ASPIRE TO MAKE A DIFFERENCE

IPDataLab

Navigating the Saudi Market: Insights into Incentives and New Regulatory Frameworks

沙特药品注册指引：深入理解激励措施和新监管框架

爱普数联 & 注册圈

2025 年 9 月 25 日

中国 北京

关于爱普数联

北京爱普数联科技有限公司（IPDataLab Inc.）专注于提供医药商业情报，助力中国药企精准出海。依托我们的独家数据、全球网络和专业团队，爱普数联旨在为药企的选品、市场评估、进入决策、国际合作等提供全生命周期、一站式的数据和咨询服务。我们的数据涵盖全球（药品的）审批、临床试验、交易、专利和市场独占权数据，尤其深耕中东及北非（MENA）市场，提供药品价格、短缺名单、合作关系等独家情报，帮助企业在新兴市场取得成功。爱普数联是北京市“雨燕行动”科技新航海生态合作伙伴。以终为始，有的放矢，助力出海！www.pharmspot.net/

爱普数联 IPDataLab

SPEAKER & Chinese Commentator 演讲嘉宾 & 中文评论员

Hazem Al-Yacoub Pi Pharma Intelligence 联合创始人

Hazem Al-Yacoub 在制药行业拥有辉煌的 20 年职业生涯，曾在拜耳、阿斯利康、辉凌和 Tabuk Pharmaceuticals 等主要公司担任过产品经理、品牌经理、BD等各种职务，这凸显了他对该领域复杂性的深刻理解。过去七年来，他转向更积极参与决策，特别是在中东地区的选品和采购方面，这展示了他的战略洞察力。Hazem拥有约旦大学药学学士学位。

hazem.yacoub@pipharmaintelligence.com

Abeer Khresha Pi Pharma Intelligence 数据团队负责人

Abeer Khriesha 药剂师和数据专家，拥有临床药学硕士学位，并热衷于数据驱动的洞察，她将科学与分析相结合，以支持更明智的决策和创新的解决方案。她的工作重点是改善医疗保健结果，同时指导她的团队提供有影响力的、基于证据的数据。

abeer.khresha@pipharmaintelligence.com

黎　邈 律师、专利代理师，北京爱普数联科技有限公司创始人

具有17年知识产权从业经验，精通主要国家专利法律制度的异同，现专注于生命科学领域的IP保护和跨境交易。曾在新奥集团和宝洁公司担任过多年的专利律师，在法律数据公司律商联讯担任过专利检索数据库的全球产品管理负责人，开发了世界上首款北美生物药专利链接数据库。黎女士拥有北京大学法律硕士学位和德国马普学会旗下慕尼黑知识产权法中心法律硕士学位，翻译并出版书籍《生命科学发明在欧洲的保护和执法——在欧洲专利公约和欧盟法的框架下》。

miao@ipdatalab.com

ASPIRE TO MAKE A DIFFERENCE

IPDataLab

Disclaimer: The content presented in this webinar reflects the independent data analysis, insights, of **Pi Pharma Intelligence** , shared solely for educational and discussion purposes. and **does not represent or act on behalf of any regulatory body or official authority in Saudi Arabia.**

免责声明： 本次网络研讨会中提供的内容反映了 **Pi Pharma Intelligence** 的独立数据分析和见解，仅用于教育和讨论目的，并**不代表沙特阿拉伯的任何监管机构或官方机构**。

Outline 提 纲

I. Market overview 市场概览

II. Regulatory requirements 监管要求

III. Accessibility vs. Affordability 可及性 vs. 可负担性

IV. Drug Pricing 药品定价

Outline 提 纲

I. Market overview 市场概览

II. Regulatory requirements 监管要求

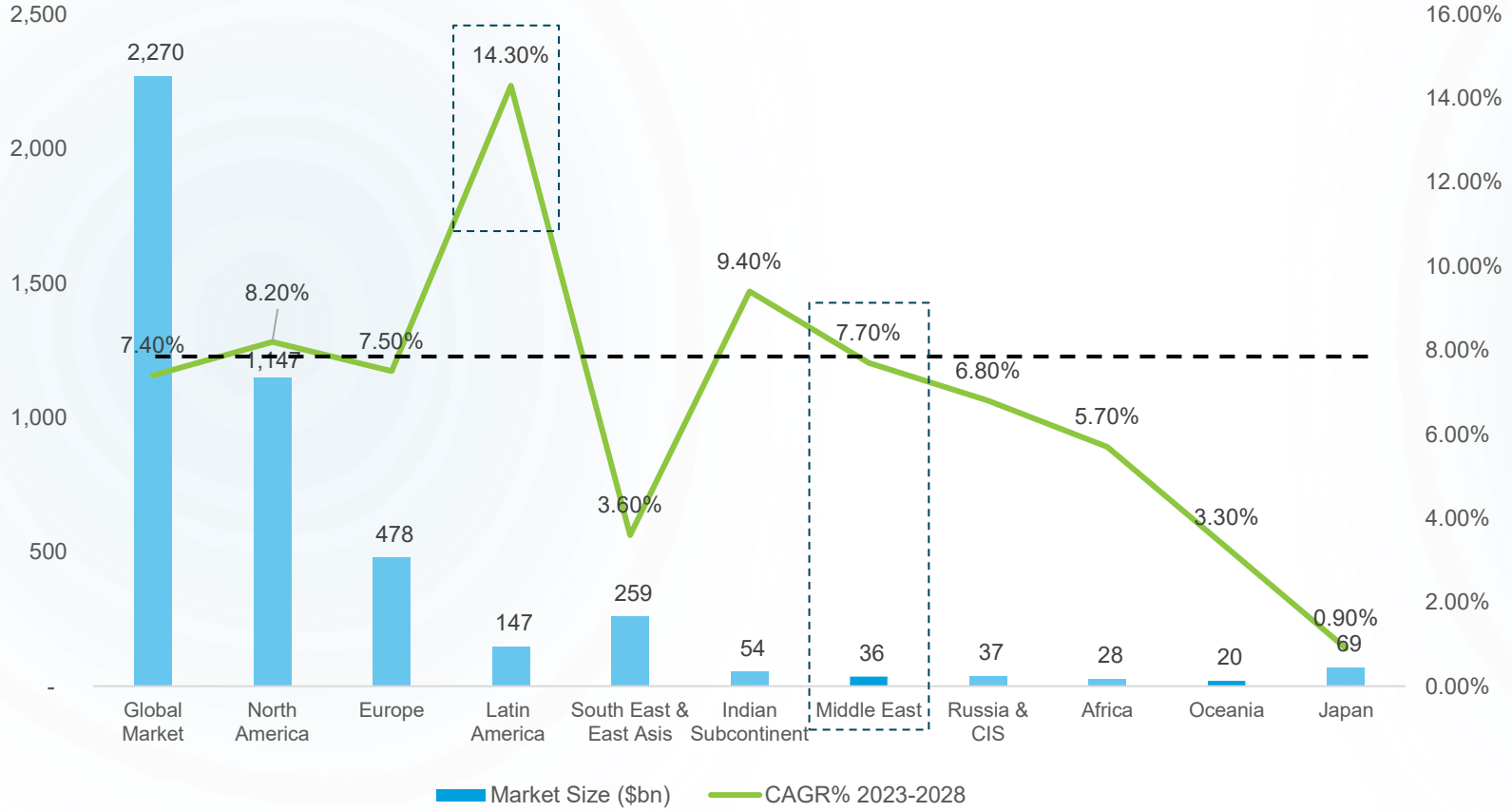
III. Accessibility vs. Affordability 可及性 vs. 可负担性

IV. Drug Pricing 药品定价

Global Pharmaceuticals Market Size 全球医药市场规模

Key Growth Drivers 关键驱动因素

Global Pharmaceutical Market Overview (Size 2028 and Growth 2023-2028)[1]
全球医药市场概览（2028市场规模以及2023-2028市场增长）



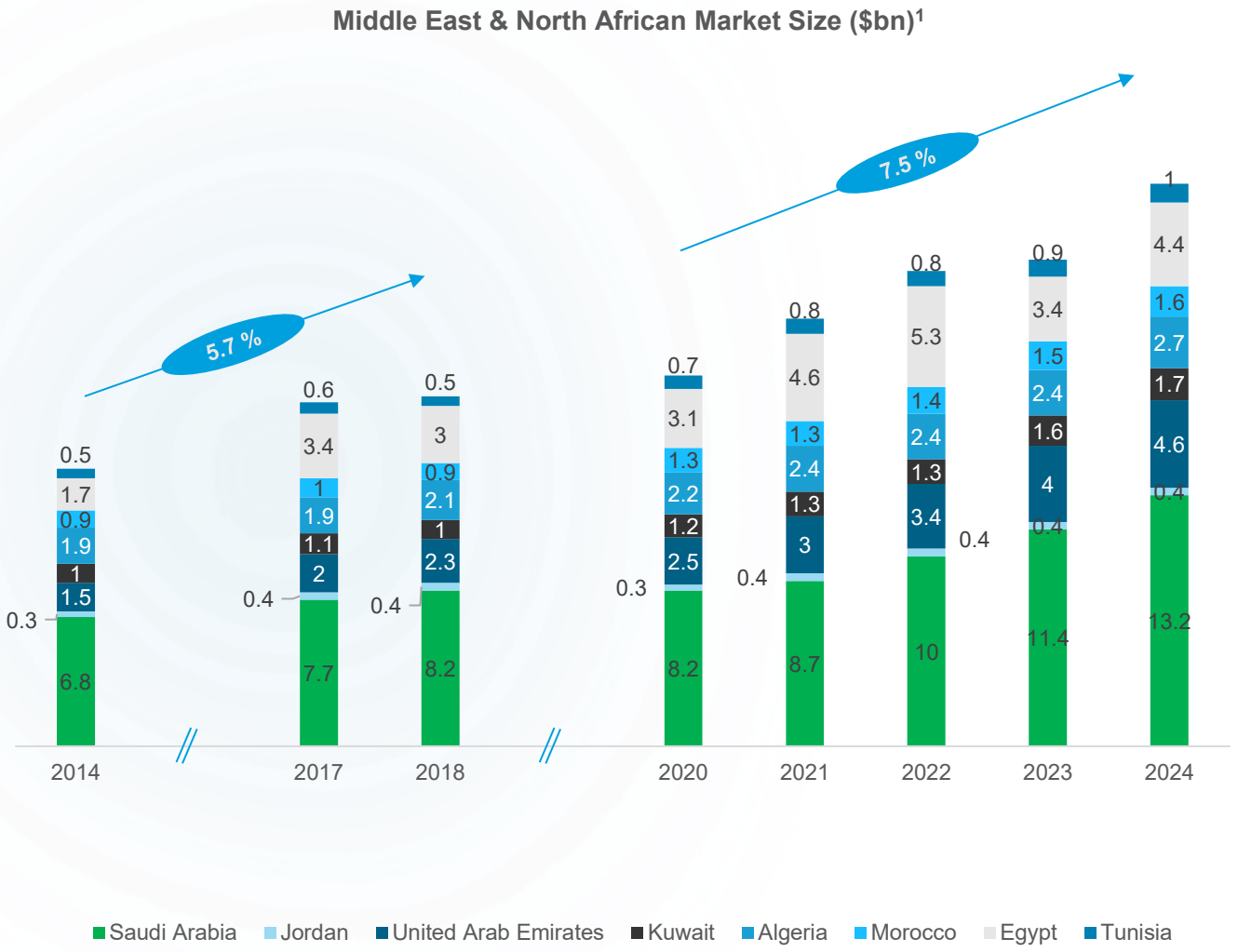
Middle East Market is expected to reach $36bn driven by the growth in the Saudi Arabian Market
主要受沙特市场增长的推动，**中东市场**预计将达到 360 亿美元

Middle East Market is growing at a rate comparable to the global average, yet it still lags behind the growth seen in other emerging pharmaceutical markets, such as Latin America and the Indian subcontinent
中东市场的增长速度与全球平均水平相当，但落后于拉丁美洲和印度次大陆等其他新兴医药市场

1Note – Size indicates 2028 Sales in LC $
Source: IQVIA Market Prognosis 2024-2028 (Sep 2024); IQVIA Market Prognosis Global summarizes the key points from each of the Regional studies and adds this to desk research conducted in seven other regions. A combination of IQVIA, official import/export and local manufacturer figures are used to compile this report and establish events that could impact the sales forecast over the period reviewed

MENA Pharmaceuticals Market 中东北非医药市场规模

Key Growth Drivers & Challenges 关键驱动因素和挑战



Population growth 人口增长
MENA 中东北非 : CAGR **1.7%** (2022: 275.3m inhabitant 2.753亿人口)
World 世界: CAGR **0.87%**

Healthcare expenditure[2] increase to 5.3% GDP in 2020 from 4.2% GDP 2013 医疗保健支出占 GDP 比重从 2013 年的 4.2% 增至 2020 年的 5.3%
MENA 中东北非 : **5.3%**
World 世界: **10.8%**

Health insurance penetration
健康保险渗透率

Projected **aging** population & **Chronic Diseases** Prevalence
预期的人口**老龄化&慢性病**患病率

Economic **transformation** & **diversification** programs
经济**转型**和**多元化**政府项目

Political instability 政治不稳定性

Currency devaluation in markets like Egypt, Sudan, and Algeria 埃及、苏丹和阿尔及利亚等市场的**货币贬值**

Focused strategies of **nationalization** rather than **integration**对**国家化**战略而非一体化战略的关注

[1]IQVIA Audited Data, MAT Q4 2018-2024, includes IQVIA private, LPO, Institutional data where available; Value sales at ex-factory price level without discount; All sales are at constant exchange rate and don't account for any currency fluctuation or devaluation
[2]Health Nutrition and Population Statistics

Outline 提 纲

I. Market overview 市场概览

II. Regulatory requirements 监管要求

III. Accessibility vs. Affordability 可及性 vs. 可负担性

IV. Drug Pricing 药品定价

SFDA Dossier Requirements SFDA申请档案要求

Dossier Application Format ,File Requirement and Validity for Registration Certificate

档案申请格式，文件要求及注册证有效期

Dossier Application Format 档案申请格式	**Validity for Registration Certificate** 注册证书的有效期	**File Requirements** 文件要求
e-CTD	Five years	**New Chemical Entity (NCE), Biologicals and Biosimilars** 新化学实体（**NCE**）、生物制剂和生物仿制药 **All CTD** modules are required 所有 **CTD** 模块都是必需的 **Generic drug** 仿制药 **M1**: All sections **M2**: 2.1, 2.2, 2.3, 2.5.2 **M3**: All sections. **M4**: NA **M5**: Only 5.1, 5.2, 5.3.1.2, 5.3.1.3, 5.3.1.4, 5.3.7, and 5.4 The stability conditions required for the dossier are Zone IVa, with a temperature of 30 °C ± 2 °C and relative humidity of 65% RH ± 5% RH. A minimum of 12 months of stability data is required Accelerated (40 ± 2 °C / 75 % RH ± 5 %) minimum time period at submission (6 months) 档案所需的稳定性条件为 IVa 区，温度为 30 ° C ± 2 ° C，相对湿度为 65% RH ± 5% RH。至少需要 12 个月的稳定性数据 提交时的加速最短时间（40 ± 2 ° C / 75 % RH ± 5 %） Inspection is required(- joint visit is applicable) 需要检查（- 适用联合检查） English -Arabic language（minimum requirement for Arabic language on outer package; trade name, pack size , generic name, strength）英语 - 阿拉伯语（外包装上的阿拉伯语最低要求;商品名称、包装尺寸、通用名称、规格） Serialization, Data Matrix, aggregation 序列化、数据矩阵、组合

SFDA Updates SFDA 更新

CPP is optional and no longer required for new Marketing Authorization applications (MAA) within all regulatory pathways. However, SFDA reserves the right to request the CPP at any time during the application process or post-authorization if deemed necessary.

所有注册路径的新上市许可申请（MAA）均不再强制要求提供CPP，因而是可选的。但是，SFDA保留在申请过程中或批准后，如有必要随时要求提供CPP的权利。

SFDA Updates SFDA更新

Clinical Trial Exceptions 临床试验例外情形

Case 1 — No Local Reference Product 情况1——无本地注册参考产品
Applies to 适用范围:

- Generics without a locally registered reference product 仿制药的参照药品未在本地注册
- New Drug Applications for Known Active Substances (KAS) 已知活性成分的新药申请

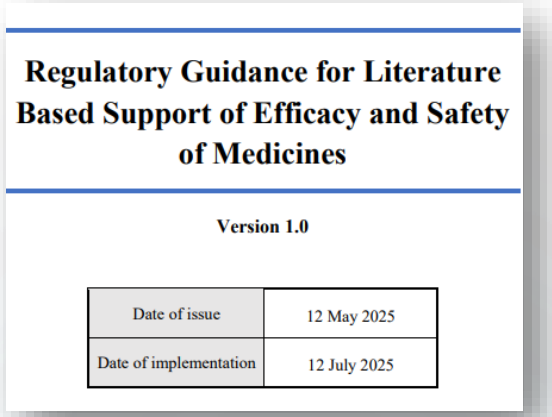
Requirement 要求:

- The applicant is advised to request a meeting **three months** before submission to discuss the literature-based submission 建议申请人在提交申请前3个月与监管部门预约会面，讨论基于文献资料的申请方案

Case 2 — Well-Established Use Medicines (WEU) 情形2——优良疗效确切的药品
Applies to 适用范围:

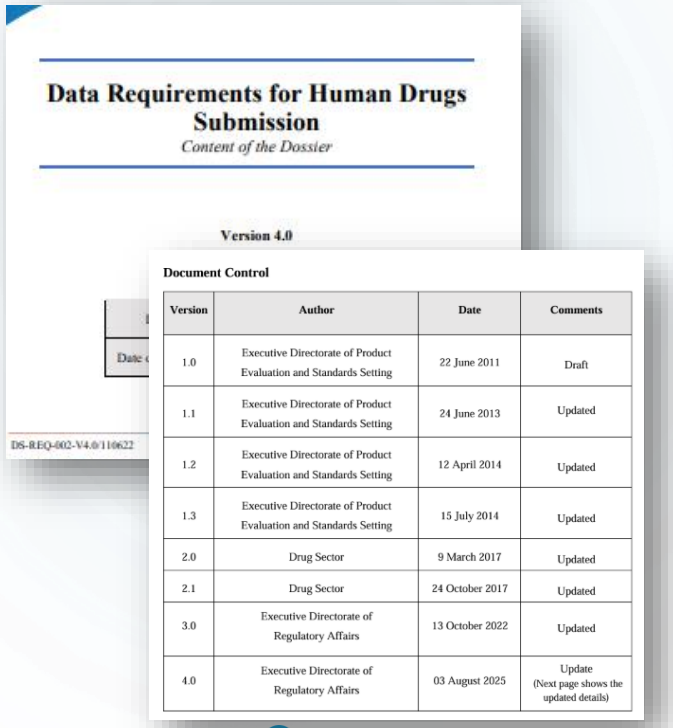
- Medicines with 10+ years of proven safety & efficacy in a Stringent Regulatory Authority (SRA), and its efficacy and safety have been well established for the claimed therapeutic indication 该药物在严格药品监管机构的监管下，已拥有10年以上安全性和有效性的临床验证记录，其对声称的治疗适应症的疗效和安全性也已得到确切证实

Instead of conducting new clinical studies, applicants may submit a comprehensive literature review, including systematic searches, meta-analyses, and published clinical data, to demonstrate safety and efficacy. The submission must follow the eCTD structure, with **Modules 4 and 5 populated by literature-based evidence**, and include a clear justification for all claims, ensuring the benefit-risk profile is adequately supported. 申请人无需进行新的临床研究，而是可以提交一份全面的文献综述，包括系统性检索、统合分析和已发表的临床数据，以证明安全性和有效性。提交的材料必须遵循 eCTD 的结构，其中**模块 4 和模块 5 包含基于文献的证据**，并包含所有声明的明确理由，确保收益-风险状况具有充分支持。


Regulatory Guidance for Literature Based Support of Efficacy and Safety of Medicines

Version 1.0

Date of issue	12 May 2025
Date of implementation	12 July 2025


Data Requirements for Human Drugs Submission

Content of the Dossier

Version 4.0

Document Control

Version	Author	Date	Comments
1.0	Executive Directorate of Product Evaluation and Standards Setting	22 June 2011	Draft
1.1	Executive Directorate of Product Evaluation and Standards Setting	24 June 2013	Updated
1.2	Executive Directorate of Product Evaluation and Standards Setting	12 April 2014	Updated
1.3	Executive Directorate of Product Evaluation and Standards Setting	15 July 2014	Updated
2.0	Drug Sector	9 March 2017	Updated
2.1	Drug Sector	24 October 2017	Updated
3.0	Executive Directorate of Regulatory Affairs	13 October 2022	Updated
4.0	Executive Directorate of Regulatory Affairs	03 August 2025	Update (Next page shows the updated details)

Key Question 关键问题:

Can I submit a generic dossier if the reference product is not approved by SFDA?
如果参照药品未经 SFDA 批准，可以提交仿制药档案吗？

In addition to the BE according to SFDA bioequivalence guideline, extensive data needed for:
除了根据SFDA生物等效性指导原则进行的BE以外，还需要以下方面的数据：

1) Module 1:
   1.4: Information on the expert 专家信息
   1.4.3: Clinical 临床
2) Module 2:
   2.5: Clinical Overview 临床概述
      2.5.1: Product Development Rationale, Address the current marketing registration status. 产品开发原理，阐述当前的上市注册状态
      2.5.2: Overview of Biopharmaceutics 生物药剂学概述
      2.5.3: Overview of Clinical Pharmacology 临床药理学概述
      2.5.4 and 2.5.5: Overview of Efficacy and Safety 疗效和安全性概述
      2.5.6: Benefits and Risks Conclusions 益处和风险结论
      2.5.7: References 参考文献
3) Module 3:
   Quality and the whole section are required 质量和完整性都是必需的
4) For Modules 4 and 5, a detailed scientific bibliography shall address non-clinical and clinical characteristics. For further details, applicants should refer to SFDA's Regulatory Guidance for Literature Based Support of Efficacy and Safety of Medicines. 对于模块4和模块5，申请者需提供一份详细的参考文献列表，其中应包含非临床和临床研究的相关文献。更多详细信息，请参阅SFDA发布的《基于文献的药物疗效和安全性评价监管指南》。

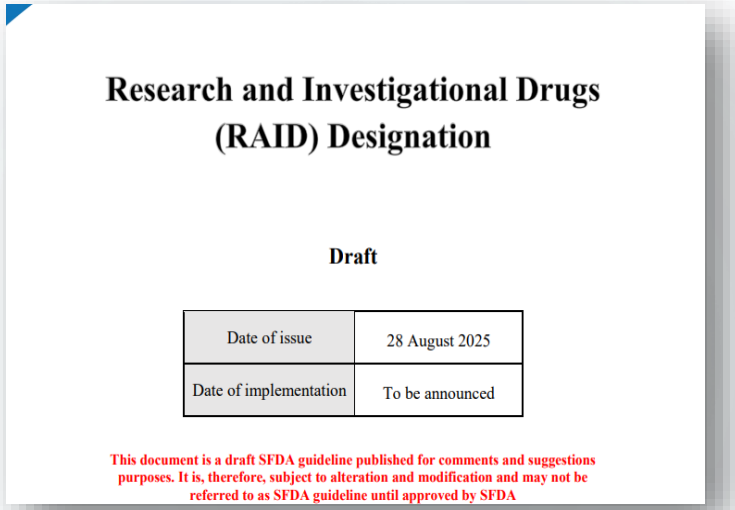
SFDA Updates SFDA 更新

New Upcoming 即将推出

Research and Investigational drugs (RAID) Designation 研究与试验药物（RAID）认定:

It aims to accelerate the development and regulatory review of drugs and biologics, expediting the availability of promising new therapies in Saudi Arabia. 该制度旨在加快药品和生物制品的研究开发和监管审批流程，从而促进具有前景的新疗法在沙特的上市。

It is an application submitted to obtain the SFDA designation for RAID to enable access to incentives when conducting research and developing (R&D) in Saudi Arabia, including running Clinical trials. 申请RAID认定需向SFDA提交申请，获得认定后，企业在沙特开展药品研究与开发（R&D）活动（包括临床试验）即可享受相关优惠政策。



Research and Investigational Drugs
(RAID) Designation

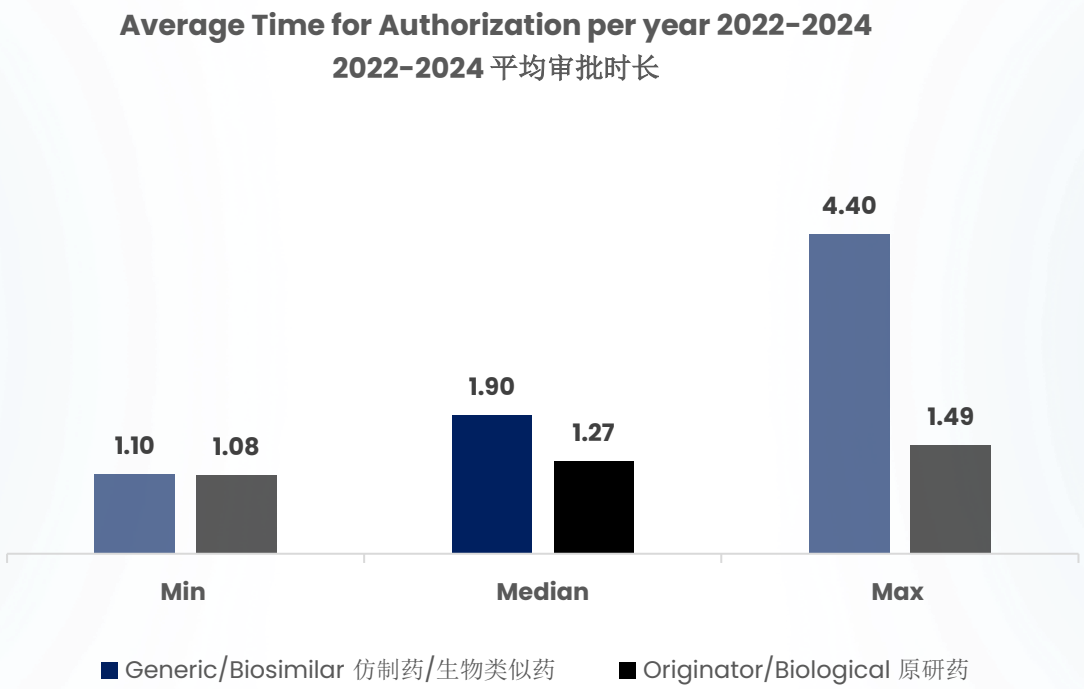
Draft

Date of issue	28 August 2025
Date of implementation	To be announced

This document is a draft SFDA guideline published for comments and suggestions purposes. It is, therefore, subject to alteration and modification and may not be referred to as SFDA guideline until approved by SFDA

Approval Timeline for Pharmaceutical Products 药品审批时间线

Duration Required to Obtain Regulatory Approvals before SFDA 获得SFDA批准所需的时间



Saudi DMF Registration 沙特DMF注册

SFDA Guidance and Requirements SFDA的指南和要求

What is a DMF? 什么是DMF?

1. Confidential CMC document 一种保密的CMC文件
2. Supports product registration (not a license) 用于支持产品注册（并非上市许可）
3. Protects DMF Holder's proprietary info 保护DMF持有者的专有信息

Who's Involved? 相关方?

1. DMF Holder → Owns & submits DMF DMF持有者：拥有并提交DMF
2. Applicant/MAH → Files product dossier 申请人/MAH：提交产品申请档案
3. SFDA → Reviews dossier + DMF (with LoA) SFDA：审核产品申请档案和DMF（需附授权函）

How It Works 流程概述

1. DMF submitted (stored by SFDA) 提交DMF文件（由SFDA保存）
2. Product dossier filed by Applicant 申请人提交产品Dossier
3. Letter of Access (LoA) issued by Holder 持有人出具授权函
4. SFDA reviews both together SFDA同时审核DMF文件和产品申请档案

DMF is a **supportive document**, never standalone; requires **product Dossier + Letter of Access** for review. DMF是**辅助性文件**，不能单独使用；审核时需要提供**产品申请档案和授权函**。

4.1 DMF Form:

The following included in the DMF Form: (All fields required)

a) Identification of submission: new, resubmission, renewal or variation
b) Procedure Type: National (SFDA) or Central (GCC-DR) procedure
c) Reference number[2]
d) Date of submission[2]
e) Active substance name
f) Pharmacopeial reference
g) Trade name[2] (Specific product covered by the DMF)
h) DMF holder name
i) DMF version number and date (yyyy-mm-dd) for the applicant's part and restricted par.
j) Manufacturer name (if different from DMF holder name)
k) Manufacturer Address
l) Typewritten name and title of the signer
m)Signature of the authorized representative

A soft copy of DMF (Restricted part) Form is available on SFDA website-Drug sector-forms

https://www.sfda.gov.sa/en/regulations/68957

Approval Fees for Pharmaceutical Products 药品注册费

Fees Required to Obtain Regulatory Approvals before SFDA 获得SFDA批准所需的费用

The SFDA invoices the following fees after submission of the eSDR application for drug registration
提交 eSDR 药品注册申请后，SFDA 将开具以下费用发票:

Type 类型	SFDA Fees (SAR)	SFDA eSDR fee (SAR)
New Drugs (including Biologicals, Biosimilars, and Radiopharmaceuticals) 新药（包括生物制剂、生物类似药和放射性药剂）	**95000**	**20000**
Additional Dosage Form 额外剂型	95000	19000
Additional Strength 额外规格	24000	3600
Additional Pack Type 额外包装类型	5000	2400
Additional Pack Size 额外包装尺寸	1000	150
Generic Drug 化学仿制药	**40000**	**8000**
Additional Dosage Form 额外剂型	40000	8000
Additional Strength 额外规格	10000	1500
Additional Pack Type 额外包装类型	5000	500
Additional Pack Size 额外包装尺寸	1000	150

Type 类型	SFDA Fees (SAR)	SFDA eSDR fee (SAR)
Health & Herbal Products 保健品&草药	**20000**	**4000**
Additional Dosage Form 额外剂型	20000	4000
Additional Strength 额外规格	5000	750
Additional Pack Type 额外包装类型	2000	200
Additional Pack Size 额外包装尺寸	1000	150
Intravenous (IV) Fluids 静脉输液	**15000**	**3000**
Additional Dosage Form 额外剂型	15000	–
Additional Strength 额外规格	1000	150
Additional Pack Type 额外包装类型	1000	100
Additional Pack Size 额外包装尺寸	1000	150

Designations 认定:

Currently, SFDA does not apply any fees for drug designations, such as Orphan Drug Designation, Breakthrough Medicine Program, and Verification & Abridged Procedure. 目前，SFDA对孤儿药、突破性疗法以及确认和简化程序等药品认定不收取任何费用。

Fees do not include the 15% VAT
1Note – Size indicates 2028 Sales in LC $
Source: IQVIA Market Prognosis 2024-2028 (Sep 2024); IQVIA Market Prognosis Global summarizes the key points from each of the Regional studies and adds this to desk research conducted in seven other regions. A combination of IQVIA, official import/export and local manufacturer figures are used to compile this report and establish events that could impact the sales forecast over the period reviewed

Renewal Fees for Pharmaceutical Products 药品注册续期费

Fees Required to Renew Drug Registration before SFDA 在SFDA续期药品注册的费用

- Renewal fees 续期费:

Type 类型	SFDA Fees (SAR)	SFDA eSDR fee (SAR)
New Drug 新药	30000	3000
Generic Drug 仿制药	10000	1000
Health & Herbal Products 保健品&草药	8000	800
Veterinary Drug 兽药	1000	100
Intravenous (IV) Fluids 静脉输液	5000	500

Variation 变更：

Type 类型	SFDA Fees (SAR)	SFDA eSDR fee (SAR)
Drug Variation 药品变更	3000	1000

Fees do not include the 15% VAT

1Note – Size indicates 2028 Sales in LC $

Source: IQVIA Market Prognosis 2024-2028 (Sep 2024); IQVIA Market Prognosis Global summarizes the key points from each of the Regional studies and adds this to desk research conducted in seven other regions. A combination of IQVIA, official import/export and local manufacturer figures are used to compile this report and establish events that could impact the sales forecast over the period reviewed

Outline 提 纲

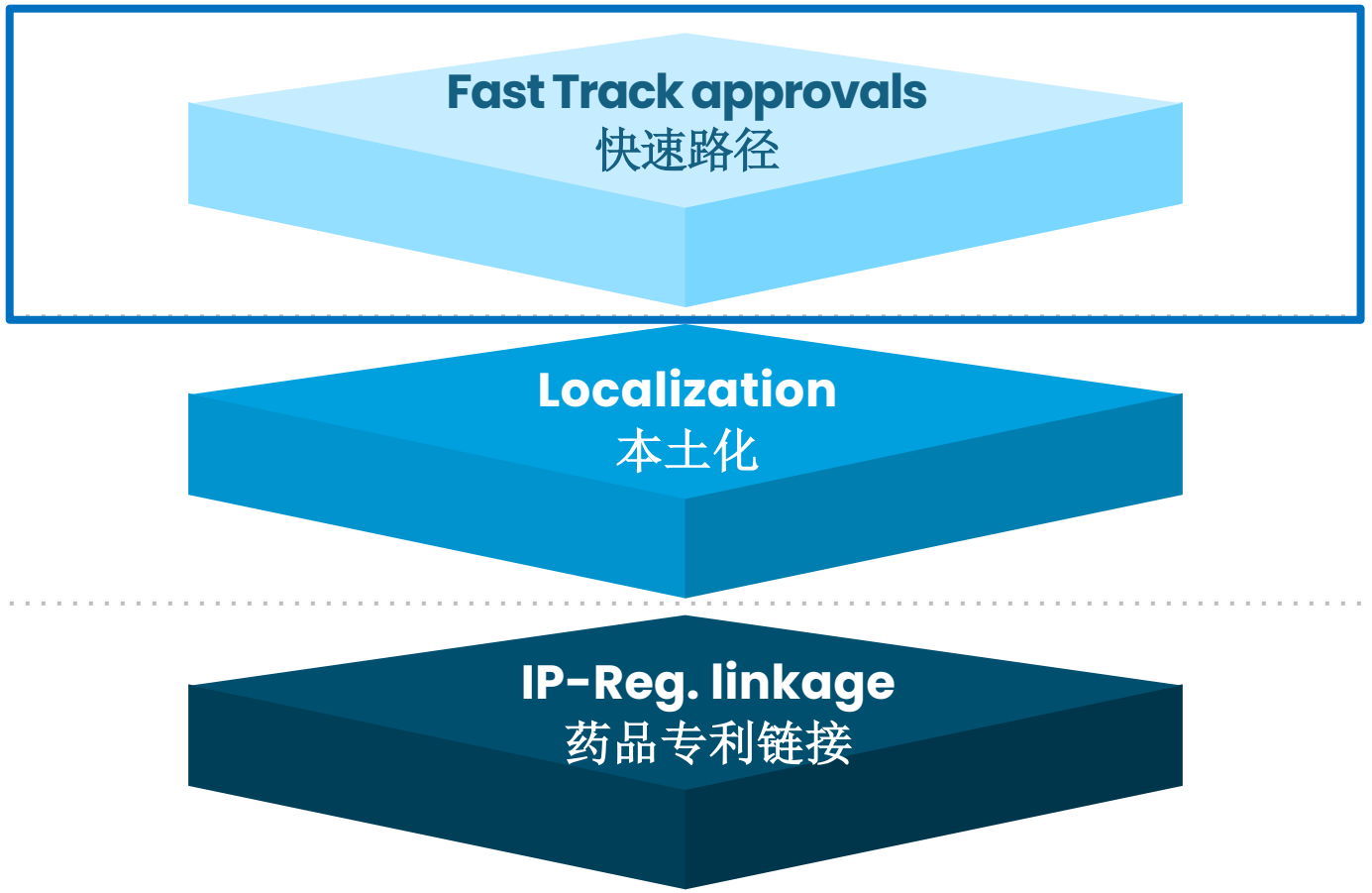
I. Market overview 市场概览

II. Regulatory requirements 监管要求

III. Accessibility vs. Affordability 可及性 vs. 可负担性

IV. Drug Pricing 药品定价

Accessibility vs. Affordability 可及性 vs. 可负担性



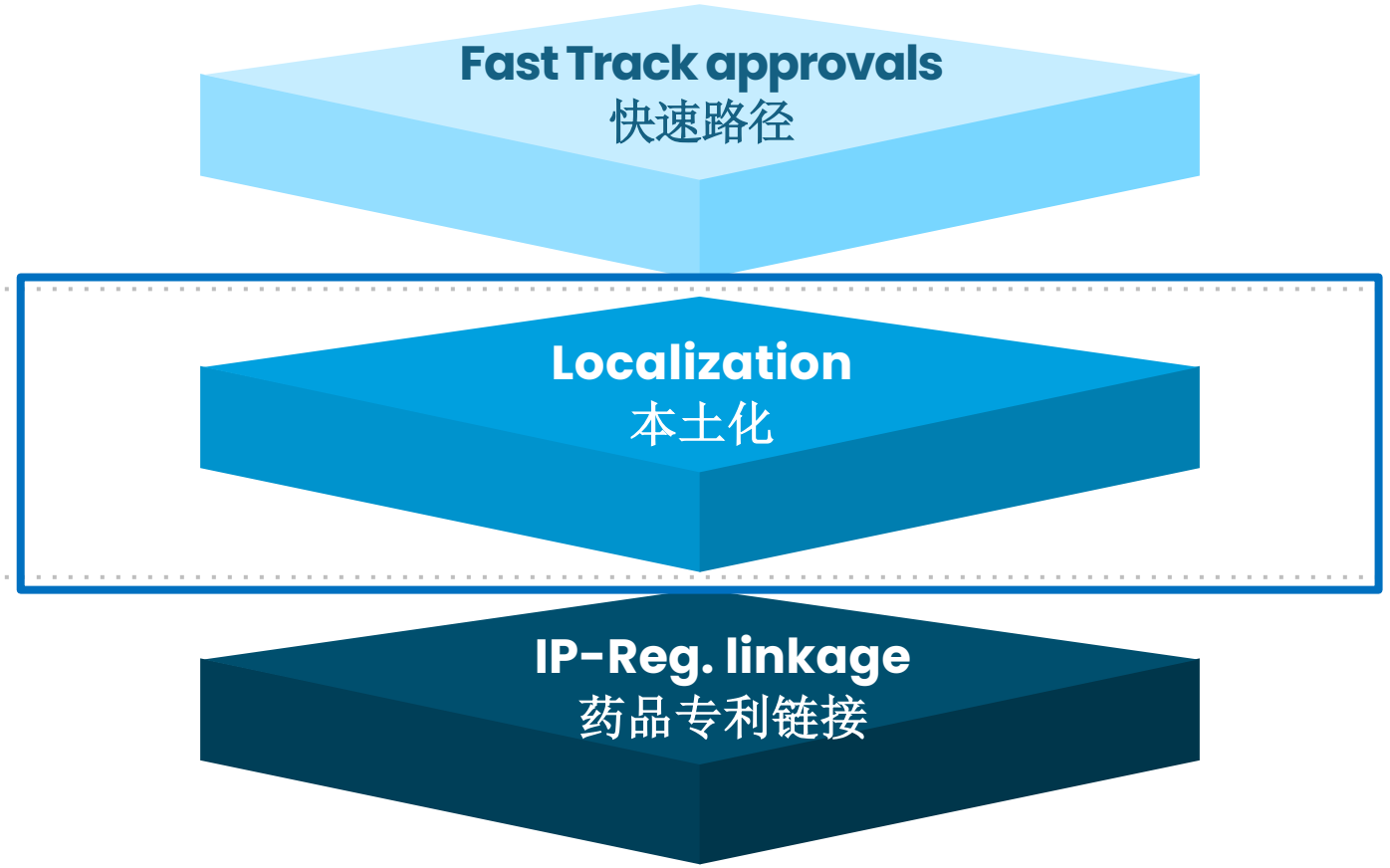
SFDA Regulatory incentives SFDA监管激励措施

Pathway 路径	Key Criteria 关键指标	Benefit(s) 益处
Verification procedure 验证程序	• New chemical entities and new biologics (excluding vaccines and blood products) registered by US FDA **and** EMA submitted to SFDA **within 2 years of approval** by the reference regulatory agencies. 已在FDA 和 EMA 注册的新化学实体和新生物制剂（不包括疫苗和血液制品），需在获得参考监管机构批准后 **2 年内**提交至SFDA。 • Manufacturer should be in one of the following countries: USA, UK, Canada, Australia, Japan, Switzerland, Germany, France, Ireland, Italy, Spain, Portugal, Finland, Sweden, Norway, Denmark, Belgium, Netherlands, Austria or Singapore. 制造商应位于以下国家之一：美国、英国、加拿大、澳大利亚、日本、瑞士、德国、法国、爱尔兰、意大利、西班牙、葡萄牙、芬兰、瑞典、挪威、丹麦、比利时、荷兰、奥地利或新加坡。	Review within 30 days 30天内评审
Abridged procedure 简化程序	• New chemical entities and new biologics (excluding vaccines and blood products) registered by US FDA **or** EMA submitted to SFDA **within 2 years of approval** by the reference regulatory agencies. 在美国FDA **或** EMA 注册的新化学实体和新生物制剂（不包括疫苗和血液制品），在获得参考监管机构批准后**2年内**提交至SFDA。 • Manufacturer should be in one of the following countries: USA, UK, Canada, Australia, Japan, Switzerland, Germany, France, Ireland, Italy, Spain, Portugal, Finland, Sweden, Norway, Denmark, Belgium, Netherlands, Austria or Singapore. 制造商应位于以下国家之一：美国、英国、加拿大、澳大利亚、日本、瑞士、德国、法国、爱尔兰、意大利、西班牙、葡萄牙、芬兰、瑞典、挪威、丹麦、比利时、荷兰、奥地利或新加坡。	Review within 60 days 60天内评审
Orphan designation 孤儿药认定	1) An unregistered drug in SFDA, or an already registered drug in SFDA with a new orphan indication, or a new dosage form, or other major variation applications that meet all relevant criteria of ODD 尚未在SFDA注册的药品；或已在SFDA注册的、具有新的孤儿药适应症、新剂型或其他符合孤儿药所有相关标准的重大变更申请的药品 2) Seriously debilitating diseases or life-threatening conditions or diseases 严重衰弱性疾病或危及生命的疾病 3) Prevalence of rare disease or condition OR lack of financial viability 罕见疾病或病症的流行，或缺乏经济可行性 4) Under development for this orphan condition 正在针对该孤儿药疾病进行研发 5) Comparison with other methods for diagnosis, prevention or treatment of the condition 与其他诊断、预防或治疗该疾病的方法进行比较	• Pre-submission meetings 提交前会议 • Priority review 优先评审 • Scientific & regulatory advice and consultation provided by the Drug sector 药品评审部门提供的科学及监管建议和咨询 • **Marketing Exclusivity 市场独占权** • **Pricing 定价**

SFDA Regulatory incentives SFDA监管激励措施

Pathway 路径	Key Criteria 关键指标	Benefit(s) 益处
Breakthrough 突破性疗法	All four criteria must be fulfilled in order to gain a breakthrough medicine designation at end of phase 2 or at any time after 在临床II期结束或之后的任何时间获得突破性疗法认定，必须满足以下四项标准: 1. Target serious, debilitating or life-threatening conditions **with unmet medical need**. 针对严重、使人衰弱或危及生命的疾病，且**临床需求尚未得到满足** 2. The medicinal product is likely to offer a major advantage over methods currently used. 该药品可能比目前使用的方法具有显著优势 3. The potential adverse effects of the medicinal product are considered to be outweighed by the benefits, allowing for the reasonable expectation of a positive benefit/risk balance. 该药品的潜在副作用被认为被其益处所抵消，从而可以合理预期获得正的效益/风险平衡 4. The product is not registered at any regulatory authority at the time of submission of the designation request. 提交认定申请时，该产品尚未在任何监管机构注册	optimize development plans and **speed up evaluation** 优化发展规划，**加快评审**
Priority review 优先评审	• **NCE & Biological** 原研药 1) A request for priority review is sent before submission, and a response to the applicant is made within 15 working days 提交前发送优先审查请求，并在15个工作日内回复申请人 2) Serious or Life-Threatening Condition 严重或危及生命的疾病 3) Demonstrating the Potential to Address Unmet Medical Needs 展现解决未满足临床需求的潜力 • **Biosimilars** 生物类似药 1) Priority review of biosimilars are requested on the eSDR application. eSDR 申请中要求优先审查生物类似药 2) first biosimilar to the innovative product that already registered in SFDA or stringent regulatory authority. 已在SFDA或严格监管机构注册的创新产品的首个生物类似药。 • **Along with Availability in Special lists** 特殊清单中的产品 1) Incentive Project List 激励项目清单 2) Shortage list with **no available generics** 短缺药品清单且**无可替代的仿制药** 3) Local Manufacturing list and Targeted Local Manufacturing list 本地制造清单以及目标清单	40% of the normal registration process 常规注册流程的40%

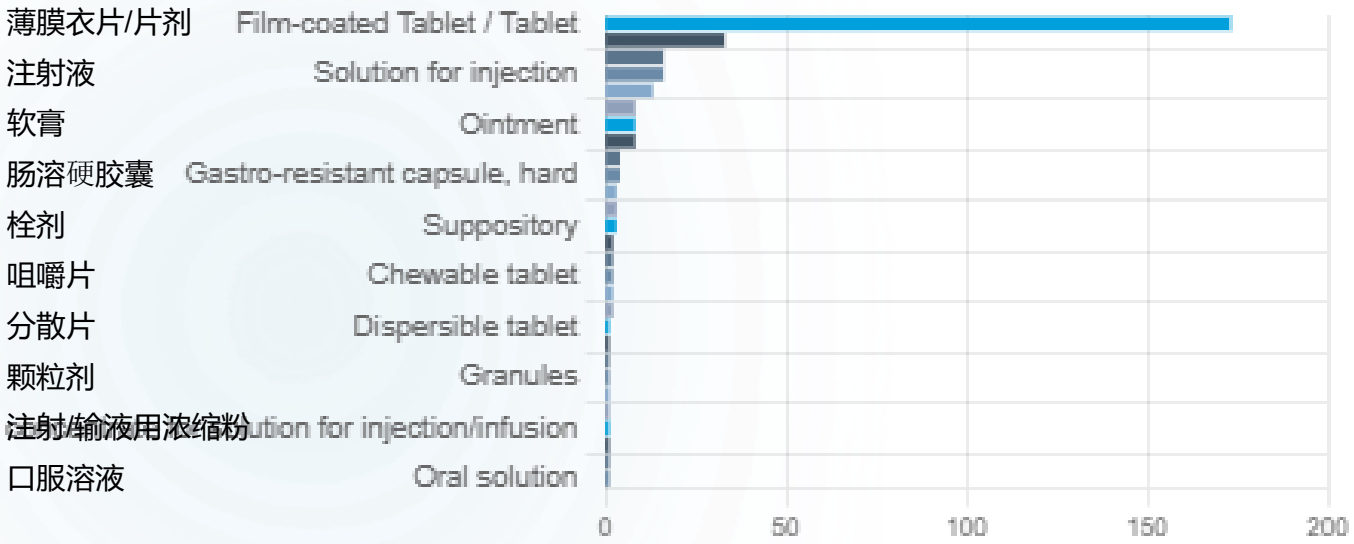
Accessibility vs. Affordability 可及性 vs. 可负担性

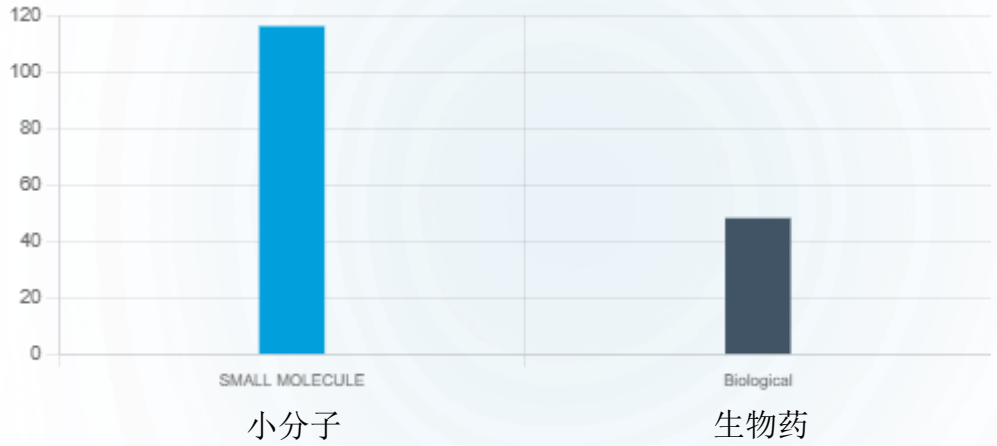


Local products 本地产品

When a product is deemed local by SFDA 何种商品被SFDA视为本地商品	
Locally manufactured product definition 本地制造的商品定义	The pharmaceutical or herbal product is considered locally manufactured if it is completely manufactured in the Kingdom. 如果药品或草药完全是本地制造的，则视为在沙特本地制造。
Complete Manufacturing of Pharmaceutical Products 医药品的完全制造	**Chemical and Herbal Products 化学药和草药:** All manufacturing process of the finished product, starting from the processing of active (raw) ingredients until the packaging stage. 成品的所有制造过程，从加工开始 活性（生）配料直到包装阶段。 **Biological Products 生物制品** Any step in the main manufacturing process producing an active ingredient or finish product. Typically, these processes start by using substances that are derived from a biological source or genetically modified cells by biotechnology through the production stages by means of incubation and purification processes. Accordingly, the manufacturing of the finished product， which often includes the addition of excipients, sterile filtration and filling, with the exception of primary and secondary packaging. 生产活性成分或成品的主要制造过程中的任何步骤。通常，这些过程从使用来自生物来源的物质开始或通过生物技术通过生产阶段进行转基因细胞孵育和纯化过程。因此，成品的制造，这通常包括添加赋形剂、无菌过滤和填充，但初级和二级包装。
Growing Local Manufacturer 成长型的本地制造商	A manufacturer with an industrial license from the related authorities in the kingdom, after three years from the date of registering the first product, it will not be considered as a Growing Manufacturer. 一家拥有沙特相关机构颁发的工业许可证的制造商，经过 3 年，则不会被视为 成长性制造商。

Localization Lists 本地制造清单



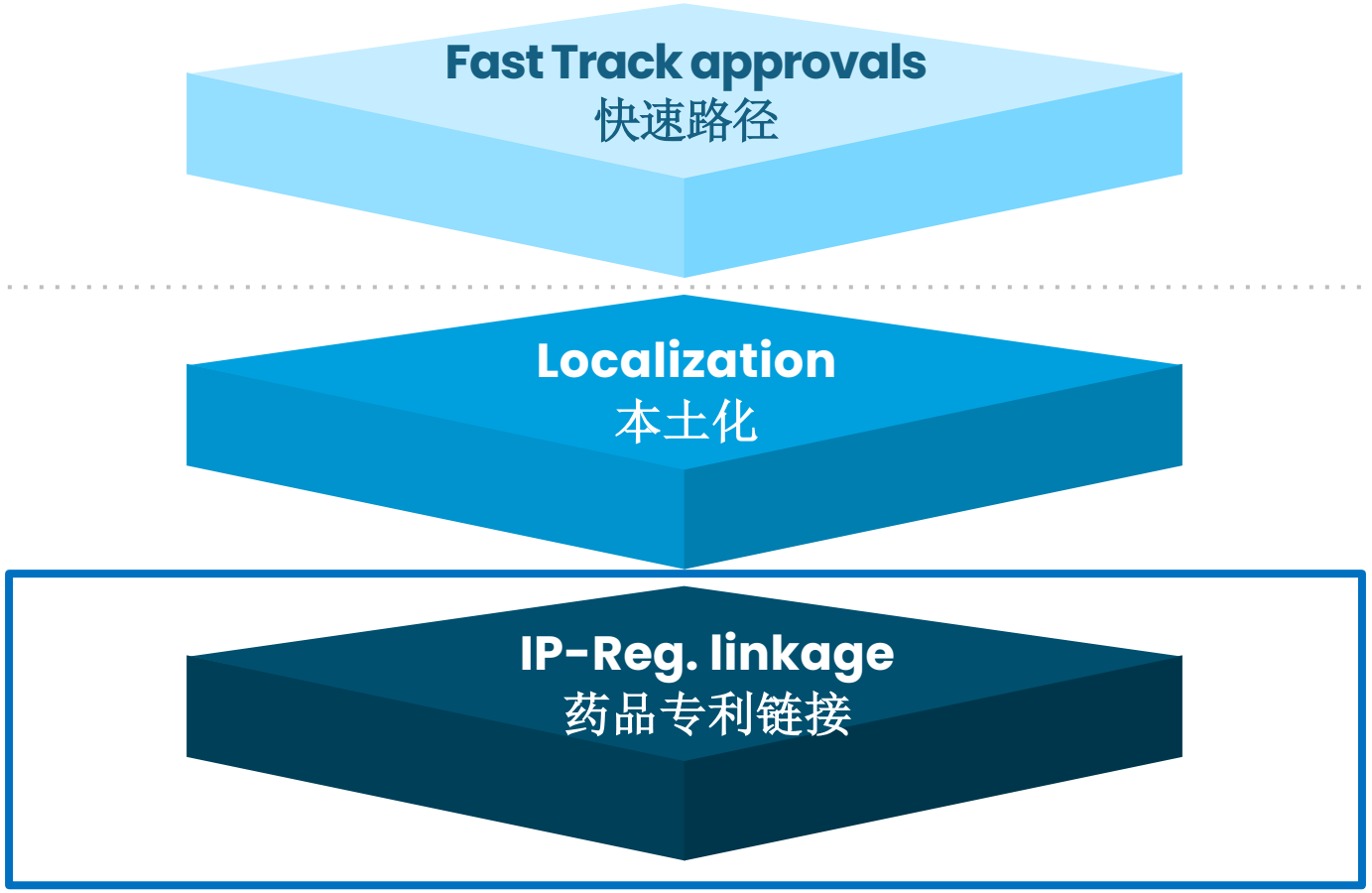


Mandatory Localized products
强制本地制造清单

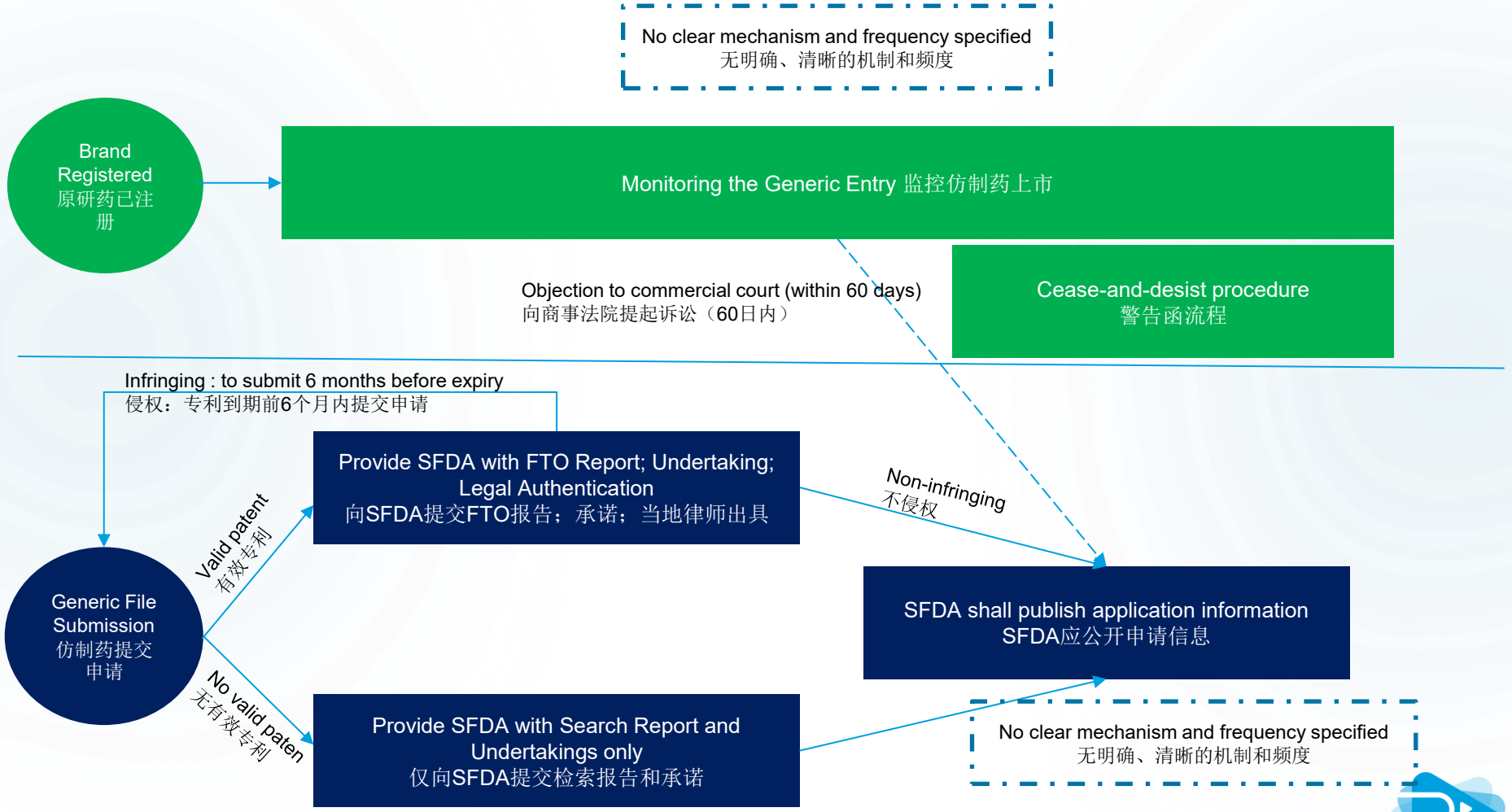
Targeted Localized List
本地制造目标清单

ASPIRE TO MAKE A DIFFERENCE
IPDataLab

Accessibility vs. Affordability 可及性 vs. 可负担性



IP – Regulatory linkage 药品专利链接



Other incentives – Exclusivity 其他激励机制 – 市场独占权

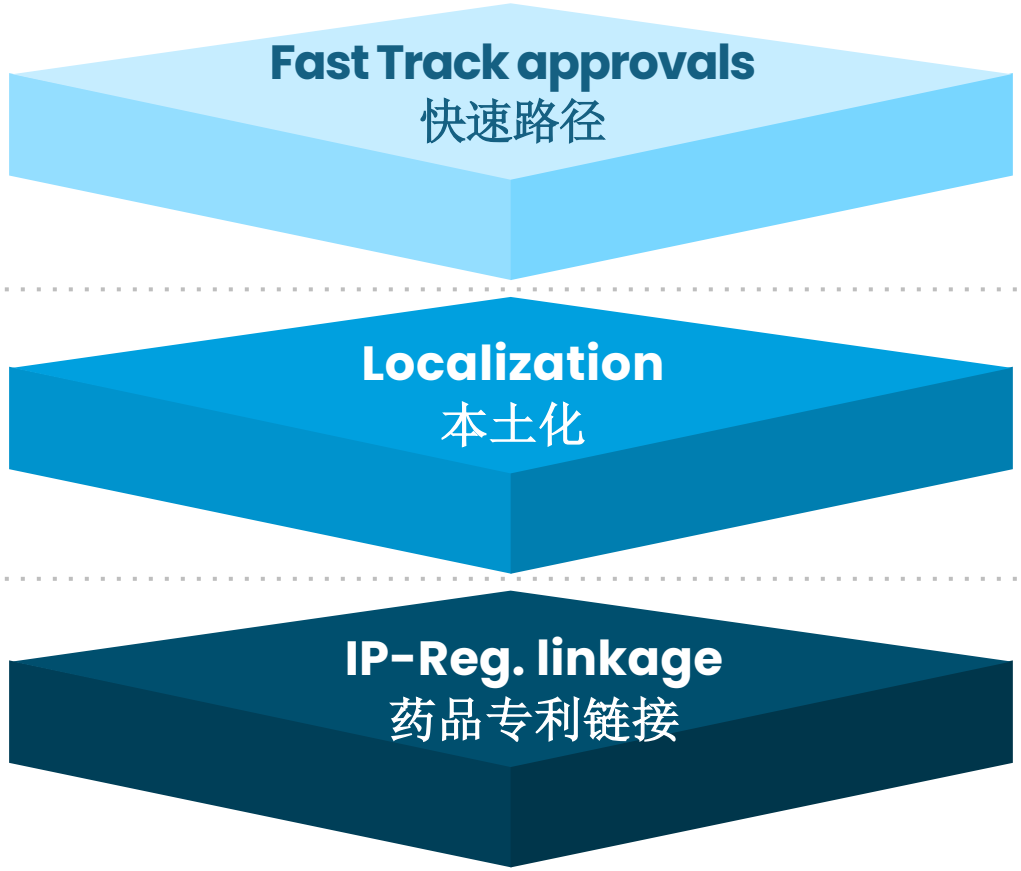
Eligibility 获得资格	Exclusivity 市场独占权	
1. WHO Essential products WHO 基本药物标准清单 2. Non-registered product or product with no alternative 尚未注册产品或无替代品 3. The product with high demand in the market (i.e. shortage reports and import license) 市场需求旺盛的产品（例如，短缺清单和进口许可证）	New pharmaceutical products: five years from the date of certificate of pharmaceutical product (CPP) 新药品：自药品证书（CPP）颁发之日起五年	Registered products: five years from the date of the marketing exclusivity approval letter. 已注册产品：自市场独占权批准函颁发之日起五年

Accessibility vs. Affordability 可及性 vs. 可负担性

IMLUNESTRANT submitted at SFDA as first country globally based on public data available.
基于可获得的公开数据，**IMLUNESTRANT** 率先向SFDA提交注册申请

No need for CPP
不再要求提供CPP

Breakthrough designation give to 5 products in last few months
过去数月，有5个产品获得了突破性疗法认定



Utilized new SFDA framework
利用了新的SFDA框架

Used lack of basic patent and submitted via legalized FTO
利用了基础专利缺失的漏洞，并提供了律师出具的FTO报告

Three **Semaglutide** biosimilars have been submitted at SFDA starting from July 2023
自2023年7月起，已有三款司美格鲁肽生物类似药向SFDA提交了注册申请。

Outline 提 纲

I. Market overview 市场概览

II. Regulatory requirements 监管要求

III. Accessibility vs. Affordability 可及性 vs. 可负担性

IV. Drug Pricing 药品定价

Public Prices 公开市场价格

Generic/ Biosimilar Pricing (Rank dependent) 仿制药/生物类似药定价（取决于排序）

	Generic 仿制药	Biosimilar 生物类似药
1st	70% of innovative brand's price 原研药价格70%	75% of biological brand's price 原研药价格75%
2nd	65%	65%
3rd and more	60%	65%

Price Margin 价格利润率

CIF Price 到岸价	Pharmacy Purchasing Price Margin 药店采购价格利润率	Public Price 公开价格
<50 SAR	15%	20%
50 - 200 SAR	10%	15%
>200 SAR	10%	10%

Public Tender 公开招标

Incentive by Local Content Authority 本地内容管理局的激励措施

01

Mandatory list 强制清单

- Government like NUPCO procure only locally produced products 类似NUPCO的政府机构只采购本地制造产品
- Eligible products : have at least 3 local manf. 产品资格审查：至少有3家本地制造商
- Factory have local content certificate 工厂有本地内容证书
- 316 Product 316个产品
- Up to 30% price ceiling 最高30%的价格上限

02

Targeted list 目标清单

- Strategic list to be locally manufactured 本地制造战略清单
- Active discussion with the authority with a clear localization plan 与主管部门积极沟通，制定清晰的本地化计划

LCGPA and NUPCO provide price preferences for public tender purchases for product who have local input depending on the degree of localization (e.g., secondary packaged and fully local manufactured products).

本地内容管理局根据本地化程度（例如二次包装和完全本地制造的产品）为具有本地投入的产品提供公开招标采购价格优惠。

LCGPA: Local Content & Government Procurement Authority 本地化和政府采购局
NUPCO: National Unified Procurement Company 国家统一采购局

References

Exclusivity
https://www.sfda.gov.sa/sites/default/files/2021-03/MarketingExclusivity-v1-EN.pdf

Incentive list
https://www.sfda.gov.sa/en/unregistered-pharmaceuticals-list

Shortage list
https://www.sfda.gov.sa/en/currentlyInShortageList

Mandatory for local production list
https://lcgpa.gov.sa/en/Regulations/Docs-Lists/Pages/MandatoryList.aspx

New product applications when the reference product is not registered by the SFDA.
https://www.sfda.gov.sa/sites/default/files/2025-05/RGLBSESM.pdf

Breakthrough program
https://sfda.gov.sa/sites/default/files/2024-05/SFDA-BMP_0.pdf

Orphan
https://www.sfda.gov.sa/sites/default/files/2023-06/OrphanDrugDesignation.pdf

Abridged and Verification
https://www.sfda.gov.sa/sites/default/files/2024-05/VerificationAbridgedProcess22_0.pdf

Priority review
https://sfda.gov.sa/en/regulations/68959

IP Regulatory linkage
https://www.sfda.gov.sa/sites/default/files/2023-02/ApproachDealingPatentsV1.pdf

ASPIRE
TO MAKE
A DIFFERENCE

以终为始，有的放矢，助力出海！

北京爱普数联科技有限公司

北京市朝阳区望京科技园 E 座一层

毕丽娟女士，总经理

JESSICA.BI@IPDATALAB.COM

+86 - 138 0106 5965

WWW.PHARMSPOT.NET

爱普数联 IPDataLab