The Access to Medicines and Vaccines in Tunisia in a post-Covid-19 Era

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SUMMARY

In countries such as Tunisia, access to medicine, vaccines, and medical devices is a challenging task, not only, but even more so before and during the 2020 Covid-19 pandemic. The high demand for those products along with an international supply chain disruption made access to healthcare and especially essential medicines more complicated both globally and in Tunisia.

This paper aims at tackling the medicine/ vaccine shortage in Tunisia in the post-Covid-19 era. We admit that this problem is complex and may not be thoroughly addressed in a policy paper only. Yet, we try to make the drug shortage problem less complex to understand. We will highlight the cons and pros of Tunisian public health politics and policies, and the potential root causes that limit the accessibility of medicines and vaccines. Finally, some recommendations for reform will be given.

THE PUBLIC HEALTH SYSTEM AND PHARMACEUTICAL SUPPLY

From a socio-economic perspective, the Tunisian public health system is based on a patient-centred approach that has the goal of bringing the less expensive and most affordable medicines and services to patients, without comprising its quality, thus ensuring the patients' well-treatment.

In terms of pharmaceutical supply, the Central Pharmacy of Tunisia (Pharmacie Central de Tunisie, PCT) is the governmental institution with the monopoly of importing medicines. This gives it the power to negotiate the price and it assures the quality of the medicines in the market.[1] The quality of the medicines is also the result of the highly regulated pharmaceutical ecosystem, a local pharmaceutical industry, and a highly qualified pharmaceutical staff.

Also, there are 169 hospitals, 2,161 primary healthcare centers, and more than 2,000 private pharmacies distributed in the country.[2] Private pharmacies are present even in small villages, with extremely poor health coverage and sometimes no doctors at all. This makes the accessibility to low priced and high-quality medicines good compared to other countries in the region.

However, after the 2010 Tunisian revolution, the number of missing drugs was critically increasing. This problem was first perceived by health practitioners, but didn't become a hot topic of public and political debate. No immediate solution took place. By 2018, the situation was getting more alarming, and vital medicines started to be missing in the pharmacies and the hospitals. This problem repeated in 2019.[3]

The complexity of the situation is admitted, and the blame could not be put on one part of the system only. Nevertheless, the seen part of the iceberg was the Central Pharmacy of Tunisia. As it is the only institution that can import medicine with limited financial resources (governmental budget), a main problem was that the payment to its foreign suppliers was regularly delayed. As the financial situation of the country got worse, the delay of payments increased in the last years, accordingly. This causes regular disruptions or limitations of supply from its pending foreign suppliers. The reason behind that is that the finances of the Tunisian health system are exhausted. The public hospital structures, the social security funds, and the national health insurance fund are registering record deficits that are affecting the financial flows of the entire health system.

In both the 2018 and 2019 medicine crises, the solution of the government was to inject the needed money into the PCT so it can pay its suppliers. This patchwork solution was only a symptomatic treatment for a chronic disease.

DIMENSIONS AND CONSEQUENCES OF THE BROKEN SYSTEM

The problem of the system break-up has various dimensions and consequences that came to light during the Covid-19 pandemic in 2020.

1 Pharmacie Central de Tunisie, http://www.phct.com.tn/index.php/apropos/historique.

2 Santé Tunisie (2018): Santé Tunisie en chiffres 2018

3 On this and the following see e.g. PBR Rating (2019): Le médicament en Tunisie de l' approvisonnement à la distribution : Immerson au cœur des failles et disfonctionement d'un système.

1) Lack of official data, lack of transparency

Given the post-revolutionary transition Tunisia moved in after 2011, and the continuation of a broken public health system, lack of official data, and/ or a lack of access to credible data appears to bureaucrats, practitioners, and reformers alike as a major problem. Any proposal to reform the system of pharmaceutical demand and supply must be based on reliable data which, so far, authorities cannot or are not willing to provide.

2) Communication, coordination, and mismanagement

This lack of official accessible transparent data is linked to an unstable political scene. Not only that numerous changes in government, including the minister of public health and other senior figures in state institutions, have been misguiding attempts to reform the system continuously and coherently. Also, political discourses on public health issues are marked by controversy and often opposite statements from various political leaders.[4] This, too, increases mistrust in public health governance.

A lack of coordination between the governmental institutions, added to that corruption and bureaucracy in the administration, created a non-efficient system. The non-coordination led to task redundancy and time delay.

3) Pandemic semi-preparedness and the effect of the political crisis

During the first wave of the Covid-19 pandemic, the governmental measures were efficient. With those measures, Tunisia kept the number of zero cases for a considerable time.[5] Also, it was one of the first countries to control the spread of the virus. And to counter an unprecedented economic crisis, many Tunisians donated money to help face the first wave and prepare for an eventual second one. According to the Ministry of Public Health, more than 200 million Tunisian dinars were collected.[6]

However, having some of the needed money and having gained some time to face a second wave was obviously not enough to be prepared. On 18 October, the prime minister announced that not a single dinar was spent out of these donations.[7] In retrospect, the administrative bureaucracy and the rigid regulations that were made to prevent corruption and to assure the good functioning of the system appear contradicting the needs for quick financial flows in times of crisis.

In addition, a political crisis happened between the two waves that led, firstly, to a political vacuum of several months, between prime minister Elyès Fakhfakh's resignation on 15 July 2020 and the approval of his successor, Hichem Mechichi's government on 2 September 2020. This has been, secondly, the second change of the entire government in six months only, partly starting from scratch, right in the middle of the pandemic.

4) Ambiguous measures to face the pandemic

To counter the contagion outbreak, Tunisia adopted a variety of measures.[8]

In March 2020, a total lockdown was ordered by state authorities. This included travel bans to and from risk countries, travel restrictions between different Tunisian provinces, closed schools and universities, general confinement and only essential sector activities remained working. On 11 May 2020, Tunisia recorded zero new cases, thus, the strict measures were slowly relaxed. On 14 June, acting prime minister Elyès Fakhfakh announced that Tunisia had "won the war against the virus".[9]

In late June, Tunisia re-opened its borders to tourists, and the summer months saw some normalization of life in public. However, the number of confirmed infections started to rise again in July. During the second wave, Tunisia did not impose any early lockdown. In contrast to the first lockdown, the measures of the second wave were more relaxed. As of 26 December 2020, Tunisia had 128,578 total cases of Covid-19 infections and 4,385 deaths.[10]

4 Nawaat.com (2020): Top officials contradict each other on Covid-19 funds.
5 Reuters.com (2020): Tunisia reports no new coronavirus cases for first time since early March.
6 La Presse (2020): Fonds 1818 : Le total des dons versés s'élève à 200 millions de dinars.
7 Watanya Replay (2020): A private meeting with the Prime Minister, Mr. Hisham Al-Mechichi.
8 On the following see e.g. Brooking (2020): Policy and institutional responses to Covid-19 in the Middle East and North Africa. Tunisia, and Konrad Adenauer Foundation (2020): How resilient are the healthcare systems in the Mediterranean? Cases of Algeria, Jordan, Lebanon, Morocco, Palestine, and Tunisia.
9 Espace Manager (2020): Elyès Fakhfakh : Notre pays est sorti vainqueur de sa guerre contre le coronavirus.
10 Ministry of Public Health, https://www.facebook.com/covid19tunisia.

Measures to increase healthcare capability have been introduced, especially in terms of human resources. However, health professionals did not receive their salaries six months after their recruitment.[11] The quantities of safety equipment remained insufficient. Compared to other countries in the MENA region, Tunisia has had the lowest number of Covid-19 tests per million inhabitants.

5) Shortage of vaccines by mismanagement

As an early measure to face the pandemic, and the second wave to hit later in 2020, medical and scientific associations had recommended a large-scale flu vaccination. It was argued that, although the flu vaccine will not protect against the Covid-19, it would reduce the number of flu infections, as well as the number of hospitalized flu patients. This could help to prevent the crippling of the healthcare system by both the Covid-19 and the seasonal flu.

However, in the fall of 2020, Tunisia faced an unpreceded shortage in the flu vaccine, not least due to a lack of coordination and poor communication management between and by state authorities. At the same time of the second wave of the pandemic, the Ministry of Public Health was encouraging the whole population (not only the at-risk group) to get vaccinated.[12] The massive sensibilisation campaign created public pressure on private pharmacies. Thus, when the vaccine was available, but faced an increased demand, it went out of stock in record time.[13]

On 15 December 2020, it was announced that a deal between Pfizer/ Biontech and the Tunisian government was made. The Covid-19 vaccine is said to be shipped to Tunisia in 2021.[14] This vaccine is an mRNA drug, and it is a first in class drug. It is still, by the time of writing, unclear how the Tunisian government will proceed to import the vaccine, to store and to distribute it, with which price, how much quantity, and with which procedure the health authority will grant the authorization for marketing and use. Regarding the registration delay in normal conditions, it is taking nowadays between 18 and 24 months at least. With an outdated regulation and the administrative bureaucracy, this time delay could take longer.

11 Jeune Afrique (2020): Coronavirus : le cri d'alarme des médecins tunisiens.
12 La Presse (2020): Le ministère de la santé lancera bientôt, une campagne de sensibilisation contre la grippe saisonnière.
13 Realities (2020): Vaccin contre la grippe saisonnière : Les pharmaciens d'officine démentent la Pharmacie centrale.
14 Le Courrier de l'Atlas (2020): Vaccin anti coronavirus : la Tunisie signe un contrat avec Pfizer.

RECOMMENDATIONS

1) Recommendations addressed to the Government and Ministry of Public Health

1.1 Restructuration of social insurance funds by implementing a new funding mechanism, and redefining the reimbursement strategy according to the national health policy.

1.2 Establishment of a National Agency for Medicines, Vaccines, and Health Products. This agency's mission could be:

a) The implementation of an inter-ministerial and inter-institutional communication plan within the Ministry of Public Health to coordinate actions in favor of good pharmaceutical governance.

b) The development and implementation of a national system for collecting data on medicines, vaccines, and health products in order to define health policies and develop the national strategy in terms of medicines. These data include the evolution of consumption and use, availability, price, consumption spending, quality, and safety.

c) The development and implementation of a national pharmaceutical policy that includes:

- Strategies for the promotion of the rational use of medicines
- Strategies to promote transparency throughout the supply chain of medicines, vaccines, and health products
- Technical support strategies that define the areas of competence improvement and their range and control of workforce, composition, training needs, and performance of pharmaceutical personnel in order to have competent and equitably distributed pharmaceutical personnel for the development, production, procurement, distribution, and appropriate use of medicines.

d) Development and implementation of a national regulatory policy defining a strategy to combat undue influence and corruption in the pharmaceutical system, particularly as it affects procurement management and the supply and distribution chain. The strategy is based on the needs of research and development, local production, registration, pricing and quality control, safety, and efficacy of local and imported products.

e) The standards of pharmaceutical systems.

f) Technical and quality control procedures and mechanisms.

g) Quality claim management, pharmacovigilance, and clinical trial management systems.

2) Economic and commercial recommendations

2.1 The implementation of commercial, fiscal, customs, and intellectual property policies focused on public health and patient-focused by:

a) Defining accelerated and facilitated procedures for priority and high value-added health products for public health needs.

b) Establishing a legal framework that encourages investment and preserves fair competition in the pharmaceutical field.

c) Developing and establishing of collaborative mechanisms for the strategic purchase of health products between the state and local and international private entities within a transparent framework and in compliance with the national pharmaceutical policy.

2.2 The fixation of the annual state budget for health products according to the needs defined during the implementation of the national system of data collection on medicines, vaccines, and health products.

3) Recommendations addressed to the Parliament

3.1 The redefinition of monopoly laws according to:

a) The evolution of the national and international pharmaceutical context by granting certain flexibility during extreme conditions, especially when there is an imminent therapeutic need and a major health problem.

b) The financing and public purchasing mechanisms in existence.

c) The national pharmaceutical policy.

3.2 Updating laws related to the right of access to healthcare, intellectual property/ patent law, competition law, personal data protection, trade, customs taxation, and anti-corruption law by harmonizing them in favor of national public health policy.

3.3 The establishment of an independent judicial control system based on a legal framework that includes texts relating to good public health governance with autonomy in the application of disciplinary measures.

3.4 The adaptation of the texts on the monitoring of pharmaceutical systems in favor of good practices in the manufacture, distribution, and dispensing of medicines and health products.

CONCLUSION

Access to medicines and vaccines is a world-wide challenge especially in countries of the Global South such as Tunisia which needs a multi-centered approach to be better addressed.

With a strong national health policy, system transparency, updated regulation, and an adapted legal framework, all stakeholders will act in a clear vision in order to maintain sustainable medicines and vaccines access. Likewise, measures to prevent the public health and medical supply system from damage due to pandemics and global crises must be taken effectively.

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