Saudi Arabia

Recent and planned developments in pharmaceutical policies 2023

CHANGES IN PRICING

- Change of reference countries in External Price Referencing by introduction of new criteria for selecting countries on basket. E.g.: Geographic Distribution, Availability of pricing policy in these countries, similar health & economic status. Result: The Basket reduced from 30 to 20 then to 16 countries.
- Date of implementation: 01/10/2022

Implementing New Policies related to:

- New Policy for Appeal & Price re-visiting on Drug Sector Decisions:
- New Policy for New Discounted Price Application.
- New Guideline for Submitting Pharmacoeconomic Studies.

CHANGES IN REIMBURSEMENT

- New HTA Centres established in the country that serve ministry of health.
- Date of implementation: 2020

- The Council of Health Insurance (CHI) adapt unified formulary for private insurance company allowing for compulsory reimbursement for drug in the formulary with fixed rate of co-payment depend on the insurance policy. The objective include:
  - Medicine (therapeutically accurate and cost effective)
  - Provide a comprehensive resource to insurance companies and HCPs
  - Standardize the prescribing practices in KSA by using the best selected evidence-based guidelines
  - Promote affordable and equitable access to healthcare
  - Improve governance on the private health care insurance sector
  - Decrease healthcare expenditure through the use of therapeutically equivalent but more affordable treatment option
- Date of implementation: 2022

OTHER CHANGES: Horizon Scanning

- SFDA initiated Horizon Scanning policy (HS) in 2022.
- HS defined as a systematic approach to an early Identify, filter and prioritize new and emerging health technologies that has a potential positive impact on healthcare systems and stakeholders.
- HS aims to encourage pharmaceutical products registration to enhance drug availability as early as possible specifically for the unmet medical needs.
- Defining the Scope
  - Follow-up the New or repurposed medicines under Clinical Trial (Phase II/III)
  - Product not registered in SFDA yet but approved by other Regulatory Authority or recommended by Clinical Practice Guideline
  - Product that lose the patency in order to promote generic registration and increase the availability with cost reduction
- Determining the Data Sources
  - Global Database, Trial registries, Regulatory authorities, pharmaceutical news sources, Pharmaceutical companies
- HS identified ~ 40 product including 13 product deemed highly important, 8 as potentially important, and 19 as not important.
- Drivers of high importance: unmet medical need, therapeutic value, issues in availability of alternatives and the estimated cost of treatment.

SPECIAL TOPIC:
Developing and implementing pharmaceutical policies in view of the current challenges (soaring inflation, medicine price increases, increasing no. of medicine shortages)

1) A centre for Drug availability including Track & Trace system (RSD) was established in 2017. RSD is an electronic system that aims to ensure drug safety by tracking all drugs in the supply chain from manufacturing till it reaches the consumer. With the possibility of direct stopping of recalled medications or the ones with warnings.
2) The problem of medicine shortages (i.e., Immunoglobulin, Paracetamol) seems to be intensified: Therefore, we have been informed by the centre of availability that the drug is subject to decrease in stock in the coming months. So, we worked early and start the negotiation with pharma company to check the possible solution to prevent such an effect. One of them is to increase the drug prices.
3) In November 2022, a new committee launched under the CEO supervision with a warm room from different institution to tackle any type of drug shortage in implementing new solution like restriction on prescribing, Quantity transfer between different accounts, increase in manufacturing capacity by the local company and the possibility to manufacture the API locally.
4) A specific policy has entered on effect on September 2022 illustrating the method for proposing an appeal to get increase in drug prices.
   - The pharma company can apply for price increase within 60 days of decision has been made and SFDA will study the request within 60 days and the result could be acceptance or rejection depend on the proposed justification
   - Other option is to apply for price revisiting where the pharma company has the right to request a price increase once in each registration cycle (5 years) if anything happened that could affect the availability.
5) New Policy for New Discounted Price Application.
   - To make sure that the newly discounted price has no negative effect or disruption on market, we allowed 180 days for pharma company to make the product available in the market with the new prices.
   - We allowed pharma company to extend the application by another 180 days by max if they have any issue that could affect the availability out of hand.
   - SFDA create freezing period from extra discount on price for at least 2 years to maintain sustainability.