Market Access Timelines to Innovation in Algeria

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OBJECTIVES:

This study aims to determine time to access in Algeria for innovative medicines.

INTRODUCTION:

Innovative medicines can nowadays open new horizons for patients with life threatening diseases; but access to health innovation is a real headache for decision-makers. The therapeutic progress brought by these innovations is often linked to a heavy cost. In Algeria, issues of access started raising since 2017 mainly because of lack of funding.

METHODS:

- Using primary and secondary data, we conducted a deep descriptive analysis of the Algerian market access process in terms of registration, pricing, reimbursement and procurement.
- In order to select the innovative medicines, a comparison between the HAS (France) and the FDA (USA) was undertaken ***(the criterion guiding our choice was the explicit recognition of the innovative character):*** a retrospective analysis of innovative products approved by EMA and FDA to constitute the study sample (BTD and ASMR 1 to 3)

FDA
- Orphan Drug
- Fast Track
- Accelerated Approval
- Priority Review
- **Breakthrough Therapy Designation**

HAS HAUTE AUTORITÉ DE SANTÉ
- Service Médical Rendu
- **Amélioration du Service Médical Rendu**

EUROPEAN MEDICINES AGENCY
- Orphan Drug
- Accelerated Assessment
- PRIority MEdicine PRIME

- Then, we determined the registration and market access timelines in Algeria in comparison with France and USA.

RESULTS:

Descriptive analysis of the market access process in Algeria:

Registration
- **National Pharmaceuticals Agency (ANPP) – Ministry of Pharmaceutical Industry (MPI)**

Pricing *(part of the registration process)*
- **Economic Committee (ANPP)**

Access
- **Reimbursement and procurement**

Pricing policies for medicines: Pricing is determines by the Economic committee at the Ex-factory price level, mainly using external reference pricing for imported drugs and internal reference pricing for local manufactured drugs).

The next step is access, there is a difference between the in-patient and the out-patient sectors:

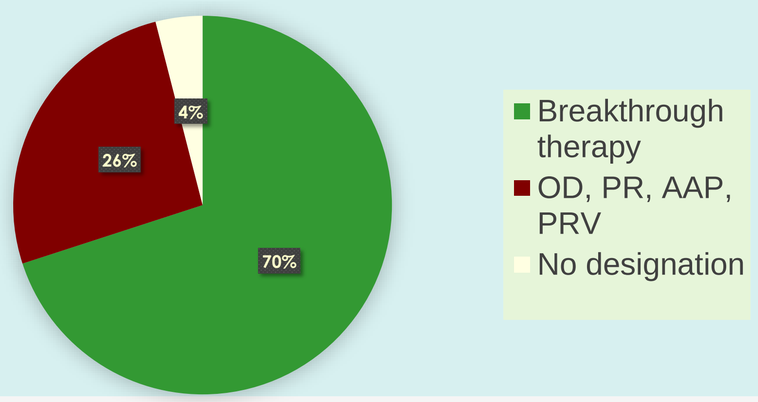
Ministry of Labour, employment and social security, Reimbursement Committee: There is a Positive list with a unique reimbursement rate (80%) Reference price system (RPS) is applied since 2006, Co-payment: 20% + difference with the reference price if applied, Mechanisms for vulnerable groups: 100% reimbursement rate for chronic diseases populations.

Hospitals provide free medicines without passing through reimbursement process, funding comes from the social security fund (20%) and the government budget (80%). Hospital formularies: There is a commercial list of PCH(Central Pharmacy of Hospitals), No co-payment, hospitals provide free health care.

Innovative medicines selection :

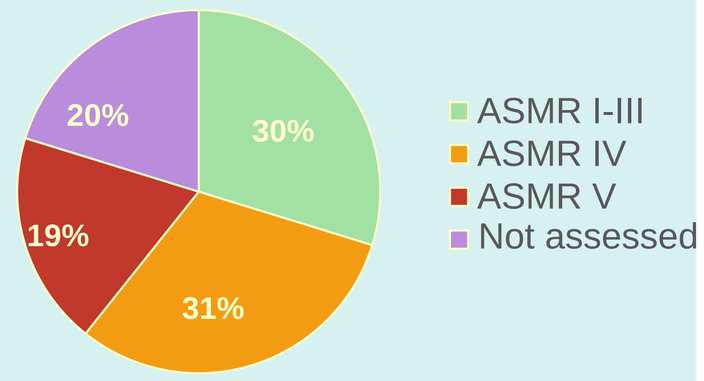
HAS HAUTE AUTORITÉ DE SANTÉ → FDA

Total ASMR I-III	**27**	**100%**
Breakthrough Therapy	19	**70,3%**
OD, PR, AAP, PRV	7	25,9%
No designation	1	3,70 %



FDA → HAS HAUTE AUTORITÉ DE SANTÉ

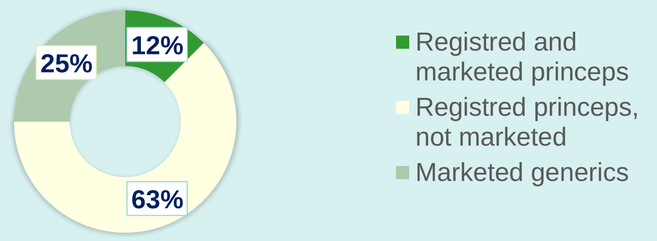
Total BTD	**84**	**100%**
ASMR I-III	25	**30%**
ASMR IV	26	31 %
ASMR V	16	19 %
Non évaluées	17	20 %



Registration timelines :

INN	Brand name	FDA	EMA	Algeria
Propranolol	HEMANGIOL®	14/03/2014	23/04/2014	29/11/2018
Ibrutinib	IMBRUVICA®	13/11/2013	21/10/2014	07/09/2018
Pembrolizumab	KEYTRUDA®	04/09/2014	17/07/2015	07/01/2018
Nivolumab	OPDIVO®	22/12/2014	19/06/2015	01/04/2018
Eltrombopag	REVOLADE® (Promacta® in USA)	20/11/2008	11/03/2010	05/03/2017
Éribuline	HALAVEN®	15/11/2010	17/03/2011	29/05/2019
Sofosbuvir	SOVALDI®	06/12/2013	16/01/2014	17/04/2016
Sofosbuvir/ Lédipasvir	HARVONI®	10/10/2014	17/11/2014	17/04/2016

Market access timelines :



DISCUSSION:

96% of the drugs that had ASMR I to III in the HAS assessment benefited from a specific process at the FDA to allows a fast access.

70% of the drugs that had the designation Breakthrough therapy in the FDA assessment did not have ASMR I to III in the HAS assessment.

Only one princeps drug from the 27 considered as innovative was marketed in Algeria: the MA was obtained 4 years after the first registration (FDA), and the first purchase was made 2 years after the registration in Algeria, which makes a total timeline of 6 years for effective market access;

Two generics were also marketed.

CONCLUSION:

The concept of innovation can be different depending on the regulatory authority assessment process and criteria. Algeria records a low rate of access to innovative drugs. Solutions should be found to address the regulatory and the funding issues in order to improve access to innovation.