New Medicine Agency, future Health Law…New opportunities and framework for the Decision making process in Algeria?
Algerian health insurance system (1)

- **Principles of health system:**
  - It’s based on the principle of solidarity
  - It is mandatory for all workers (employed or self-employed)
  - Covers specific categories such as retired workers, the disabled who are unable to work, students,…
  - Almost 85% of the population is covered

- **Health system funding sources:**
  - Government budget
  - Social Security
  - Household contribution
Expenditure in Pharmaceutical and Healthcare in Billion USD

<table>
<thead>
<tr>
<th>Year</th>
<th>Pharmaceutical</th>
<th>Healthcare</th>
</tr>
</thead>
<tbody>
<tr>
<td>2013</td>
<td>4.17</td>
<td>12.25</td>
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<tr>
<td>2014</td>
<td>4.64</td>
<td>13.56</td>
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<td>2015</td>
<td>4.12</td>
<td>12.06</td>
</tr>
</tbody>
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Source: BMI 2016
Principal Policy Makers in Pricing and access

- **Directorate of Pharmacy**: Is part of the Ministry of Health, is responsible in the evaluation, registration, pricing, marketing, import and export of pharmaceuticals.

- **LNCP**: Is under the responsibility of the Ministry of Health, is a public administrative body, which assess the Quality of the medicines for registration decision.

- **CRM**: Is under the responsibility of the Ministry of Labor, is an interministerial committee, which is responsible of reimbursement decisions for «outpatients drugs».

- **PCH**: Is under the responsibility of the Ministry of Health, is a Central Hospital Pharmacy Agency (PCH), is responsible in the tendering and purchasing of «inpatients drugs».
Current decision-making process for Inpatient medicines (1)

- Pricing decisions for public sector, hospitals and inpatient drugs:

  According the Ministerial Decree № 137 / MSPRH / MIN of 18\textsuperscript{TH} October 2005:
  - Assessment by Economic Committee under The Directorate of Pharmacy
  - Price setting (Free of board price) by Directorate of Pharmacy
  - Criteria:
    - National list of Medicines,
    - registered products,
    - Clinical and Economic Consideration
    - External price referencing
  - Drug access by:
    - Purchases by Central Hospital Pharmacy Agency (PCH)
    - For all public sector health facilities
    - Funding from Ministry of Health Budget
Current decision-making process for outpatient medicines (2)

- Pricing and reimbursement for outpatient drugs

After Drug registration and Price FOB setting, The Committee for Reimbursement of Medicines (CRM) assess and decides on the level of reimbursement:

- Responsible of assessment:
  - Clinical value
  - Clinical added value

- The CRM defines the reimbursement rate according to the disease:
  - 80% for ordinary diseases
  - 100% for chronic diseases
Current decision-making process for outpatient medicines (3)

1/ Pharmaceutical registration Services
   Criteria: Quality, safety, efficacy

2/ Economic Committee (inter-ministerial committee)
   Criteria: clinical
   And Economic considerations
   External price referencing

Central Hospital Pharmacy Agency (PCH)
   Call for tenders Criteria: Contract awarded to the cheapest tender

Ministry of Health / Directorate of Pharmacy

Pharmaceutical Products Control National Laboratory: LNCP
Criteria: Quality
Current decision-making process for outpatient medicines (4)

1. Decision making Process for reimbursement (CRM)

- Clinical value: Efficacy, Risk / benefit ratio, Disease Severity, Unmet need, Interest for public health
- Clinical added value: Effectiveness, Place in the therapeutic strategy
- Local production

Assessment: based on level on clinical evidence

SMR grade: 100%
ASMR grade: 80%
Registration in the Positive list: No
Current decision-making process for outpatient medicines (5)

2. Public Price setting for outpatient drugs

- Major additional benefit
  - Important
  - Public Price setting
  - Publication in the Official Journal (Price & reimbursement rate).
- Additional benefit
  - Yes
    - Price negotiation
    - Price referencing: Same price to standard treatment
  - No
    - Price decrease: Price less than standard treatment
- Minor
  - No additional benefit
  - Not reimbursed
  - According:
    - The level of price
    - Local Production
Outlook and perspectives (1)

- The New Medicine Agency, in Algeria the “Agence National des Produits Pharmaceutiques” ANPP:
  - Responsible in the drug and medical device approval
  - Provide Explicit framework for decision making registration
  - Develop Health technology assessment activities (still not defined by the Law)
  - Involve in the Pricing (still not defined by the Law)

- Effect expected of the new agency ANPP:
  - Simplification of Decision making process
  - Transparency in the process (explicit criteria, explicit delay of assessment…)
  - Development and implementation of HTA activities
Outlook and perspectives (2)

- Future health Law:
  - Confirm the right to « health for all »
  - Contracting out schemes
  - Public Private partnership promoted
  - Importance of non communicable diseases
  - New regulation for outpatient drug

- In the view of the arrival of innovative drugs, the CRM would like to include in the future Law:
  - a new criteria: **Cost effectiveness analysis** for innovative drugs (With Important Clinical added value).
  - New mechanisms such Managed entry agreement: “**Payment based to performance**”
Thank you

Amine AISSAOUI
Pharm D, MSc, PhD(c)
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