Interview: HÃ©ctor Castro â?? Director of Medicines and Healthcare Technologies, Ministry of Health, Colombia

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HÃ©ctor Castro, director of Medicines and Health Technologies at the Colombian Ministry of Health since 2016, explains how the regulations and quality standards implemented have contributed to make Colombiaâ??s healthcare system one of the best in Latin America.

You were appointed director of Medicines and Health Technologies at the Ministry of Health and Social Protection last year after working as the founding executive director for the Health Technology Assessment Institute-IETS. What have been your main priorities since you took over the role?

The directory of *Medicines* and Healthcare Technologies has a broad scope of responsibilities. We are commissioned to regulate the quality, safety and standards for medicines, medical devices, and anatomic components. Our main priority has been to advance the regulation pertaining to medical technologies. Recently, the Colombian health system has been struggling to be sustainable in the long run. While weâ??ve achieved universal healthcare coverage; technological, social, and media pressures, as well as the epidemiological transition have put us at risk of being unsustainable in the long-term. For this reason, we are attempting to regulate prices, currently using an international benchmark of 17 countries. We expect this strategy will generate around USD 100 million savings per year. To date, we have had a good success using International Reference Pricing and setting the willingness to pay the price at 25 percent of the observed markets.

Secondly, weâ??ve launched a centralised program to negotiate hepatitis C-related treatments. In Latin America alone, 14 million people are affected by such condition. Through aggregating demand within the region and the technical support of the Pan-American Health Organization (PAHO) we will save our country another USD 100 million annually. Therefore, it is of paramount importance that we do our best to provide affordable access to these medicines. We are working on standardising the nomenclature and adopting an international classification system for medical devices.

Thirdly, we are also working on strengthening our institutional capacity. A year ago, the Ministry of Health started the redesign of entry requirement mechanisms; this will consist of requesting laboratories to provide additional information on the comparative safety and efficacy of new products. From comparing the new products to existing ones, the Ministry will be capable of regulating products in a more precise manner and assess the added value of upcoming technologies. This new approach in Colombia will be a similar model to the French HAS (High Authority for Health) and German IQWiG (Institute for Quality and Efficiency in Healthcare).

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The Directory of Medicines and Healthcare Technologies is looking at increasing its price-regulating power. This in the light of Articles 71 and 72 of the National Development Plan concerned with centralised purchasing price control. Indeed, the creation of a purchasing unit within the Ministry of Health attached to the Directory for Medicine and Healthcare Technologies should increase our price regulating power. This secretariat will engage developers and conduct budget impact analysis, calculate expected demand using international reference pricing among other sources of data. This unit will be particularly focusing on orphan diseases and chronic conditions requiring very specific treatment.

The Directory of New Medications and Technologies also intends to introduce risk-sharing agreements with pharmaceutical companies within the Colombian Health sector.

Several months ago, you stated that the Ministry of Health will control the prices of 3,000 high-cost drugs to achieve savings for the system up to 400 billion pesos. However, the Association of Pharmaceutical Laboratories (AFRIDO) claimed that this measure was unforeseen and asked the government for greater predictability in the applications of the methodology, as they consider the announcement to be out of sync. What is your assessment on this and how do you plan to work with the associations in the future to ensure the best interest of everyone was achieved?

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Our relationship with affiliates has evolved in a positive manner. While players in the industry donâ??t have always their way, they definitely have their say. Indeed they were requesting more transparency in regards to the predictability of our regulation agenda. In an attempt to satisfy such demand and make the regulation changes more predictable, the Ministry of Health took an unprecedented initiative to publish a timescale of all the regulatory projects underway on its website (https://www.minsalud.gov.co/salud/MT/Paginas/transparencia-medicamentos.aspx). We extended to a 15-day period the timespan to comment drafted regulation on the website. On the other hand, whenever we will assess the value of technologies, we will engage in early dialogues and horizon scanning with the product developers. This way weâ??re in a position to discuss what key performance indicators matter most in terms of efficiency and similar concerns for patients once the negotiation proceeds.

As a final message for our international readers, what do you wish to communicate to restore faith back into the Colombian healthcare system?

Colombia aspires to be a major player in the global arena. Therefore, the Colombian health institutions have placed an emphasis on the application of internationally recognized good practices. Our indicators and benchmarks have been set to improve Colombiaâ??s performances in this regard. As a result, Colombia has taken the lead in Latin America regarding the development of pharmaceutical policies. Weâ??re on the right path to achieve a fair and sustainable universal healthcare system. For example, in 2014 the Colombian Ministry of Health built the standard regulation of biotechs and biosimilars in accordance to FDA and EMA technical guidance. All parties entering the Colombian market need to follow that guidance.

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