Roundtable discussion "Regulation and policy"

By Peter Homberg

The participants of this roundtable very lively discussed the different environments in various jurisdictions with respect to regulation and policies in the healthcare industry. The discussion mainly focused on three different areas which are outlined below:

Marketing Authorizations and Reimbursement

a) Marketing Authorizations

With respect to obtaining marketing authorizations for novel pharmaceuticals it was pointed out by the various participants that the rules and regulations significantly differ from country to country and even within the countries of the European Union. The requirements for obtaining marketing authorizations have increased in the last years and will become more difficult for the pharmaceutical industry in the future. With respect to Russia it was pointed out that Russia has implemented an accelerated procedure for obtaining marketing authorizations for novel pharmaceutical products whereby Russia will very much follow similar procedures as the EMA.

Such accelerated procedure will provide the applying pharmaceutical company in Russia within a timeline of 210 days with a decision whether the product will obtain marketing authorization or not. However, the duration of such procedure maybe extended to one year.

In order to streamline the approval for novel pharmaceuticals Russia, Belarus, Kazakhstan, Kirgizstan and Armenia have initiated a joint approach whereby it is still unclear whether the mutual recognition procedure as known within the member states of the European Union will be mutatis mutandis applicable to those countries.

b) Reimbursement

The current difficulties regarding obtaining "fair reimbursement" for novel pharmaceutical products were discussed. Prices for pharmaceuticals are currently significant under pressure in the German market with the consequence that a number of Pharmaceutical companies desist from entering the German market as the relatively low price in Germany could be taken as a reference by other European authorities.

In addition, the reimbursement structure in the USA was discussed. In particular that in six classes of pharmaceuticals (e.g. oncology, HIV, immunosuppressant) no negotiations regarding the price between the authorities and the pharmaceuticals companies will take place. This situation heavily influences the development targets of the pharmaceutical industry with the consequence that in these six classes the R&D activities have been intensified over the last years.

Collaborations

It was pointed out by the participants of the roundtable that the stricter compliance rules and regulations have a significant impact on the collaborations between the different market participants. The required transparency of all kind of collaborations between doctors and the pharmaceutical industry, which in particular is stipulated in the French Sunshine Act and in other transparency regulations all over the world, put a significant burden on the market participants. This results in an upcoming reluctance to enter into such collaborations.

Lobbying

The participants of the roundtable further discussed the contents of successful lobbying. In this respect, the aim of lobbying activities was discussed which the participants defined as “Assuring that the legislative understand the consequences of their decisions”.

Furthermore, it was pointed out that the pharmaceutical industry needs to improve its reputation as currently through the various negative communications of the legislators the reputation of the pharma industry has suffered. In this respect it was noted that the self - persecution of the industry significantly differs from the actual reputation in the public. Thus, the industry needs to get a more sophisticated awareness of how the industry is currently perceived in the public and then take the necessary steps.