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A high-level civil servant at the ministry for labour explains in depth the social welfare system in Algeria and specifically how pharmaceutical products are registered and the mechanism for state reimbursement of medicines.

Can you please start by introducing the social security system in Algeria, highlighting those features that make it unique across the region, especially in regard to the decision process for drug reimbursement ?

The Algerian social security system is based on the principle of solidarity and sharing. It is mandatory for all workers, whether employed or self-employed, and even covers specific categories such as students, retired workers, and the disabled who are unable to work. In this way, over 85% of the population is today guaranteed social security coverage.

This system includes all branches of social security provided for within the Conventions of the International LabourOrganisation (ILO): health insurance, maternity insurance, disability insurance, life insurance, retirement, accident at work, occupational disease, family benefits, and unemployment insurance. All of these combine to make it a very thorough and comprehensive system.

National social security system is effectively financed through contributions from the national workforce, irrespective of whether salaried or self employed and is supplemented by a contribution from the state which subsidizes the most vulnerable groups, or those who have no fixed income, such as students and others. Any insured person who contributes provides coverage to his or her immediatefamily, whether that entailsdependent children, dependent parents, or female collaterals.The system is therefore considerablein terms of coverage. The breadth of serviceseven extends to a large coverage, with level of reimbursement of at least 80% increased to 100% when it comes to chronic diseases or low-income patients. Currently a full 26 chronic illnesses are eligible for full coverage including: diabetes, cardiovascular,cancer, respiratory diseases and other serious diseases.

Algeria enjoys an exceptional level of medicament accessibility. Since the advent of the electronic card for social security or â??CHIFAâ?? in 2007, there are now more than 10.4 million families enrolled which translates to around 34 million beneficiaries. This card enables direct third party payment from the social security system to pharmacies which received the Social Security Agreement, the insured does not pay the amount of the order covered by social security. Over 10,000 pharmacies are part of this scheme and citizens enrolled in the CHIFA can go to any of them to collect his or her medication, irrespective of his or her place of work or residence.

Sufferers of chronic illness enjoyaccess to third party billing, with no caps, for their prescriptions although limited in case of abuse, duplication or fraud, which can be identifies by adequate control mechanisms in place. Insured persons without chronic illness, meanwhile, are subject to a ceiling of two prescriptionsworth 3,000 dinars per person per quarter (which is roughly 77 USD per person per quarter) for their direct third party billing. Once this threshold is exceeded, which is rare for those without chronic ailments, then the standard reimbursement system kicks in.

However a study has shown that average maximum consumption for non-chronic suffers was of two drugs prescriptions per quarter. This is less than 6,000 dinars per person per quarter, namely below the 50 USD mark.

What is of upmost importance, however, is that in all instances the principle of universal coverage is always upheld. Algeria has made a giant leap in medicament accessibility, and the same cannot be said for many countries. For us, â??Accessibilityâ?? has become a key word. The challenge now is how to manage the evolution of social security expenditure once the challenge of accessibility of the citizens has been overcome.

What is the breakdown between the financing based on labor income contributions, and the share of state funding?

At present, workplace contributions finance the bulk of Algeriaâ??s national health insurance. Although the unemployment rate has been steadily declining and a greater portion of the population are contributing, the pharmaceutical expenditures is increasing at a faster rate than revenue growth can match. The contribution base is calculated in view of the economic realities of the moment â?? notably the minimum wage, while the reimbursement is mainly based on the costs of external production, since we import more than we currently produce. This is precisely why the state is so keen to promote local pharmaceutical manufacturing. The good news is that this policy is working and the ratio of national production is increasing. We buy at a high price healthcare products produced in countries â??â??with much higher salaries, and we reimbursed them to the insured in Algeria. Therefore there is a gap between matching the evolution of the expenditure with the receipts in order to maintain the financial balance of the social security system in order to ensure sustainability of the system, for everyoneâ??s interest. First the citizens, but also the partners.

Our main preoccupation is to ensure the sustainability of our healthcare system in the face of escalating costs and that is why we have had to adopt a national policy for drug reimbursement. We cannot unfortunately reimburse the totality of products available on the market, it is simply not economically feasible to do so and thus we have to take difficult choices in selecting which products should be eligible. Decisions are ultimately grounded on the scientific facts taking into account therapeutic value, side-effects, effectiveness of active ingredients, the risk-benefit balance and cost-benefit ratio.

Aside from this, there are some â??universalâ?• approaches. Algeria has been vigorously promoting generic products wherever they exist because it is less expensive, providing they are well controlled and the requisite quality standards maintained, they offer the same therapeutic benefits as the originator products but for a fraction of the price. This, in turn, allows us to release more funding to pay for the treatment plans of other citizens. Moreover, in line with the national policy, we are also committed to local production and encourage balanced partnerships between local and foreign producers, to promote the transfer of technology and know-how.

The third key point of our work is focused on strengthening our relationship with the world of prescription on the basis of rules of good practice, and that, in order to strengthen the quality of care that will ultimately be reimbursed.

Can you please describe to us thedecision-making process of drug reimbursement?

The keystone social security legislation for drug reimbursement constitutesAct 83-11 on social insurance. Outlined within that law, it is clearly stated that reimbursable medicines are those on a list determined via regulation, and that the reference rates of reimbursement of listedmedicines are also set by regulation (article 59 of Act 83-11). The current text in force was passed back in 2003 and provides for the establishment of across-sectoral Committee for Reimbursement of Medicines (CRM) to undertake that regulatory function. This multidisciplinary committee essentially brings together representatives of social security, the laboratory for control of pharmaceuticals, national pharmacovigilanceapparatus, the Ministry of Commerce, and the Ministry of Health.

Once a medicament is awarded its registration and placed on the market, laboratories have full discretion whether or not to submit a request a refund by filing an application with the committee. The submission is then transferred to a technical secretariat, made up of health practitioners, including a doctor, a pharmacist and a statistician. A number of documents are attached to this technical review, including a copy of the official registration decision and a formal request from the laboratory making the submission. The committee then reviews the application according to set procedures and assessment criteria which differ depending on whether the product is one where there are no other equivalent molecules on the market or one where there are other drugs available of the same class or therapeutic category. The idea is that the majority of new products being awarded reimbursement should either be bringing a new medical benefit to the market or an improvement on what is already in existence.In instances where there is no demonstrated improvement in actual benefit (that is to say, it is a request for what we call a â??me tooâ?• product), then the Committee also considers the economic dimension attached to this drug. If this â??me tooâ?• product is being imported and is more expensive than equivalent products already in the country, then ithas little chance of being awarded a positive reimbursement decision (which is consistent with a 2009 directive currently in force that promote the domestic pharmaceutical production over imported products) . If that same molecule has beenlocal manufactured, then it is much more likely to interest the committee.

If a medicine has no obvious competitor product and provides a new answer to a real healthcare need, then the committee in principle has absolutely no objection to a request for reimbursement. In such instances, the procedure moves to the next stage: a decision to accept the refund is issued and an order confirms the decision.

What about the pricing? How is that determined?

In the case of drugs without generic competitors in the market, the manufacturerâ??s price is submitted along with the application for reimbursement. That price is then reviewed against a benchmarking price grid. This comparative evaluationtakes into account the base price before taxfor the product and its equivalents across 5 or 6 foreign countries, allelse being equal. In cases where the price of the medicament is higher, the technical secretariat requests the custodian laboratory to decrease its prices so as to end up with a preferential price in Algeria compared to the price in the home country. The rationale for this approach is very simple: the laboratories are well aware that the Algerian statedoesnâ??t possess the same means as some OECD countries, but is able to ensure sales volumes once it decides to grant reimbursement by virtue of our distinctive, â??free-at-the-point-of-deliveryâ?? social security system. This assured volume offers laboratories enough leeway to comfortably make some concessions by revising their prices downwards.

In instances where generics exist, then the setting of the reference rate will be based on the median price of the generics or cheaper, so long as the generics have sufficient capacity to properly cover the national market. If the foremost generic is assessed to havea fragile market position, then the reference will be set against the second or third generic product in ascending order of price, to ensure the price reference correlates with national coverage needs. This is feasible because we possess the data for both prices and sales volumes.

This mechanism ensures the sustainability of the health system. It meanscitizens donâ??t have to pay excess charges upfront or otherwise to receive their treatment. It means our social security system can control its spending and continue to offer a service based on solidarity. Finally it even assists operators in how to position themselves in the competitive marketplace.

In addition, we realized that in some cases the reference rate was not enough. Consequently, following surveys conducted from 2007, the social security bureau decided in 2009 to establish, a

reference rate per therapeutic class for certain classes of drugs. This initiative was set in order to ensure the efficiency of the reference rate scope of action and the financial balance. This is an approach that is ultimately in the interest of all: for the patient, who should benefit from the sustainability of the social security system; for our partners, who are the actors of the pharmaceutical world and will be able to set a long-term perspective to work and bring technology and know-howin Algeria as well as to employ Algerians. The result of this endeavour is that our partners have understood us, and the market is nowadays aligned with the reference rates, including international manufacturers based abroad.

Social Security also contributes tothe efforts to encourage local manufacture of drugs. Whether by local or foreign or mixed capital, the most important thing for us is to make an impact on the local pharmaceutical industry in terms of domestic economic value. We have chosen to financially encourage prescribers (doctors) and pharmacists to promote pharmaceutical products manufactured primarily in Algeria. The pharmacistin particular is being given a 20% markup on every product manufactured in Algeria that he dispenses using his right of substitution. Note that this incentive covers both generic and originators, with the sole condition that they are manufactured in Algeria and their prices are inline with the reference rate. This incentive costs us over 7 billion Dinars every fiscal year. However this has created an indirect savings of 35 billion dinars, not mentioning the job creations. Moreover, the improvement of the financial conditions of 10,000 pharmacies under agreement withSocial Security, benefit from the incentives and markups that I have just mentioned and led to the hiring of nearly 30,000 people.

We harness various instruments of levels of scientific proof,ie â??Evidence Based Medicineâ?•,to assess drugs reimbursement claims. This is conducted on the basisof meta-analyzes and methodologically sound clinical trials resultswherever possible. The analysis of the scientific evidence of superiority of one drug over another is conductedthrough targeted and complementary techniques along with sources of additional information. Whenever a product is not judged superior to an existed item on the market, we conclude that there is a lack of Improved Medical Service Rendered.

Some actors are very critic with regard to the reimbursement committee comments, but we have no choice: the growth of drug reimbursement expenditure in Algeria has been in double digits for the last 5 years (between 15 and 20%), which is huge, when in other countries this growth is between 4 and 6%. The improvement of accessibility is a real benefit for our patients and for the economic sphere. Everyone must understand the significance of these decisions, which are sometimes considered as restrictive, because of the breadth and potential of the national industry.

It is important that our partners invest in local production of essential drugs. They have everything to gain, and we will support all investment initiatives. We need their investments, their expertise, and their job creation.

We understand that cancer drugs are not currently covered by reimbursements. Why is this?

Algeriaâ??s social security system finances public hospitals through an annual budget that is really very substantial. Whatâ??s more, this annual budget is set to undergo a significant increase for 2015 so as to continue to be able to finance a whole array of hospital activities including ambulatory care services delivered on an outpatient basis. To put the magnitude of this spending into perspective, it represents over half the amount of the national pharmaceutical bill.

Under ActNo. 85-05, currently in force, the public hospitals are responsible for the dispensation of onerous, high expense drugs that require supervision to be administered. These hospital-supervised

prescription drugs are provided to all citizens free at the point of delivery, irrespective of whether the medicaments are being administered at the hospital or in the home and whether the patient has no social security coverage.

Moreover, cancer is a disease that is part of a national program funded by the state budget, with special envelopes, the state provides to all, not just the insured, oncology drugs. This is why today oncology drugs are not reimbursed because it falls under the responsibility of hospitals thanks to an annual financing from Social Security and especially thanks to a financing provided by the state. The state has mobilized a lot of money in the fight against cancer and is actually in the process of formulating a revised national program which reapportions the load distribution across the various stakeholders involved.

It is imperative for the prescription world to better organize itself and achieve more consensual solutions for alternative treatment options that better reflect the availability of resources that the state has at its disposal when countering the more onerous diseases. Ultimately every country has to take its own public healthcare policy decisions based on the availability of finite resources. With regard to targeted therapies, if one day social security will be more involved, we will be strong advocates of carrying out a broad consultation where agreement can be reached. We will need to identify at best the patients who would benefit from these expensive therapies to prevent their abuse without significant therapeutic outcome, which can sometimes exist and be prohibitively expensive for the community.

The State spends a lot of money, but the sphere of healthcare must improve its organization and efficiency. Under the new cancer program which will come about through a final consultation with an expert appointed by the President of the Republic, each player will assume a defined role. The screening will be optimised and social security will ensure its assigned role, especially for the use of certain tools, such as social security accord with doctors.

We must take into account the financial capacity of each country,and make efforts to make sure ensuring the sustainability of access to healthcare and their funding sources. This will inevitably have an impact on the global pharmaceutical industry in general. It is imperative that we gather around the table all relevant stakeholders and discuss the ethical and deontological aspects that are tied to healthcare issues such as cancer. Social security is sometimes somewhat portrayed in a negative light when decisions are taken not to reimburse a certain drug prescription. Weâ??re striving to establish arbitration that works and ensures optimum accessibility of patients to essential medicine.

In this case, there is also an issue of the price of new drugs and a particular issue price of in particular in regard to targeted therapies, for which will have to discuss with pharmaceutical companies.

What is your opinion about Algeria as a regional hub and what are the chances of the country of playing a regional role in the field of pharmaceutical and healthcare?

We actually conducted a comparative study on this question. The public health structures in Algeria are much more appreciated than in manyother countries. This is because of the wide accessibility of free healthcare and a state budget oriented towards the construction of new healthcare facilities to meet growing demand. If we are not already a regional champion then we will soon become one in terms of value and volume.

Aside from its pharmaceuticals sector, Algeria enjoys growth of 3-4% excluding its hydrocarbons wealth and is now the largest country in Africa. The opportunities are therefore simply enormous. Now that the country has set a target of covering 70 percent of its medicine requirements through local manufacturing, the opportunities will become even more accentuated. In the pharmaceuticals

sector, it is fair to say that there are entire market niches that have yet to be properly tapped. The final word is that all good intentions and investments in Algeria are welcomed and the social security apparatus is ready to assume the role of facilitator.

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