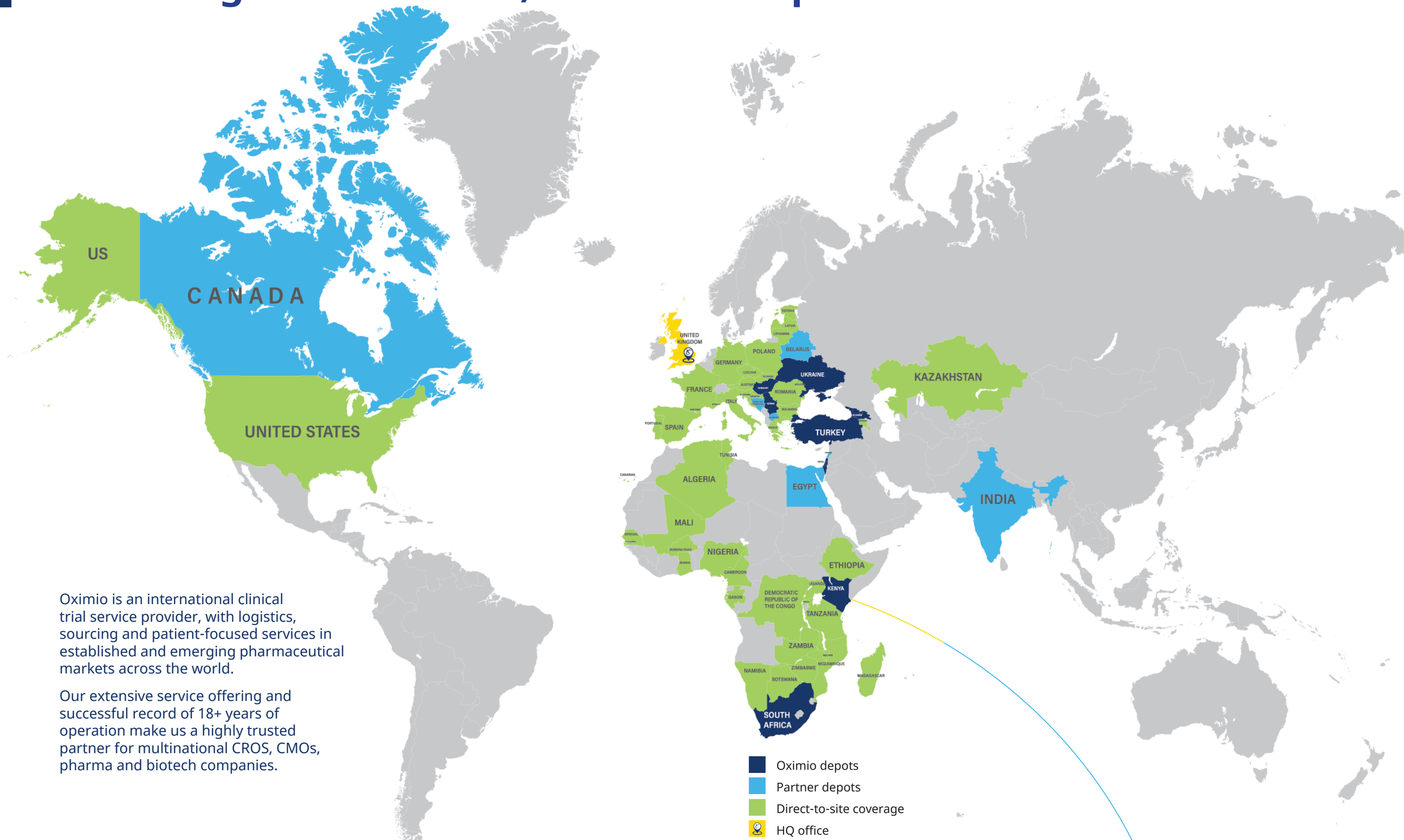
OXIMIO

Depot Guide

2022

Oximio’s global network, with local expertise



Oximio is an international clinical trial service provider, with logistics, sourcing and patient-focused services in established and emerging pharmaceutical markets across the world.

Our extensive service offering and successful record of 18+ years of operation make us a highly trusted partner for multinational CROS, CMOs, pharma and biotech companies.

Services available per location

Country	Customs Clearance and IoR			Sourcing for Clinical Trials			Packeging / Labeling		Storage conditions	
	IoR	Customs	QP Release	Drug Sourcing	Ancillary sourcing	Equipment Rental	PKG	LBL	(+15°C +25°C)	(+2°C +8°C)
Post-Soviet Countries										
Ukraine	•	•		•	•	•	•	•	•	•
Georgia	•	•		•	•			•	•	•
Moldova	•	•			•					
Belarus	•	•		•	•			•	•	•
Armenia	•	•								
Kazakhstan	•	•								
Middle-East										
Israel	•	•	•	•	•		•	•	•	•
Turkey	•	•			•		•	•	•	•
Egypt	•	•		•	•				•	•
Lebanon	•	•		•	•			•	•	•
Balkans										
Serbia	•	•		•	•			•	•	•
Bosnia&Herce-govina	•	•		•	•			•	•	•
Macedonia										
European Union										
Hungary	•	•	•	•	•			•	•	•
Poland					•					
Czech Republic					•					
Romania					•					
Slovakia					•					
Slovenia					•					
Bulgaria					•					
Croatia					•					
Austria					•					
Lithuania					•					
Germany					•					
Spain					•					
France					•					
Italy					•					
Latvia					•					
Portugal					•					
Estonia					•					
Greece					•					

Country	Storage conditions			Returns Management		DTS	Patient Centric Services				
	(-40°C to -20°C)	(-80°C to -60°C)	Cryogenic	Returns Management	Destruction	DTS	EAP	DTP	Home Healthcare	Patient Travel Management	Bio sample services
Post-Soviet Countries											
Ukraine	•	•	Per request	•	•	•	•	•	•	•	•
Georgia	•	•		•	•	•		•	•	•	
Moldova				•	•	•					
Belarus	•			•	•	•					
Armenia				•		•					
Kazakhstan				•		•					
Middle-East											
Israel	•	•		•	•	•					
Turkey	•	•		•	•	•				•	
Egypt	•			•	•						
Lebanon				•	•	•					
Balkans											
Serbia				•	•	•					
Bosnia&Herce-govina	•			•	•						
Macedonia											
European Union											
Hungary	•	•		•	•	•					
Poland				•		•					
Czech Republic				•		•					
Romania				•		•					
Slovakia				•		•					
Slovenia				•		•					
Bulgaria				•		•					
Croatia				•		•					
Austria				•		•					
Lithuania				•		•					
Germany				•		•					
Spain				•		•					
France				•		•					
Italy				•		•					
Latvia				•		•					
Portugal				•		•					
Estonia				•		•					
Greece				•		•					

Oximio depot Partner`s depot Direct-to-site coverage

Services available per location

Country	Customs Clearance and IoR			Sourcing for Clinical Trials			Packeging / Labeling		Storage conditions	
	IoR	Customs	QP Release	Drug Sourcing	Ancillary sourcing	Equipment Rental	PKG	LBL	(+15°C +25°C)	(+2°C +8°C)
Africa										
South Africa		•		•	•	•		•	•	•
Kenya	•	•		•	•	•		•	•	•
Uganda	•	•								
Nigeria		•								
Tunisia		•								
Tanzania		•								
Zimbabwe	•	•								
Malawi	•	•								
Ghana	•	•								
Zambia		•								
Burkina Faso		•								
Ethiopia		•								
DRC		•								
Algeria		•								
Cameroon		•								
Mali		•								
Mozambique	•	•								
Gabon		•								
Gambia		•								
Algeria		•								
Namibia		•								
Botswana		•								
Madagascar		•								
Senegal		•								
Rwanda		•								
Asia										
India		•		•	•		•	•	•	•
North America										
Canada	•	•	•	•	•		•	•	•	•

Country	Storage conditions			Returns Management		DTS	Patient Centric Services				
	(-40°C to -20°C)	(-80°C to -60°C)	Cryogenic	Returns Management	Destruction	DTS	EAP	DTP	Home Healthcare	Patient Travel Management	Bio sample services
Africa											
South Africa	•	•	•	•	•	•		•			
Kenya	•	•	•	•	•	•		•			
Uganda				•		•					
Nigeria				•		•					
Tunisia				•		•					
Tanzania				•		•					
Zimbabwe				•		•					
Malawi				•		•					
Ghana				•		•					
Zambia				•		•					
Burkina Faso				•		•					
Ethiopia				•		•					
DRC				•		•					
Algeria				•		•					
Cameroon				•		•					
Mali				•		•					
Mozambique				•		•					
Gabon				•		•					
Gambia				•		•					
Algeria				•							
Namibia				•		•					
Botswana				•		•					
Madagascar				•		•					
Senegal				•		•					
Rwanda				•		•					
Asia											
India	•			•	•						
North America											
Canada	•	•		•	•	•					

Oximio depot | Partner`s depot | Direct-to-site coverage

In Ukraine

Local depot

Office address: 172 Antonovycha str, BC Palladium city (11 floor), Ukraine, Kyiv, 03150

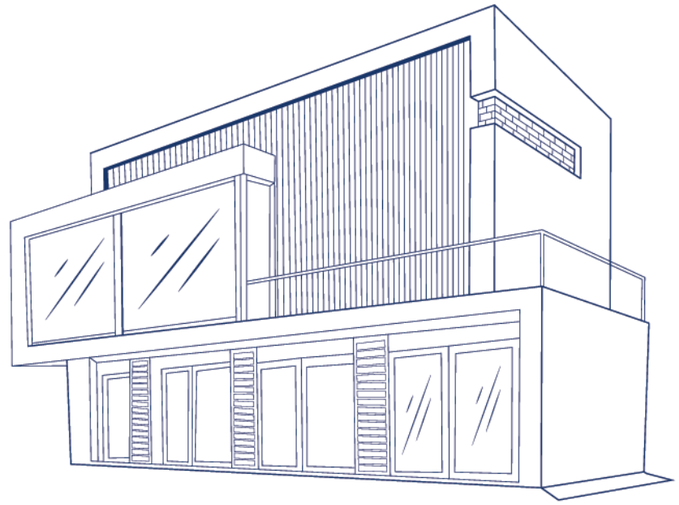
Main depot address: 4, Kolhoznaya str., Krushynka, Kyiv region, 08635, Ukraine

Regional depot address: 6 Polna str., Brody city, Lviv region, Ukraine

E-mail: depot-ua@smo-group.com

Ukraine in facts and figures

- Regulatory environment in process of harmonization with the EU
- Growing presence in the clinical research landscape that offers high-quality clinical sites and motivated investigators
- No import and export licenses required for study drugs and clinical trial materials
- Prospective patient population of 40 million
- Centralized healthcare system with a large pool of treatment-naive patients



Certification

- Import license of medicinal products
- ISO9001:2015 Certification
- Wholesales License of medicinal products

Storage conditions

Overall main storage cap. of 1440 m²

- Uncontrolled ambient
- Controlled ambient: +15°C to +25°C
- Refrigerated: +2°C to +8°C
- Frozen: -25°C to -15°C
- Ultra-low: -80°C to -60°C
- Cryogenic: On request

Overall regional storage cap. of 850 m²

- Uncontrolled ambient
- Controlled ambient: +15°C to +25°C
- Refrigerated: +2°C to +8°C
- Frozen: -25°C to -15°C

List of documents required for project start-up

- Copy of contract between parties
- Power of Attorney from Sponsor/Study Applicant
- Copy of Study approval issued by the Ministry of Health (MoH) of Ukraine
- Significant amendments to the Study approval, if applicable
- Pictures of packaging and labels of each kit (English and Ukrainian versions)
- Certificates of analysis for all IMPs
- Material Safety Data Sheets for the IMPs
- Laboratory Manual (if applicable)
- Depot Project Instruction
- Site list
- Codes for IRT system (if applicable)

Product Types

- Biological Goods
- Blood Product or Derivative
- Genetically Modified Organism (GMO)
- Antibiotic
- Cytotoxic

In Georgia

Local depot

Depot address: Georgia, 0141 Tbilisi, 36 Ksani Street

E-mail: depot-ge@smo-group.com

Located in the capital of Georgia and one of the first country in Oximio`s geo expansion story.

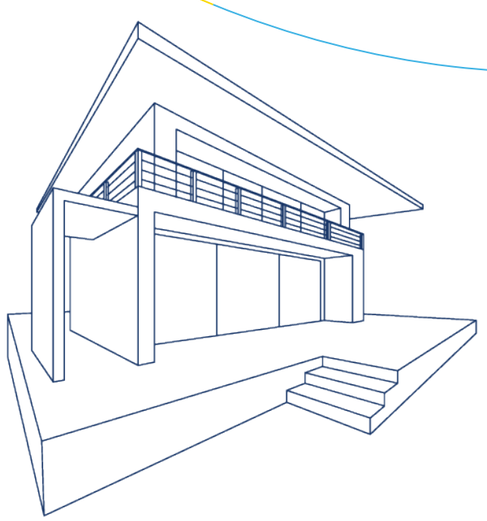
Transit depot

Depot address: Georgia, Tbilisi, Gldani-Nadzaladevi District, Omar Khizanishvili Street 264

Products for re-export are not required customs clearance tax.

Georgia in facts and figures

- Short approval timelines and friendly regulatory environment: the timeline from approval to first patient screened is the shortest in the region
- No import license for clinical trial materials, including investigational products
- Clear and effective regulatory process and streamlined customs clearance
- No VAT and customs duties for investigational products
- Considerable quantity of treatment patients, who are highly motivated to take part in Trials
- Expedited trial start-up period, which is one of the shortest in the world.
- Highly qualified and motivated medical staff representing high quality of Study data that is accepted by the FDA and proved by FDA inspections.
- Reasonable investigator fees



Local depot

Certification

- GDP Certificate
- ISO 9001:2015 Certificate
- Wholesale Distributor License

Storage conditions

Overall storage capacity 600 m²

- Uncontrolled ambient
- Controlled ambient: +15°C to +25°C
- Refrigerated: +2°C to +8°C
- Frozen: -25°C to -15°C
- Ultra-low: -80°C to -60°C

Product Types

- Biological Goods
- Blood Product or Derivative
- Genetically Modified Organism (GMO)
- Antibiotic
- Cytotoxic

Transit depot

Certification

- GDP Certificate
- ISO 9001:2015 Certificate
- Wholesale Distributor License

Storage conditions

Overall storage capacity 294 m²

- Non-Controlled Ambient
- Controlled Ambient: from +15°C to +25°C
- Controlled Ambient: from +2°C to +8°C

List of documents required for project start-up

- Copy of Contract between parties
- Power of Attorney from Sponsor/Study Applicant
- Copy of Study approval issued by the Ministry of Health (MoH) and Permit certificate
- Decision of the Ethical Commission to conduct clinical research
- Copy of study protocol
- Certificates of analysis for all IMPs
- Deport Project Instructions
- Site list
- Material Safety Data Sheets for the IMPs
- Codes for IRT system (if applicable)

In Israel

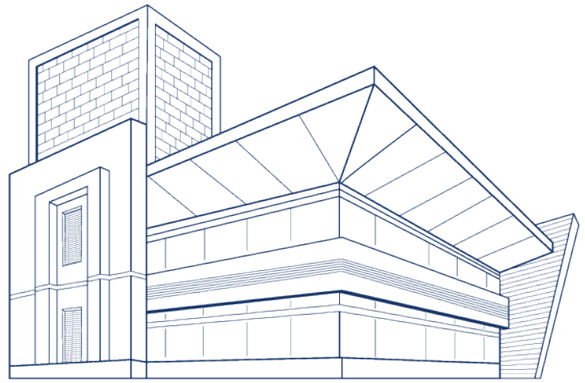
Local depot

Depot address: 3079863, Israel, 6 Bareket Street, Industrial Park North

E-mail: depot-il@smo-group.com

Israel in facts and figures

- With more than 8.5 million people, Israel is an attractive location for conducting clinical studies
- There are cost advantages compared to Europe, US, and certain Asian countries
- All imported IMPs need licenses. Most of the exported drugs do not require export license
- 66% of its total 1380 life science companies are less than a decade old, according to the Israel Advanced Tech Industries Group
- The Israeli population is insured through national health insurance, the medical history of individuals is easily tracked over time, meaning that the Israeli healthcare system offers important advantages in the long-term monitoring of participants



Certification

- GMP License
- GDP License
- MIA License
- ISO9001:2015 Certification

Storage conditions

Overall storage capacity of 1654 m²

- Uncontrolled ambient
- Controlled ambient: +15°C to +25°C
- Refrigerated: +2°C to +8°C
- Frozen: -25°C to -15°C
- Ultra-low: -80°C to -60°C
- Cryogenic: On request

List of documents required for project start-up

- MSA between parties
- Quality Agreement (Applicable when import of medicinal products is included in the scope of services)

Product Types

- Dangerous Goods (DG)
- Biological Goods
- Blood Product or Derivative
- Genetically Modified Organism (GMO)
- Antibiotic
- Cytotoxic

QP Documents for IMPs:

- Invoice
- Shipping documents: Packing list, AWB
- Temperature (if applicable - humidity) monitoring results during shipment
- Label proofs: primary and secondary
- Form 7
- CoA from manufacturing site
- Authorized person statement of release
- GMP compliance certificates of all manufacturing chain facilities, inc. product manufacturing, testing, labelling and packaging
- Pedigree documentation - all involved in the manufacturing chain: manufacturing, testing, packaging and labeling, storage must be included
- Declaration stating if a product contains/ does not contain ingredients originated from human blood or plasms
- Lot linking documents in case of kit, linking the kit lot number and the lot number of product/s inside

Confirmation on the product cytotoxicity:

- Label proofs for all IMPs
- Clinical Trial Instruction (CTI)
- Site list
- Logistics documents: Temperature monitor instruction sheet, Request for order to site, Request for collection of return forms site to depot, request for destruction
- Codes for IRT system (if applicable)

In Turkey

Local depot

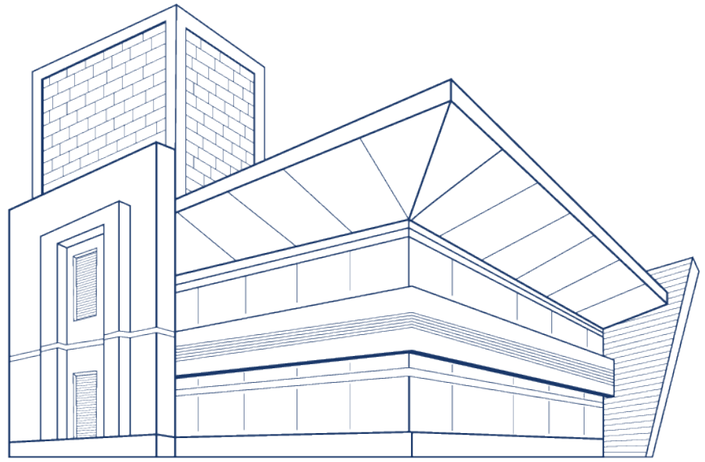
Depot address: Cigli Izmir-Turkey, 10053 sokak no 7/1 35620

E-mail: depot-tr@smo-group.com

In operation since 2019, it is the largest facility in the Oximio network.

Turkey in facts and figures

- Turkey is a home to more than 80 million
- EU harmonized clinical trial research legislation and fully in line with European Commission Directives
- Lower costs of conducting a clinical trial than in EU and US
- Due to competitive pricing and highly motivated GCP-trained investigators, investments rate in R&D is higher than in EU
- Turkey has a strong healthcare infrastructure and universal health insurance coverage that provides accessible, high-quality healthcare services for all with a very efficient data infrastructure.



Certification

- License for importation of medicinal products
- ISO 9001:2015 Certificate
- Depot License №66175679-514.99-E.247017

Storage conditions

Overall storage capacity 4 730 m²

- Uncontrolled ambient
- Controlled ambient: +15°C to +25°C
- Refrigerated: +10C to +40C
- Refrigerated: +2°C to +8°C
- Frozen: -25°C to -15°C
- Ultra-low: -80°C to -60°C
- Cryogenic: Per request

List of documents required for project start-up

- Copy of contract between parties
- Power of Attorney from Sponsor/Study Applicant
- Copy of Study approval issued by the Ministry of Health (MoH) of Turkey
- Copy of study protocol
- Certificates of analysis for all IMPs
- Material Safety Data Sheets for the IMPs
- Depot Project Instructions
- Site list
- Codes for IRT system (if applicable)
- Import License if Oximio is IoR

Product Types

- Controlled Drugs (CD)
- Dangerous Goods (DG)
- Biological Goods
- Blood Product or Derivative
- Genetically Modified Organism (GMO)
- Antibiotic
- Cytotoxic

In Serbia

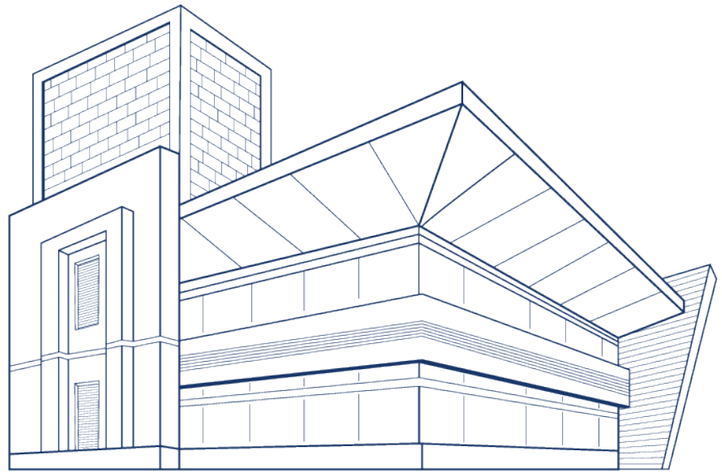
Local depot

Depot address: 11147, Serbia, Belgrade, ulica Mihaila Shushkalovica 13

E-mail: depot-rs@smo-group.com

Serbia in facts and figures

- Healthcare providers deliver high quality clinical trial data derived under GxP guidelines and can facilitate reduced study timelines
- Typical clinical trial approval application timelines of 60 days
- Parallel applications to ethics committees and MoH
- Pharmaceutical industry is a government priority for economic growth
- Import and export licensing ensures safety, transparency, and minimal risk for clinical trials



Certification

- License for wholesale in medicines for clinical trials and registered medicines
- License for wholesale of medical devices for clinical trials and registered medical devices
- ISO 9001:2015 Certificate

Storage conditions

Overall storage capacity 748 m²

- Uncontrolled ambient
- Controlled ambient: +15°C to +25°C
- Refrigerated: +2°C to +8°C
- Frozen: -25°C to -15°C (only for gel-pack preconditioning)
- Ultra-low -80°C to -60°C: On request

List of documents required for project start-up

- Copy of contract between parties
- Power of Attorney from Sponsor/Study Applicant
- Copy of Study approval issued by the Ministry of Health (MoH)
- Significant amendments to the Study approval (if applicable)
- Pictures of packaging and labels of each kit (in English)
- Material Safety Data Sheets for the IMPs
- Deport Project Instructions
- Site list
- Codes for IRT system (if applicable)

Product Types

- Biological Goods
- Blood Product or Derivative
- Genetically Modified Organism (GMO)
- Antibiotic
- Cytotoxic

In Hungary

Regional depot

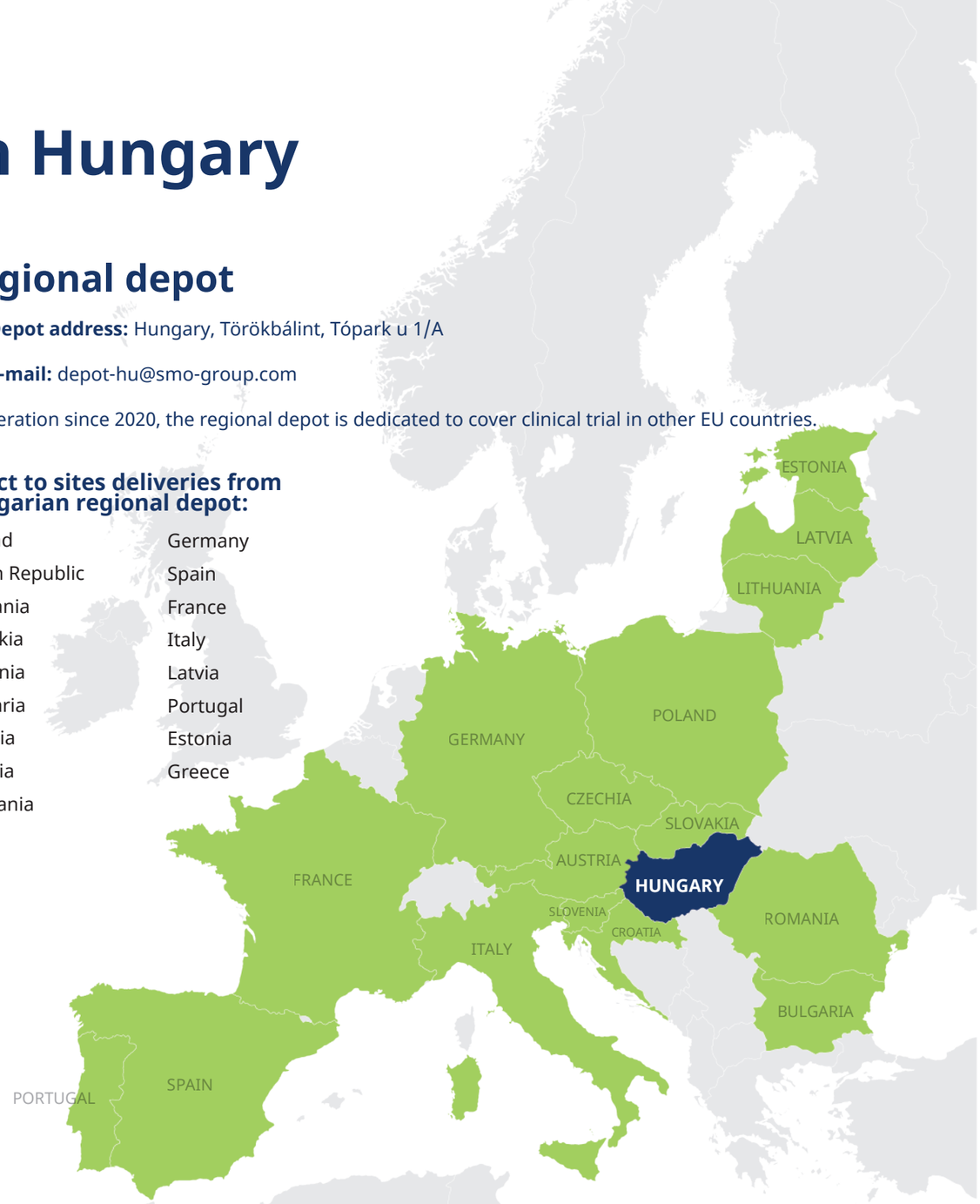
Depot address: Hungary, Törökbálint, Tópark u 1/A

E-mail: depot-hu@smo-group.com

In operation since 2020, the regional depot is dedicated to cover clinical trial in other EU countries.

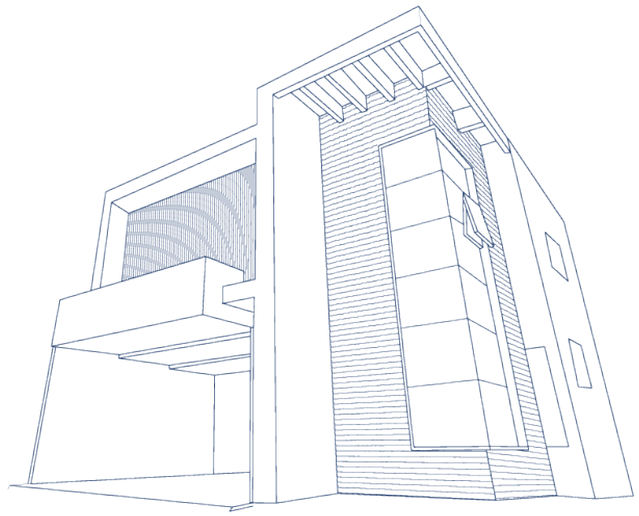
Direct to sites deliveries from Hungarian regional depot:

Poland	Germany
Czech Republic	Spain
Romania	France
Slovakia	Italy
Slovenia	Latvia
Bulgaria	Portugal
Croatia	Estonia
Austria	Greece
Lithuania	



Hungary in facts and figures

- Hungary exhibits all the important aspects of an emerging market: fast enrolment, lower prices, and low procedure costs, compared to more established markets
- Hungary has strong medical schools and developed infrastructure for medical research
- Clear regulatory environment and favourable study start-up timelines: average time from submission to approval – 10 weeks
- Proven Clinical Quality Standards



Certification

- ISO 9001:2015 Certificate
- HU-D-SMOG OGYÉI

Storage conditions

Overall storage capacity 1440 m²

- Uncontrolled ambient
- Controlled ambient: +15°C to +25°C
- Refrigerated: +2°C to +8°C
- Frozen: -25°C to -15°C
- Ultra-low: -80°C to -60°C
- Cryogenic: On request

Product Types

- Blood Product or Derivative
- Genetically Modified Organism (GMO)
- Antibiotic
- Cytotoxic

List of documents required for project start-up

- RA approval of Clinical Trial (OGYÉI)
  - Contract between parties
  - IMPD for IMP only
- Study Protocol
- Product list (MIA of importer)
- Site list
- IVRS-codes (if applicable)
- Power of Attorney from Sponsor
- Depot instruction
- Certificates of analysis, Batch certificates
- QP-releases FROM EU
- MSDS

In South Africa

Local depot

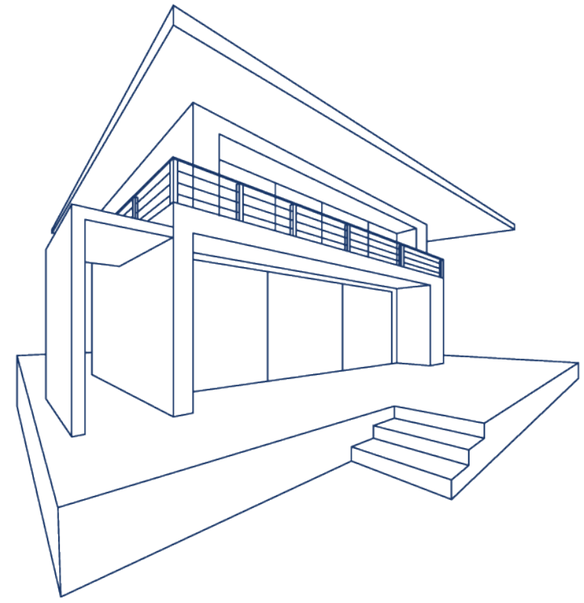
Depot address: 0157, South African Republic, 22 Venturi Crescent, Hennopspark

E-mail: smo-depot-za@smo-group.com

A-class storage facilities operates since 2019.

South Africa in facts and figures

- With a population of more than 50 million people and almost half of the continent's clinical trials, South Africa is a popular research choice for the multinational pharmaceutical industry
- A growing pharmaceutical market offering many cost benefits
- Established research infrastructure with more than 500 sites, top-tier hospital and clinic facilities and experienced clinical research professionals
- Diverse population with a variety of genetic backgrounds
- Easy and rapid patient recruitment and high-quality clinical data
- Highly motivated and experienced investigators
- A demonstrated commitment to healthcare R&D from the government and a strong policy to guide the country's innovation system



Certification

- Department of Health – Wholesale Pharmacy
- SAHPRA – Wholesaler of Medicines
- SAHPRA – Wholesaler of Medical Devices
- ISO 9001:2015 Certificate
- SAPC – Wholesale Pharmacy

Storage conditions

Overall storage capacity of 1656 m²

- Uncontrolled ambient
- Controlled ambient: +15°C to +25°C
- Refrigerated: +2°C to +8°C
- Frozen: -25°C to -15°C
- Ultra-low: -80°C to -60°C
- Cryogenic: On request

List of documents required for project start-up

- SAHPRA document: Acts as Import License, all Clinical Trial materials and supplies have to be listed on it
- Commercial invoice
- CoA's for each given batch
- MSDS
- DWI (Working Instruction)
- Site List
- IVRS Codes (If applicable)

Product Types

- Controlled Drugs (CD)
- Dangerous Goods (DG)
- Biological Goods
- Blood Product or Derivative
- Genetically Modified Organism (GMO)
- Antibiotic
- Cytotoxic
- Radioactive

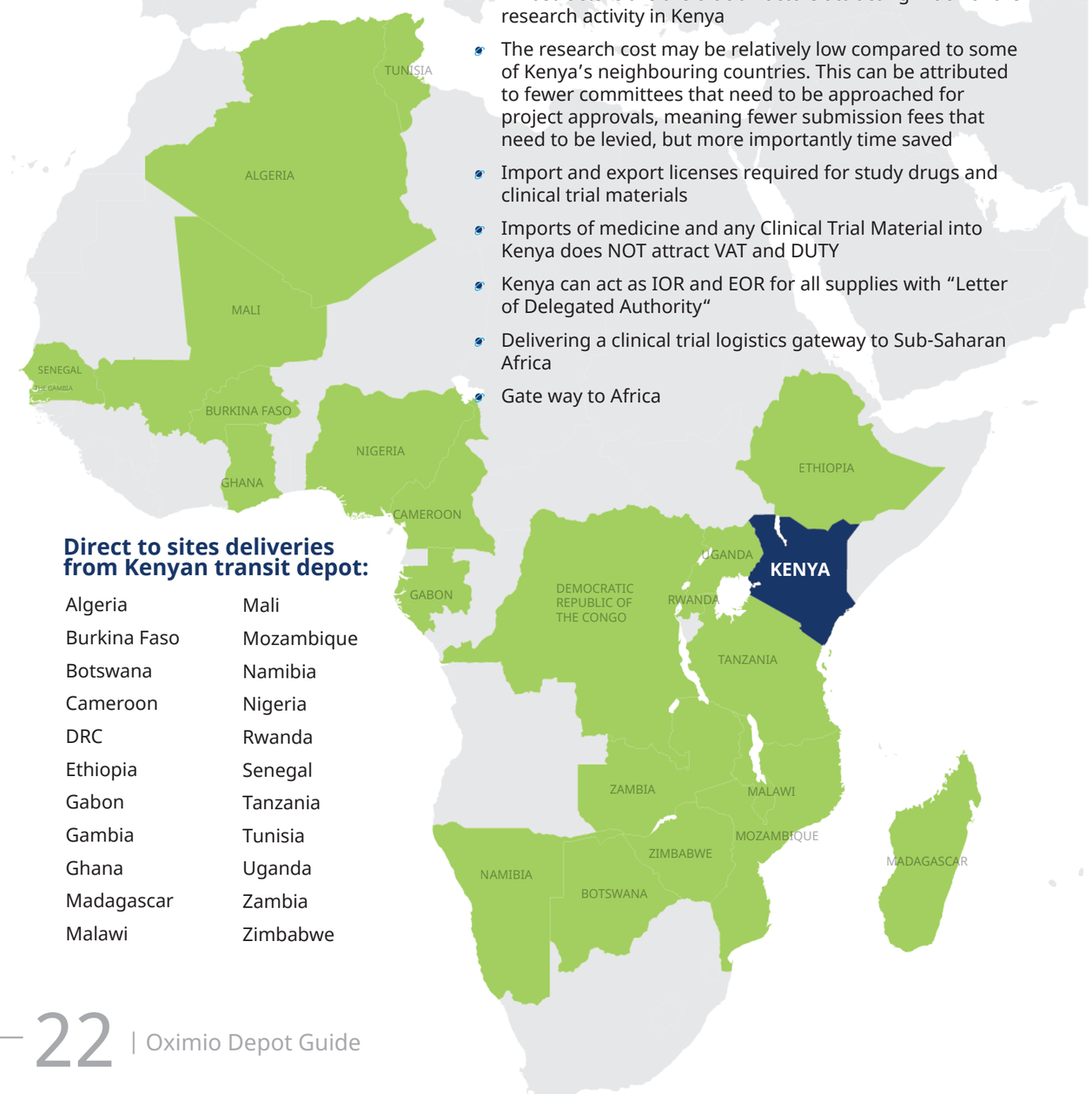
In Kenya

Transit depot

Depot address: LP West Logistics Park, Tilisi, Eldoret–Malaba Road, Limuru, Kenya

E-mail: depot-ke@smo-group.com

With in-house local knowledge and expertise, the Kenya bonded with transit depot supports sponsors in East, Central and West Africa.

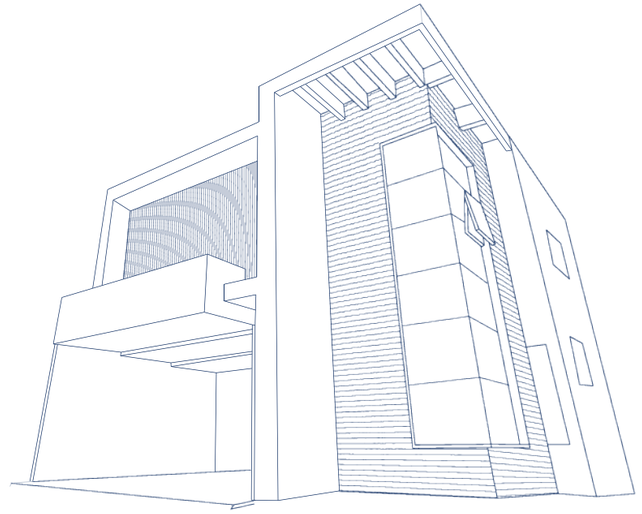


Kenya in facts and figures

- Rapid economic growth with advances in health care infrastructure are the crucial factors attracting much of the research activity in Kenya
- The research cost may be relatively low compared to some of Kenya's neighbouring countries. This can be attributed to fewer committees that need to be approached for project approvals, meaning fewer submission fees that need to be levied, but more importantly time saved
- Import and export licenses required for study drugs and clinical trial materials
- Imports of medicine and any Clinical Trial Material into Kenya does NOT attract VAT and DUTY
- Kenya can act as IOR and EOR for all supplies with "Letter of Delegated Authority"
- Delivering a clinical trial logistics gateway to Sub-Saharan Africa
- Gate way to Africa

Direct to sites deliveries from Kenyan transit depot:

Algeria	Mali
Burkina Faso	Mozambique
Botswana	Namibia
Cameroon	Nigeria
DRC	Rwanda
Ethiopia	Senegal
Gabon	Tanzania
Gambia	Tunisia
Ghana	Uganda
Madagascar	Zambia
Malawi	Zimbabwe



Certification

- Wholesale dealer's License
- Certification for registration of premises
- Practice licence for pharmacist

Storage conditions

Overall storage capacity of 472 m²

- Uncontrolled ambient
- Controlled ambient: +15°C to +25°C
- Refrigerated: +2°C to +8°C
- Frozen: -25°C to -15°C
- Ultra-low: -80°C to -60°C
- Cryogenic: On request

List of documents required for project start-up

- Copy of contract between parties
- Letter of delegation authority (should be signed by Sponsor)
- Ethical Committee Approval
- PPB Expert Committee on Clinical Trial Approval (MOH approval)
- Pictures of packaging and labels of each kit (English version)
- Certificates of analysis for all IMPs
- Material Safety Data Sheets for the IMPs
- Deport Project Instructions
- Site List
- Codes for IRT system (if applicable)

Product Types

- Controlled Drugs (CD)
- Dangerous Goods (DG)
- Biological Goods
- Blood Product or Derivative
- Genetically Modified Organism (GMO)
- Antibiotic
- Cytotoxic

Partner depots

Canada

Depot address: Ontario city

Storage conditions

Overall storage capacity 2322 m²

- Uncontrolled ambient
- Controlled ambient: +15°C to +25°C
- Refrigerated: +2°C to +8°C
- Frozen: -25°C to -15°C

Belarus

Depot address: Minsk City

Certification

- GDP №BY 16-139A
- ISO 9001:2015 Certificate № BY229480
- Wholesale license №02040/704
- Controlled drugs license №02040/760

Storage conditions

Overall storage capacity 2400 m²

- Controlled ambient: +15°C to +25°C
- Refrigerated: +2°C to +8°C
- Frozen: -25°C to -15°C

Bosnia

Depot address: Sarajevo city

Storage conditions

Overall storage capacity 360 m²

- Controlled ambient: +15°C to +25°C
- Refrigerated: +2°C to +8°C
- Frozen: -25°C to -15°C

Egypt

Depot address: Obour City

Storage conditions

Overall storage capacity 2084 m²

- Controlled ambient: +15°C to +25°C
- Refrigerated: +2°C to +8°C
- Frozen: -25°C to -15°C

Lebanon

Depot address: Beirut city

Storage conditions

Overall storage capacity 233 m²

- Controlled ambient: +15°C to +25°C
- Refrigerated: +2°C to +8°C

Republic of Moldova

Depot address: Chisinau city

The depot serves as transit facilities form import goods and further local direct to sites shipments

India

Depot address: Pune city

Storage conditions

Overall storage capacity 278.7 m²

- Uncontrolled ambient
- Controlled ambient: +15°C to +25°C
- Refrigerated: +2°C to +8°C
- Frozen: -25°C to -15°C

For questions related to the partner depot, please contact: communications@smo-group.com

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