Act (Act No 101 of 1965 as amended) as well as the Hazardous Substances Act (Act No 15 of 1973).


Vision
A agile and responsive African Health products regulator that is globally recognised an enabler of access to safe, effective and quality health products in South Africa.
Values
Ubuntu
Responsiveness
Integrity
Transparency
Efficiency
Excellence
Mission
To promote access to health products and protect human and animal health in south Africa through making science-based regulatory decisions

- **The Constitution of the Republic of South Africa, 1996;**
- **The National Health Act, 2003 (Act No. 61 of 2003);**
- **Medicines and Related Substances Act, 1965 (Act 101 of 1965) , as amended;**
- **Hazardous Substances Act, 1973 (Act No. 15 of 1973)**
  - Provides for the establishment of a new regulatory authority (SAHPRA)
  - Provides for transition of MCC to SAHPRA
  - Provides for expansion of the regulatory mandate of the Authority to include the regulatory oversight of Medical Devices
  - Promulgation: June 2017
- **Regulations for Medical Devices & IVDs:**
  - Publication 9 December 2016, Government Gazette No 40480, No 1515

- Medical devices play a major role in health systems, th ey are needed to address the burden of disease, econo mic challenges, and infrastructure of African nations rat her than just using medical devices that were designed for the needs and resources of high-income countries.

- The regulation of medical products has become increa singly complex with the globalization of product develo pment, production and supply and the rapid pace of tec hnological and social change in the context of limited fi nancial and human resources.

- any instrument, appliance, material, machine, apparatus, implant or diagnostic reagent-

  (a) used or purporting to be suitable for use or manufactured or sold for use in-

  (i) the diagnosis, treatment, mitigation, modification, monitoring or prevention of dis ease, abnormal physical or mental states or the symptoms thereof; or

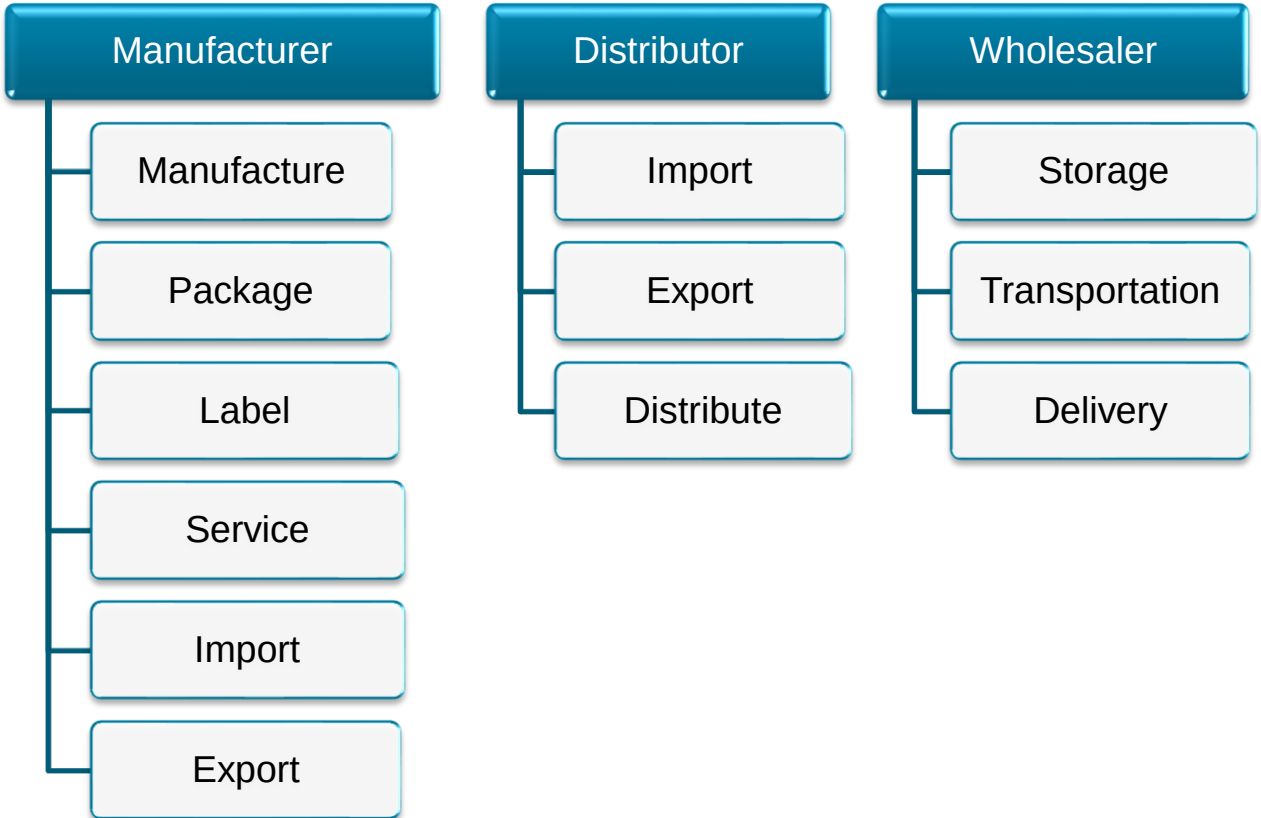
  (ii) restoring, correcting or modifying any somatic or psychic or organic function; or

  (iii) the diagnosis or prevention of pregnancy, and which does not achieve its purpose through chemical, pharmacological, immunological or metabolic means in or on the h uman body but which may be assisted in its function by such means; or

  (b) declared by the Minister by notice in the Gazette to be a medical device, and includes any part or an accessory of a medical device

Medical Devices Establishment licence

- Three types of licences for medical device establishments as per Section 22C of the Medicines and related substance Act 101 of 1965:



License

In terms of Section 22C(1)(b) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) and Regulation 5 of the General Regulations on Medical Devices:

- A manufacturer,
- distributor (including importer and/or exporter) or
- Wholesaler referred to in Section 22C(1)(b) of the Act

Prior to commencing business, organisations needs to apply to SAHPRA for a licence to manu facture, distribute (including import and/or export) and/or wholesale medical devices or IVDs ;

and

Appoint and designate an Authorised Representative who must reside in South Africa and be responsible to SAHPRA for compliance with the Act.

The classification levels for medical devices are:

Classification	Level of risk
Class A	Low risk
Class B	Low–moderate risk
Class C	Moderate – high risk
Class D	High risk Where risk relates to the patient or to public health

Post Marketing Activities = Vigilance: AEs, Complaints, Issuing of permits

Enforcement activities

Investigations/recalls

Performance Evaluation (Laboratory tests): Covid-19 test kits

Clinical trials

RUO

Advertising Management

Donations management

Conformity Assessment Bodies

Application for an establishment licence

- Any individual/company, located in South Africa must submit an application to SAHPRA to be licensed as a manufacturer/distributor/wholesaler of a medical device/s.
- The application forms are available on the SAHPRA website (www.sahpra.org.za):

- a. 6.21 Licence to Manufacture (Manufacture/Import/Export/Distribute)
- b. 6.22 Licence to Distribute (Import/Export/Distribute)
- c. 6.26 Licence to Wholesale (Wholesale)

Show 10 entries Search:

Number	File Name	Year	Version	Document Type	Download
6.21	Licence Application Medical Device Manufacture	2016	3	Application Form	DOWNLOAD FORM
6.22	Licence application to distribute (import/export) medical devices	2016	1.2	Application Form	DOWNLOAD FORM
6.26	Licence application to wholesale medical devices	2017	2	Application Form	DOWNLOAD FORM

- 16.03 Guideline for a Licence to Manufacture, Import, Export or Distribute Medical Devices and IVDs provides guidance pertaining to the requirements for the licence application process.

Application submission

- Cover Letter
- Quality related document (per product risk and application requirements)
- Quality Manual/Site Master File
- **Signed Application form** in both:
- Excel spreadsheet
- PDF copy
- Proof of Payment (PoP)

- **Email: mdcovid@sahpra.org.za & mdadmin@sahpra.org.za**

Fees Payable

1. Manufacturer= R25 200
2. Distributor = R15 000
3. Wholesaler = R15 000

Reference documents on the website:

- MD019: Processing of MD establishment license applications made to SAHPRA
- 16.03: License Medical Devices IVD's

Communication Response :

- Cover Letter
- Response to queries as indicated i n query letter (follow the numberin g for easier reference)
- Respond to all identified queries in one communication

Payment/Fees
R3400

SAHPRA
South African Health Products Regulatory Authority

SAHPRA Head Office
Building A
Loftus Park
2nd Floor
402 Kirkness Road
Arcadia
0083

Enquiries: Medical Device Unit
Tel: 012 501 0300
Email: [ ]
Reference: [ ]

[Company Name]
[Company Address]

Telephone number [ ]
E-mail address [ ]

ATTENTION:

Dear Sir/Madam,

RE: NOTIFICATION OF LICENCE APPROVAL
NEW/ AMENDMENT TO MEDICAL DEVICE ESTABLISHMENT LICENCE

1. This letter serves as notification to the applicant that the licence for a medical device establishment has been approved by SAHPRA.
2. Kindly note that the licence collection fee is now payable in terms of the fees regulation 6(d) of Section 22C(1)(b) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965).

3. Payment should be made to:

Bank: ABSA
ACCOUNT NAME: SOUTH AFRICAN HEALTH PRODUCTS REGULATORY AUTHORITY
ACCOUNT TYPE: CHEQUE ACCOUNT
ACCOUNT NO: 40-5939-2080
BRANCH CODE: 632005

4. Kindly use payment reference "MD" followed by the company name
5. Kindly email proof of payment to xxx (Email: xxx)

Yours faithfully,

_____

Name:
Designation:
Date: Date

- AMENDMENT OF AN EXISTING SAHPRA LICENCE
- Medical device establishments that have a valid SAHPRA licence may not manufacture, distribute a nd/or wholesale medical devices that have not been listed on their licence application.

- Medical device establishments that have a valid SAHPRA licence and that are authorised to manuf acture, distribute and/or wholesale Class A, B, C and/or Class D medical devices must apply for a li cence amendment to update the product listing and include any COVID-19 molecular test kit/s (cla ssified as Class D medical devices).

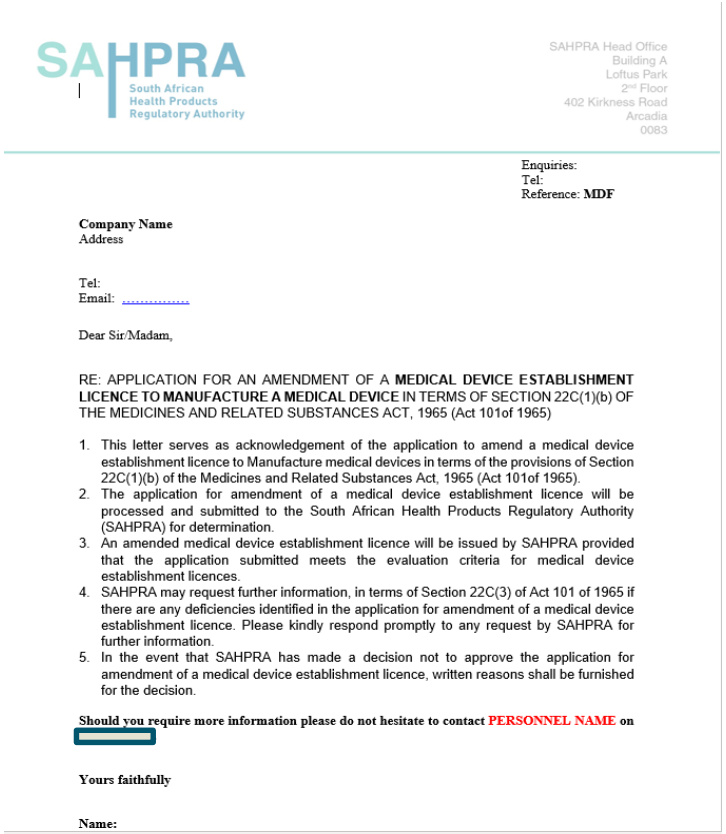
- The notification process for the amendment of a SAHPRA medical device establishment licence ma y not be used for Class D COVID-19 molecular test kits.

- Medical device establishments that have a valid SAHPRA licence may not manufacture, distribute a nd/or wholesale COVID-19 molecular test kits, included in the application for licence amendment, until authorisation has been received from SAHPRA to do so.

Cover Letter

1. Quality related document (per product risk and application requirements)
2. Quality Manual/Site Master File
3. **Signed Application form** in both:
   a. Excel spreadsheet
   b. PDF copy
1. Proof of Payment (PoP)
2. Revised application form as application form (Amendment)

Payment/Fees
R5300



SAHPRA
South African Health Products Regulatory Authority

SAHPRA Head Office
Building A
Loftus Park
2nd Floor
402 Kirkness Road
Arcadia
0083

Enquiries:
Tel:
Reference: **MDF**

Company Name
Address

Tel:
Email: .....

Dear Sir/Madam,

RE: APPLICATION FOR AN AMENDMENT OF A **MEDICAL DEVICE ESTABLISHMENT LICENCE TO MANUFACTURE A MEDICAL DEVICE** IN TERMS OF SECTION 22C(1)(b) OF THE MEDICINES AND RELATED SUBSTANCES ACT, 1965 (Act 101of 1965)

1. This letter serves as acknowledgement of the application to amend a medical device establishment licence to Manufacture medical devices in terms of the provisions of Section 22C(1)(b) of the Medicines and Related Substances Act, 1965 (Act 101of 1965).
2. The application for amendment of a medical device establishment licence will be processed and submitted to the South African Health Products Regulatory Authority (SAHPRA) for determination.
3. An amended medical device establishment licence will be issued by SAHPRA provided that the application submitted meets the evaluation criteria for medical device establishment licences.
4. SAHPRA may request further information, in terms of Section 22C(3) of Act 101 of 1965 if there are any deficiencies identified in the application for amendment of a medical device establishment licence. Please kindly respond promptly to any request by SAHPRA for further information.
5. In the event that SAHPRA has made a decision not to approve the application for amendment of a medical device establishment licence, written reasons shall be furnished for the decision.

Should you require more information please do not hesitate to contact PERSONNEL NAME on

Yours faithfully

Name:

Non- compliance

- **MD012: Notice of contravention with provision/s of the Medicines and Related Substances Act, 1 965**

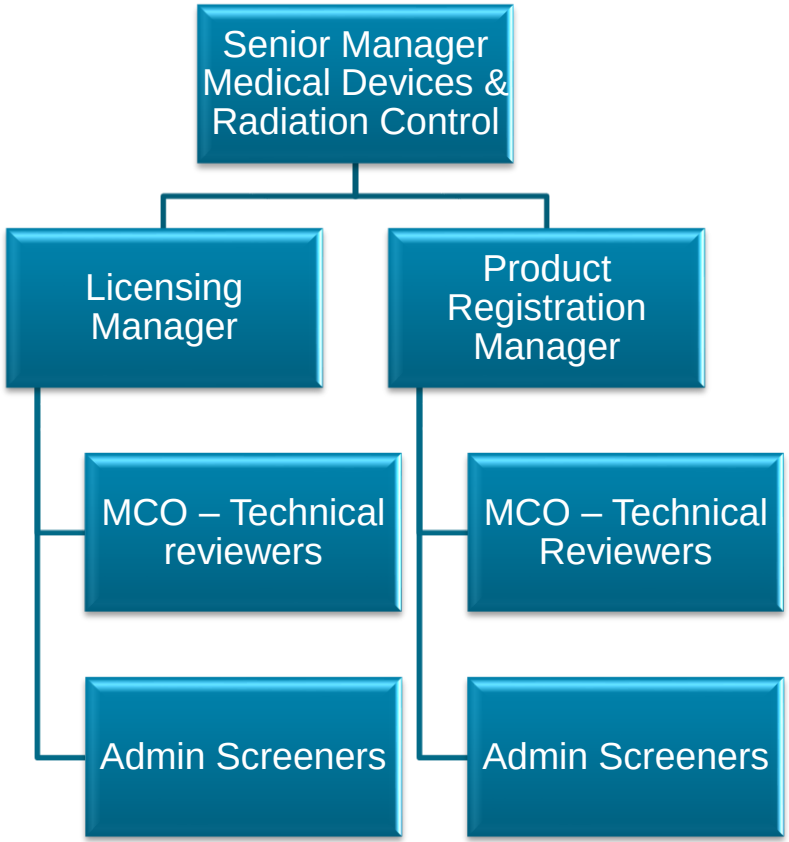
You may not manufacture, distribute (including import and/or export) and/or wholesale a medical devi ce or IVD without a valid SAHPRA licence.

- In terms of Section 22C(1)(b) of the Medicines and Related Substances Act, 1965 (Act 101 of 1965) and Regulation 5 of the General Regulations on Medical Devices
-

You may not advertise Class C and Class D medical devices to the public. For example it is illegal to adve rtise COVID-19 rapid test kits to the public.

- In terms of the General Regulations for Medical Devices, Regulation 21. Advertising of medical dev ices or IVDs only Class A and Class B medical devices and IVDs may be advertised to the public or la y person.
-

CONTRAVENTION OF ACT 101 OF 1965 7. Any individuals, companies and medical device establishment s that have contravened or have failed to comply with the provisions of Act 101 of 1965 will be notified in writing by SAHPRA of such offence/s.


Senior Manager Medical Devices & Radiation Control
Licensing Manager
Product Registration Manager
MCO – Technical reviewers
MCO – Technical Reviewers
Admin Screeners
Admin Screeners


International organizations
General public
International organizations
HP Industry (Researchers)
Media
SAHPRA
Other regulators
Other Government department
Healthcare professionals, related organizations
‘Academia & Research Institute
Donors & partners

Thank You