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Djaouad Braham Bourkaib, Director General of Social Security at the Algerian Ministry of Labour, Employment and Social Security, outline recent regulatory reform in the North African nation and the future of Algeriaâ??s healthcare system.

What can you tell us about the Algerian national policy of health expense reimbursement?

We are acutely aware of the importance of explaining the process in detail to our partners right across the healthcare and life sciences spectrum. We understand that this kind of transparency and clarity is at first very much in the interest of patients and in that of the national social security and the national economy.

Algeria has been expanding the scope of its public health offering across all services related to drugs and medication. Over 14 million people now hold a CHIFA card, which is an electronic card for every socially insured person. Often, each household has one Chifa card covering all family members. As a result, more than 38 million people can actually benefit from national social insurance. Drugs are very much our strong suit, as we implemented a generalized third-party payment system under which patients do not pay a single penny when they go to their pharmacy especially whom are suffering from chronic illnesses, with some extremely minimal exceptions.

Meanwhile, there are over 11,300 pharmacists across the entire Algerian territory. Every single pharmacy is registered with the CNAS (for employees) and the CASNOS (for independent workers). Each and every one of these pharmacies is equipped with specific software programs for drug reimbursement, meaning that they possess card readers and can invoice electronically. In concrete terms, a diabetic patient for example, can go to his pharmacy with his prescription, get the necessary drugs for 3 months of treatment worth thousands of dinars, and go back home without having to pay anything whatsoever. This is absolutely unique in the North African region.

What are your main focal points today?

Our priorities are to focus in on three major axis of work. The first one is to constantly enhance drug access, both to essential medications and to real innovative drugs. The reimbursement of innovative drugs depends on a number of conditions, like the actual gain brought by the treatment to the patientâ??s health with an appraisal based on level evidence. Our second objective is to promote and foster domestic manufacturing of drug, both by Algerian and international companies that have settled in Algeria. Our reimbursement policy explicitly and steadfastly supports the development of a local pharmaceutical industry. Our third priority relates to ensuring our system remains viable in the long term, which means it has to be financially sustainable. To do so, a holistic approach involving all stakeholders is necessary. This encompasses the patients, the industry, prescribers and of course the funder that is mainly the Social Security. Our operating procedures and modus operandi are crystal clear. Everyone knows them, and we have refundable drug lists that are regularly updated using more

and more reliable appraisal with evidence-based medicine and pharmacoeconomic tools.

How would you describe the Algerian drug reimbursement decision process? And how is it evolving over time to reflect the latest developments in medical science?

Like many healthcare systems around the world, Algeria ensures each and every drug proceeds through a number of steps before we decide to reimburse them. Drugs are either manufactured here or imported. The manufacturer submits a case to obtain Marketing Authorization, which is the registration that verifies safety, quality and toxicity. On the entire market, the biggest funder is the Social Security. It sorts the drugs according to appraisal as mentioned above the improvement compared to the available drugs in actual benefit or according to efficiency. Moreover, as science evolves and new facts are brought to light, the lists are modified to reflect the latest information. Similarly, drug prices can change, so we take that into account.

The foremost tool of the Social Security, being the first buyer on the market, comprises its lists of reimbursable drugs and reference prices. The role of generics is also to lower the price when they are available in the market. It is the place of the buyer to choose at what price to buy a given medical service, provided marketing authorization has been granted. The second item in our toolbox is the Chifa card and the partnership with the Algerian pharmacists to provide access. The third mechanism is not yet in place, we are working on it. It concerns the changing of framework to provide access to the most expensive innovative treatments.

We needed to formulate and define another set of rules that may be a bit more complex, but in exchange we will open rationally the access to innovative drug and will share with pharmaceutical companies a financial risk and prevent budgetary drift. From now on, we will be able to imagine contracts based on price and volume with an annual expense limit. These contracts will depend on the nature of the drugs and on the estimated need of the market. It will be assessed based on epidemiological data.

Furthermore, we are starting to offer performance-based contracts as a way of delivering access to innovative drugs where the medical risk is not covered. There is a certain degree of uncertainty related to those products, yet they definitely bring a real solution to certain patients. These contracts are a possible answer to provide the patients with these treatments when it is necessary. We can implement it because the Social Security now possesses a medical big data system that allows for us to follow and evaluate in real time the real benefit of the contracts. 1,000 consulting physicists, amongst the staff of the Social Security can be involved in these contracts with other stakeholders and the contracts will provide a frame to the partnership. Most importantly, this framework will be objective, based on facts, on accurate numerical indicators and precise contractual clauses between the parties.

How does the Social Security practically juggle tasks like price setting and health technology assessment in a manner that is perceived as fair, objective and scientific?

Regarding the â??regularâ?• procedure, our evaluation is based on the following elements: each newly registered product is auditioned by an interdepartmental committee led by the Ministry of Labour with the members coming from the Ministry of Health, the Department of Commerce, the Social Security, the Laboratory of Control and the Laboratory of pharmaco-vigilance. There is an evaluation grid, the drug is registered and authorized on the Algerian market, but the funder needs to evaluate the medical service rendered or the improve of this service if other refundable drugs of the same therapeutic class or the same indications are available before they decide to reimburse it. If that medical service is sufficient, then we take the next step, which is about asking whether the corresponding illness is already covered by other drugs. Presuming that is the case, we verify if the service rendered is more interesting. Obviously, our evaluation is also based on the level of evidence and the sources of evidence-based information (institutions), the healthcare professionals and expertsâ?? judgment and the documents provided by the pharmaceutical companies. We also quantify that improvement of medical service rendered and label it on our scale: major, important, moderate, minor, none. We generally decide to reimburse the drugs that are labeled moderate and above.

It can happen that we negotiate the price with the manufacturer, even though that step was already covered previously. It is always well founded for the Social Security to negotiate if it can ensure public interest, while at the same time ensuring win-win deals to our partners. The industry understands our intentions, so most of the time they do their best to find common ground. Now, in the case of a drug with no proven significant improvement of medical service rendered, if it is imported and more expensive than other similar drugs that are produced on the territory, we have to refuse to reimburse them. The other solution, that happens in general, is for the manufacturer to align his prices with the reference class price.

Those reference class prices are median prices between original drugs and generics. This is a way to ensure coverage of the market by several brands, to prevent shortages. We launched that system in 2008. Sometimes, the laboratories set their price a bit higher, the remainder is then at the expense of the patient. Generally speaking, we encourage the laboratories that are really interested by the Algerian market to make an effort to reduce that amount to a minimum. One must never forget that a great many Algerian citizens, typically the ones with a chronic disease, cannot afford the expense.

We had to deal with certain products that would bring interesting improvement of medical service, but only on 1 out of 3 indications for instance. We used to add them

to our lists with certain conditions. Then we started to discern in a more sharpened way, and to reimburse solely when prescribed for the 1 indication with a proven improvement of medical service. Now, the manufacturers are handed a document that states specific conditions for reimbursement, in particular when a reimbursed use of the drug is based on specialist prescriptions.

What options do you have at your disposal for greater financial risk sharing?

Sometimes we also ask for drug efficiency to be tested every 6 months, or for reimbursement to be re-approved periodically. For instance, Interferon beta drugs used in multiple sclerosis as disease-modifying drug in the hope of reducing the frequency of relapses and slowing progression of disability, but some patients develop resistance to the medication and no longer benefit from it. The thing is that these drugs are very expensive, so we want to verify in relationship with healthcare professional and be certain that the patient is still benefiting from the treatment before continuing to pay for something useless.

Then, with the progress of science, we need to find a new approach to evaluate innovative medication, such as new therapeutic classes, where the risk of budgetary impact has been massive. Our doctors do their best to offer tailored treatments to their patients, yet it has happened in the past that we have witnessed massive prescription of certain drugs that were relevant only to a limited pool of patients. The consequences were grave: it cost us a lot and jeopardized the system and its development. We have therefore resolved upon a new approach in which we collaborate closely with the respective drug manufacturers and experts.

First we must define together the best use and best type of patients for their drug, and we usually agree on that scientific issue: international available data is very accurate. Secondly, either we estimate the annual need and re-evaluate it by the end of the year, or we negotiate a rebate agreement. The manufacturer does not follow the reference price, they can sell the product at the authorized price for example, but they repay a certain amount to the Algerian Social Security to compensate for the additional expense. Price/Volume agreements can also be used to de-risk some of the cost of these therapies.

Performance contracts must be simple, intelligible, with identifiable success and failure criteria, a contractual evaluation and patient follow-up registersâ?¦ We have an important database with precise medical criteria to check across the country, so the tools are already available. There is no reason not to work on improving the access to a number of drugs. We are already well grounded enough to be able to work together with the industry in rolling out some of these win-win solutions for financial risk sharing.

How many performance contracts has Algeria signed so far?

None, because we are in the finalizing stages of both application decrees of the bill. They will be finalized in the upcoming weeks. They had to be postponed in 2017 because, as it turned out, it was more intricate than expected, plus other priorities emerged at that time. So both texts are to be presented to the stakeholders, modified according to their suggestions if they are considered as reliable and relevant, and we can officially announce that they will be finalized before the end of the year 2018.

Our team covered and participated this year in organizing a round table on diabetes in Algeria, a number of issues were underlined then. How do you plan to broaden the access to innovative treatments for the disease?

There is the case of the VictosaÂ© drug, which is not yet on the market although efficient in certain particular cases. It will be included through the new procedures that I described earlier. It will be a contract based both on volumes and performance, the targeted population will be specified. We already have a 2-page document, the modalities are already ready on our part. It would be reimbursed for diabetic persons type 2 with inadequate glycemic control on dual therapy with overweight in whom weight loss and avoidance of hypoglycemia is a primary consideration and who put on weight when they are put on insulin. As you see, the definition is very specific. The particular laboratory concerned agreed to these conditions.

Presently, diabetic people are treated with metformin, aka â??the gold moleculeâ?•. It costs 5 euros per month. VictosaÂ© can costs up to 250 euros a month, and there are 2.5 million diabetic people in the country. No budget could ever cover for that expense of this new product in case of non-compliance with particular condition, it would crash the Social Security budget, which would be a disaster for everyone, patients and industry alike. The contract could, however, contain performance clauses, so the manufacturer would pay us back in case of therapeutic failure or a pancreatitis for example. This is an incentive to the seller, who will be cautious not to oversell the product and to be very precise in their marketing efforts.

So in the case of that product, the stakeholders already agree on the principle. The prescribers will be informed by the Social Security, the Ministry of Health and the Laboratory. This case is a great example of what a win-win strategy can look like. Nowadays, in an era of stressed public healthcare budgets and ever greater demand on the system we all need to join forces in coming up with these kinds of enlightened solutions whereby everyone wins.

What is your opinion of the current state of the industry in Algeria?

The pharmaceutical industry, and all its investors in the country, are confronted with the reality that the domestic market cannot absorb the entirety of manufactured pharma output for certain products. They will have to consider exporting. We want Algeria to become a regional market. If our neighbors are buying, the Algiers factory will be able to respond to the need. Not only is Algeria a more interesting local market, but it is a potential center of commercial influence. There are challenges to be met, but the authorities have made many decisions to facilitate this. Institutions like ours will also accompany the movement. I believe that the circumstances will quickly become much favorable.

What are the other expensive drugs that the Social Security wishes to add to their lists of reimbursed treatments?

We study the cases of registered drugs only. We always work one step ahead: in the entire world, biotechnology will probably take over chemical drugs for instance. So our priority is to flesh out the new legal arsenal, as it is in its infancy, in order to have a transparent framework to work within. Immunotherapy is one example of hospital dispensing drugs. Together with the Ministry of Health, we want to enhance the access of our hospitals to that type of technology. Risk sharing is in the interest of everyone, because even the hospitals do not have the budgets to do it on their own. The system must be preserved with the help of our new legal procedures.

We also need to find the rules based on the best international practices. There are good provisions in the new health law to apply on the issue of biosimilars. This is important for the funder like social security in terms of rationalization of expenses. Transparency is key. If we manage to do it within a determined framework.

Where are the bottlenecks preventing a wider uptake of biosimilars in the local market?

This is a question for my colleagues of the Ministry of Health to answer, it is not my place to express my views on that. The Social Securityâ??s place is to work after a decision has been made by our Ministry of health. They have a great expertise in that matter.

Last time we met, you wanted to strengthen your pharmacoeconomics expertise. Where are you on that?

We contacted renowned universities in Algeria to set up new academic programs in that field. There is also a Higher School of Social Security, and we are considering setting up a Masterâ??s degree in pharmacoeconomics, with the help of Algerian

experts working abroad, among others. That is the first step.

Regarding our expertise in the evaluation of medical service rendered, we work with the case file of the applicant, but we also invested a lot into our documentary database that compiles and collates every serious and significant scientific study from all around the globe. This database is updated monthly, so that we have visibility when it comes to drug assessment and critical analysis. Our role is also to track the real effects, on the ground, of the drugs that are subject to a performance contract.

I say that, providing the system proves itself without the seller feeling wronged, the way we do transparency and risk sharing in Algeria could become an example to follow. Our Healthcare system is important, Algeria has many physicists and doctors across its territory, it will become even more of an inspirational system to other countries in the future. We are new in the field of pharmaceutical contracts between pharmaceutical companies and social security, but we are working hard on this. It is very important for our patients, for our economy, for the country as a whole. Presently, and maybe unfortunately, the priority regarding the Algerian Social Security remains its budgetary balance, and the impact of reimbursement on the financial capacity of the Institution. This accounting vision will soon give way to a more analytical vision. Contractualization, meanwhile, will allow for a wider, holistic approach of the evaluation.

What steps are being taken to ensure ready access to drugs that manage chronic diseases?

Of course, this approach is already in place when it comes to chronic diseases and their impact in the country. Morbidity and mortality reducing drugs are definitely favored compared with drugs that did not prove the efficiency in that regard, even when they are eligible, even when they are less expensive. We are very particular about chronic diseases. Several long-term studies are conducted in Algeria on diabetes for example. We are now developing pharmacoeconomic evaluation. I believe that 2019 will be a pivotal year in many aspects, notably the renewed impetus from the Drug Reimbursement Committee.

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