



“Transparency in Regulatory Entities: The Pharmaceutical Industry Dimension”

We have conducted extensive interviews with the relevant Turkish authorities in Ankara and with various Commission representatives in Brussels.

What is the purpose of the report?

Turkey started accession negotiations with the European Union on 3 October 2005.

Indeed Turkey and the EU have had a Customs Union since 31 December 1995. The Customs Union requires Turkey's alignment with the EU acquis on a number

of areas regarding the free movement of goods, which does affect the pharmaceutical sector as well. Now with the accession talks, Turkey's alignment with the EU acquis will have to be completed. Therefore, the report aims to analyze the gap between the EU acquis and Turkish legislation regarding the pharmaceuticals. Particular attention has been devoted to transparency, since this is among the main pillars of the EU acquis.

Transparency becomes specifically important in a sector like pharmaceuticals, particularly due to the very important regulatory role of the authorities.

Could you please give us some information about the preparation process?

We have conducted extensive interviews with the relevant Turkish authorities in Ankara and with various Commission representatives in Brussels. Obviously this involves a lot of desk research as well.

The report was prepared with the contributions of the AIFD (Association of Research Based Pharmaceutical Companies). However, the arguments and views expressed in the report belong solely to Istanbul Ekonomi Consultancy and may not necessarily be shared by AIFD.

How would you describe transparency in the pharmaceuticals industry and how is it different when compared to other industries?

In the social sciences, transparency refers to openness, communication and accountability. The principle of holding public employees accountable is an important factor in the fight against corruption. Transparency is also important in terms of good governance, as it requires decisions to be taken on certain criteria established in written rules (such as laws, regulations, etc.). This should include discussions on these rules by all relevant parties, thereby creating an opportunity to reach mutual understanding and agreement. It establishes a mechanism that prevents the abuse of public authority.



Since transparency involves participation, it is an important factor in the development of a modern democracy.

When it comes to the pharmaceutical industry, transparency plays an important role within the EU acquis. Indeed it has been a key component in the EU for over 20 years. Transparency becomes specifically important in a sector like pharmaceuticals, particularly due to the very important regulatory role of the authorities. Regulation

in this sector is necessary mainly because of what we call “information asymmetry”. In the pharmaceutical industry the information acquired and developed by industry representatives, doctors and pharmacists is incomparable to the limited information of patients who use medications. Thus the relationship between the producer/seller and the buyer is very different than in other industries. Therefore, the regulatory authorities have the task of protecting public health through regulations they implement

■ Transparency thus would play a crucial role for an increase in the investments.

However, the regulatory bodies at the same time need to encourage the development of the industry, to improve public health. Transparency comes in at this stage and enables the sector to develop while protecting the interests of patients.

Which processes do you think are lacking transparency? What steps should be taken in these areas?

Turkey has taken important legislative steps in the pharmaceutical sector since 2004. Indeed alignment with the EU *acquis* has been the *leit motif* behind the changes. Therefore, a number of improvements were realised. Now the regulatory authorities need to implement the changes. Nevertheless, there also remain further improvements to be made, and these are mostly related to transparency. The greatest need for improvement is in the area of reimbursement decisions. Unfortunately, there are no open and known criterias used by the regulatory authorities for reimbursement decisions; yet this is of paramount importance both for the industry and patients. It is important for patients because, due to the existing uncertainties, a number of important medications can not be had. This is particularly concerning for drugs used in cancer treatments or in similar diseases requiring immediate treatment. It is simultaneously important for the industry because companies efforts are made in vain if the medication is not on the reimbursement list. Since there are no publicly available criteria, the industry is blind until a verdict is reached by the reimbursement committee. The EU *acquis* does not allow such uncertainties. Indeed the Transparency Directive of the EU clearly states that the regulatory authorities should make decisions with clearly defined and open criteria. Therefore, Turkey will need to

align with the Transparency Directive.

What are the conclusions of the report?

In short, the report states that Turkey's legislative changes are moving in the right direction. This is particularly true for the registration process. The new Turkish legislation has taken the EU *acquis* as an example. However, implementation is equally important and the regulatory authorities have not yet proven that the changes are fully implemented. There are even signs of misinterpretations. On the other hand, the reimbursement process continues to be problematic, particularly in terms of transparency. While it is understandable that financial implications are serious considerations for the budget, particularly in an indebted developing country like Turkey, budget considerations can not be an excuse for not defining reimbursement criteria. Moreover,

examples like Ireland indicate that when suitable conditions are established, the pharmaceutical industry can make a huge contribution to the economy. Thus, transparency plays a crucial role in increasing investments. The report also concludes that the role of the Ministry of Health (MoH) shall be limited to the preservation of public health. In other words, MoH should not play a role in financial aspects such as reimbursement. MoH's involvement in financial decisions complicates the picture and clearly runs against transparency. ■

