Message from the Health Sector’s Leading Partner

PwC Mexico

Without a doubt, scientific advances in recent years have challenged the way we do things. With the arrival of biotechnology various industries have been assessing its value and capitalizing on the opportunities that it offers. There are some examples in the agro-industrial, food industry and of course the pharmaceutical and medical equipment sectors. In all cases, the tendency is centred on greater efficiency, accessibility and competitiveness.

On a global scale, the investment in biotechnology has demonstrated the ability to revive the economy for companies, sectors and countries. In Mexico, biotechnological applications are currently used daily to maintain and improve the population’s situation and quality of life. Examples of this are its use in optimizing food production, preservation and transportation systems as well as the enriching of the nutritional content of food and the production of personalised medicines according to the population’s genetic profile, among others.

In PwC Mexico we consider that the transformation in this sector is subject to the degree of knowledge advancement and the creation of mechanisms that allow the development of appropriate platforms that bring together the different interests of industry, thereby promoting access to new products and services based on biotechnology.

We are aware that the risks in this sector require careful analysis but, as your strategic alliance partner for business, we should not turn a blind eye to the opportunities and on the contrary communicate all that biotechnology is willing and able to offer to your company.

Jose Alarcon Irigoyen

Eduardo Valencia
Managing Director of BIODETECTA S. A.

Genetic disease predisposition tests: a new technology in Mexico

Mexico’s new Federal Government has generated high expectations around a probable increase in funding for R&D activities, as well as support for new entrepreneurs in the innovation sector. If that turns out to be the case, the field of molecular biotechnology would appear to have a very interesting panorama in our country over the next few years.

Molecular diagnosis is already a clear trend in the life sciences sector, as regards both human and veterinary medicine. This technological platform brings with it a new kind of very high precision and allows for results to be available in a much shorter time than through traditional diagnosis. Furthermore, people can get to know more about their genetic history and their predisposition towards certain diseases even before these actually develop, bringing with this an element of very early prevention.

The BIODETECTA Group is really a cluster of companies dedicated to service provision of genetic testing related to probable predisposition to diseases and the design of preventative measures using prophylaxis. In Mexico today this kind of testing is being carried out in the veterinary field, but the service techniques exist to do this in humans and Mexico is on the verge of developing this market. For this reason, Quo Vadis decided to interview Managing Director Eduardo Valenzuela.

Molecular diagnosis lets people know more about their genetic history and their predisposition towards certain diseases.
What do you consider to be the future challenges in genetic disease predisposition testing?

Mr Valenzuela commented that the development of biomarkers is a key issue. Molecular tests are trivial when we know which biomarker is associated with which disease. We need to carry out more regional and tribal research in Mexico, that is to say that ethno-genomics, with the aim of finding more markers. He defined the key players in this research as being: The National Institute for Genomic Medicine INMEGEN (genetics), the National Cancer Institute INCAN (cancer), the National Institute for Medical Sciences and Nutrition “Salvador Zubiran” INCMNSZ (nutrition), the National Institute for Respiratory Diseases INER (respiratory infections), the Genomic Science Centre of the National Autonomous University of Mexico UNAM, the Biomedical Research Institute at UNAM and the Centre for Research and Advanced Studies CINVESTAV at the National Polytechnic Institute (IPN Zacateno Campus).

How do you see the role of the pharmaceutical industry as regards genetic testing?

Regarding the pharmaceutical industry’s perception of genetic testing in Mexico, every day there are more medicines on the market that need to take into account the patient’s genetic make-up and the manufacturers want patients to have information about possible interactions with their specific biomarkers. This is due to the fact that the availability of such information simply adds more market value. This concept started with orphan medicines, but today it is growing in the field of well-known medicines and generics. Carrying out genetic tests defends the value-added in the marketplace. The private sector will champion this technique, especially in so-called “cocktail” medicines, such as those used to treat AIDS.

What might the obstacles be in introducing this kind of technology in Mexico?

Talking about possible obstacles, I consider that the regulatory environment is not a problem. The biggest obstacle is the traditional resistance to change, on the one hand in industry and on the other with doctors. BIODETECTA has met with the majority of pharmaceutical manufacturers in Mexico, both multinationals and domestic producers, and there is a lot of interest in personalized medicine and the company’s services. Currently BIODETECTA is making contact to establish international alliances to bring genetic methodology to apply in humans.

What are your views as a businessman on the degree of competitiveness in the genetic testing market?

The crisis in Europe is causing companies on that continent, especially Spanish ones, to seek market opportunities in Mexico. Several molecular genetic diagnosis companies are starting to operate in Mexico, with the corresponding technology transfer, investment and the creation of highly specialized jobs. On a consumer level, US companies have made alliances with local nutrition practices to carry out genetic tests regarding predisposition to obesity. However, they have to send the tests to labs in the US, thereby reducing the benefit to a handful of the population who can pay the cost of this service.

What will be BIODETECTA’s next step in Mexico?

NOVIK, part of our Group, is starting to create a synthetic biology cluster in the AGROBIOTECH Science Park in Irapuato, Guanajuato State. This began with a T4 OLIGO line, which is currently operating and producing oligonucleotides (primers and nucleic acid agents) which are diagnostic tests used in molecular biology. This year the T4 ENZIMES line will start and in 2014 we will see the start-up of biopacks for industry.
In terms of medical care quality it’s no longer enough to get a prescription from the physician, it’s necessary to make sure the patient receives the medication.

**Media Register**

**Medicine Supplies**

In 2012 Mexico achieved universal health coverage by affiliating all its inhabitants in different health protection schemes. As a result, in recent years we have observed a 4% reduction in out-of-pocket health costs. On the other hand, public health expenditure dedicated to medicines acquisition has increased 86%, reaching at a federal level $US 3,745 million, of which 80% is used by IMSS, 15% by ISSSTE and the remaining 5% by other social security institutions (SEDENA, SEMAR, PEMEX). This does not take into account the expense by the National Commission for Social Protection in Health, also known as Seguro Popular, on a state level.

Paradoxically, Mexico’s medicine market is the second largest among OECD member states, representing around $US 14,200 million, growing at an annual rate of 16%. If we break down this cost by type, then we see that Mexicans continue to spend 28.3% of their household income on medicines, when the OECD average is 17%. In other words, it would seem that the money spent by government on medicine to improve health has not resolved the problem of medicine scarcity.

Added to this, the growing incidence of chronic degenerative diseases such as Diabetes Mellitus, high blood pressure or chronic obstructive lung disease, will imply a constant demand for medicines in an attempt to control the advance of such diseases. However, today new molecules exist that have demonstrated greater efficacy in treating certain diseases, yet unfortunately they are more expensive. For example, cancer medicines represent 9.8% of total medicine costs and over the past 5 years have increased over 60% in price.

The President of the Health Select Committee in Congress pointed out that the Coordinating Council for the Negotiation of Medicine Prices has not been required to prove its accountability for the past 3 years since its creation. This means that there is no comparison between the budgetary cost of operating the Council and any proven savings in the medicine acquisition budget.

According to Guillermo Carrasco Acevedo, Coordinator for Pharmaceutical Management at the Monterrey Tec, while the demand for medicines is huge, still the mechanisms for satisfying that demand have not been found, due to the lack of planning, organization and development in the public tender process.

From the viewpoint of Armando Arredondo, Researcher in Health Systems and Policies at the National Institute for Public Health (INSP), the problem is furthermore related to the assigning of budget.

For Juan Raul Maldonado, Professor at the Pan American University, the fragmentation of the system is the root cause, since this encourages duplication of functions and the inefficient use of resources. Examples of this can be found in the INS report “Medical Supply Organisation in State Health Systems: The potential consequences of a Public-Private Mix”, which highlights the differences in the acquisition, supply and access to medicines, with examples regarding huge medicine price differences, depending on the geographical zone.

**Alternatives for improving medicine access**

For many, the practice of granting coupons to those who could not obtain their prescribed medicines in the public social security institutions, will only serve to hide the problem. Furthermore, many private pharmacy chains are unwilling to participate in such schemes unless there is greater clarity about how the reimbursement system would work.

Another alternative could be to outsource the logistics and distribution services to the private sector, whether this were to one supplier or a hybrid system involving various distributors, and creating competition among them. For Tomas Rodriguez Weber, President of the Association of Pharmaceutical Product Distributors (AMPROFAR), it does not make sense to operate two distribution networks (one for the private sector and one for the public one) – it would be better to operate just one, thereby improving efficiency and avoiding duplication.

For its part, in recent years IMSS has introduced new ways of doing things such as reverse auctioning or, as was the case in 2012, consolidating public tender among different public health institutions. COFEPRIS has also carried out actions to reduce the increase in healthcare costs by pushing through fast track authorization procedures for generic medicines, in this way reducing medicine costs by 66% in the private sector and 70% in the public one. Today more than 80% of medicines purchased in the public sector are generics and this has naturally favoured Mexican manufacturers over and above the transnationals, although there are some exceptions. According to Rafael Macias, President of the Mexican Association of Interchangeable Generics Manufacturers (AMEGI), the main sector leaders are Apotex, Teva, Hormona, Psicofarma and Sandoz.
The tax pathway

Objection by the tax authorities to the deduction of travel expenses by operating companies

On 31st December, the Official Gazette published non-binding criterion number 08/ISR entitled “Third party expenses. Expenses incurred by persons with whom there is no labour relationship or who do not render professional services are not deductible.”

The above criterion establishes that strictly indispensable expenses do not include expenses incurred in the absence of a labour relationship or the rendering of professional services between the person on behalf of whom said expenses are incurred and the taxpayer who wishes to apply the respective deduction, even when the said expenses are designated for personnel provided by third parties.

For the purpose of the foregoing, unlawful tax practices are considered to be incurred by taxpayers that sign agreements with individuals or business entities for the rendering of a service and then deduct the related welfare benefit and travel expenses incurred in Mexico or abroad, when said beneficiaries are individuals hired by a service company or a shareholder thereof.

It is important to mention that one of the practices of the Pharmaceutical Industry is to provide support to doctors so that they may attend events and conventions to become acquainted with the properties of their pharmaceutical products, so that they prescribe them to treat different illnesses without putting the health of patients at risk, for which purpose they are paid travel and lodging expenses. It is therefore important to review the scope and evaluate the impact of the criterion issued by the tax authorities.

The matter pertaining to the objection by the authorities to the deduction of travel expenses incurred by operating companies that have no personnel, has been addressed in court and a favourable ruling was issued by the Metropolitan Regional Chamber of the Fiscal and Administrative Federal Court, whereby confirmation was made regarding the deduction of travel expenses incurred by operating companies on behalf of employees of companies that provide them with personnel services. One of the arguments used to support the foregoing has been that expenses are incurred on behalf of persons that render professional services under a professional service agreement.

In view of the above, it is important for companies that rely on business models or arrangements whereby operating companies receive the services of the personnel of another company or group of service companies or from third parties, as well as companies of the Healthcare Sector incurring travel expenses for medical conventions when there is no labor relation or where said services do not relate to the rendering of independent services, to evaluate this matter and implement the necessary measures to reduce the effects that the said new criterion may have, and which will at some point have to be cleared up by the Company in court.

1 Non-binding tax criteria (unlawful tax practices) represent the interpretation of tax and customs provisions considered by the Tax Administration Service to be damaging to the revenue service. Their purpose is to alert taxpayers with regard to alleged unlawful practices that have been identified and sanctioned by the tax authorities and that should have to be reported by any certified public accountants auditing companies that apply them.
In accordance with the rules set out in the Regulations under the General Health Law regarding health research, each institution carrying out research that involves people should have an Ethics Committee. However, in Mexico there are very few of these Committees in operation and their tasks were seen as an enigma by scientists, the population and the Mexican pharmaceutical industry, so finally at the end of last year and the beginning of this, clear regulations were set up for Ethics Committees.

The 1966 International Agreement on Civil and Political Rights has a natural linkage for Mexico and in its Seventh Clause it establishes precisely that no-one shall be submitted to medical or scientific experiments without their free approval.

In this sense, a person’s rights as a research subject are set out in the 1973 and 1982 Health Code, with the later obligation to set up Ethics Committees in establishments where biomedical research is carried out, to review and in the event approve the research protocols to be executed. This requirement remains in force and was extended in the 1984 General Health Law.

As recently as December 2011 the General Health Law was reformed as regards public, private and social healthcare establishments that carry out research in human beings so that they are required by law to have an Ethics Committee responsible for evaluating and approving human research protocols, formulating the corresponding ethical recommendations, as well as the obligation to create institutional and ethical guidelines.

In October 2012 a decree was published to establish general guidelines for the establishment and operation of Ethics Committees, granting them autonomy to:

1. Contribute towards protecting the rights, wellbeing and security of research participants,

2. Act in the interests of research participants, taking into consideration national and international regulations regarding research and

3. Ensure that the benefits and risks involved in research are equally balanced across all society’s groups and classes.

Now the responsibility to install an Ethics Committee falls to the Director of the establishment.

It is important to note that now the responsibility to install an Ethics Committee falls to the Director of the establishment, who should emit a certificate to each member of the Committee. For their part, the members must accredit their professional excellence in the field of research and/or research ethics, as well as their personal background that demonstrates their appropriateness for the task and ethical conduct. The only exception to this is the community representative on the Committee.

This being fulfilled, in order to operate a Committee it is necessary for members to sign an Act of Constitution and to design the operating rules as approved by the Director of the establishment. Thereafter, once approved by the National Bioethics Commission, it must be registered at the Ministry of Health.

Once constituted, the Committee should follow a specific methodology in order to evaluate research projects. The process is designed to promote the learning process in order to improve knowledge about the ethics review process and to develop innovative proposals in research.

Finally, it will be necessary to fulfill the Ethic Committee standards which will come into force in May 2013 in order to avoid punishment and fines set out in the General Health Law.

By Cesar Lara
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Biotechnology

A team of researchers at the University of Cambridge led by Dr Amer Rana supports the theory that blood could be one of the simplest and safest sources of stem cells. In a study published in Stem Cells Translational Medicine and financed by the British Heart Foundation, the Medical Research Council and the Wellcome Trust, a new type of cell has been discovered that travels in the bloodstream, repairing any kind of damage to the vessel walls. Once converted into stem cells, they are recognized as their own by the immune system and therefore there is no risk of rejection. It is extraordinarily simpler to obtain a blood sample than to obtain umbilical cord cells or a skin biopsy.

Epidemiology

The World Health Organisation (WHO) has confirmed the existence of a new virus, a member of the coronavirus family, which is related to seasonal influenza and Acute and Grave Respiratory Syndrome (AGRS). The new coronavirus was isolated and confirmed by the Erasmus University Medical Centre in Holland at the beginning of September. It appears to originate in Saudi Arabia and three deaths have been confirmed: one Saudi and two Jordanians. A Qatar citizen was treated in time and is now fully recovered. Apart from serious respiratory symptoms, this new virus is characterized by kidney failure. It appears that there is no evidence that the virus was transmitted from one human being to another.

Pharmacological Informatics Innovation

At the Novartis research facility in Basil, Switzerland, a team of 150 scientists and biologists are on the verge of launching an “intelligent pill”. This contains a microchip within the active substance which, once swallowed, emits signals to a computer (or even a mobile phone). The signal begins by sending the time, date and frequency of treatment. Then it sends information on whether the medicine being taken is adequate, if it is causing side effects and if the patient is adhering to treatment. Although this information is transmitted using Bluetooth, it is sent in encrypted form and can be copied to the patient’s mobile phone.

Oncology

A new study produced by the University of Yale Cancer Centre called “Targeting Cancer with a Lupus Antibody” has been published in the medical journal Science Translational Medicine. Lab tests have shown that 3E10 antibodies against lupus, due to their ability to penetrate nuclei and alter the DNA, can weaken cancerous cells, thereby making them more susceptible to chemotherapy and radiotherapy. Furthermore, they act as tumour suppressors in cases of breast, ovary, pancreas and prostate cancer. This antibody is considered safe in humans because it has already been tested in clinical trials as a possible vaccine against lupus, without causing side effects. Therefore Peter Glazer, Research Team Leader, considers that this new treatment will be available in the market in as little as three years.
Insurers who anticipate and plan for change can create their own future.

Insurance 2020: Turning change into opportunity

Future of Insurance is a new research study from PwC. We’re exploring the drivers of change for the insurance industry. Bringing together PwC insurance professionals from around the world to share perspectives and challenge research findings, we have created new insight that will provide an important discussion tool to shape strategic thinking and direction.

In the Future of Insurance, we explore not only the key drivers of change for the insurance industry as a whole, but also the implications for your insurance business. Our extensive research reviews the sweeping changes across social, technological, environmental, economic and political perspectives, providing the knowledge to evaluate scenarios of maximum relevance to your business. We view through a regional lens as well as a functional one so we’re able to help you prepare yourself strategically for the evolving future.

Using PPPs to drive investment in global healthcare systems

Government spending on healthcare around the world is growing at a pace that is likely to be unsustainable unless new funding sources are found and more efficient delivery methods are sought. As this reality dawns governments are increasingly looking to PPPs to solve the larger problems in care delivery that are driving spending.

Health PPPs have evolved significantly over the last 20 years. They started as a way for governments to build new or revamp crumbling hospital infrastructure in countries like the UK and Canada. More recently their scope has expanded from a primarily infrastructure oriented model to a clinical services delivery model; some projects include both. Examples of such projects can be seen in Spain, Brazil, the Caribbean and the UK.

Biotech

What’s next for the big molecule business?

If the biotech industry’s contribution to productivity is still subject to debate, what about its traditional business model? Two years ago we said that this model based on external investment —namely venture capital as the source of a novel idea arising from an entrepreneurial source— was collapsing. Again, the news is mixed, and the international financial crisis has indeed exacerbated this fact.

The number of alliances has started to grow again to include new partners in philanthropy, venture capital, academic medical centers, competitors and new technology players.
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