Hungary: HCA and NIPN conclude cooperation agreement for pharmaceutical consumer protection cases

Pharmaceutical companies and other healthcare suppliers have always been of special interest to the Hungarian Competition Authority (HCA) due to the associated public health concerns. In light of this, the HCA has concluded several cooperation agreements with other agencies to facilitate the investigation of these markets. Initially, the agreements were developed with the authorities responsible for the authorisation and monitoring of medical devices and food supplements.

Based on the opinions of the cooperating authorities, the HCA imposed penalties in several cases for unfair commercial practices. In most cases, the infringement constituted the use of false statements pertaining to disease prevention and therapeutic effects to promote a product.

The cooperation agreements have procedural consequences in court proceedings. For example, in a recent judicial review case the court confirmed that when the HCA has collected the relevant information from the competent pharmaceutical or nutrition authorities, there will be no need to order further scientific expert opinions.

In September 2015 the HCA concluded a cooperation agreement with the National Institute of Pharmacy and Nutrition (NIPN). This update summarises the scope and practical consequences of the HCA’s cooperation with the NIPN.

Cooperation with NIPN

The key feature of the cooperation agreement is that it enables the HCA to consult the NIPN and request professional opinions, which are mostly required in consumer protection cases. Accordingly, if the HCA raises concerns about the validity of promotional communication relating to a pharmaceutical product, it can cooperate with the NIPN to assess the medical content of the communication.

The HCA may also request information from the NIPN regarding ongoing or completed proceedings. If the NIPN refuses to issue marketing authorisation for a pharmaceutical product on the basis that it does not meet the scientific requirements for medicines (rather than because of safety concerns), the product may still be marketed as a food supplement or other food product. In such cases, the HCA will usually investigate the promotional communications relating to the product to ensure that they do not contain any claims regarding therapeutic effects or disease prevention. If the company has made such claims, the rejected marketing authorisation application will be sufficient grounds to establish the violation of the consumer protection regulation (ie, no further NIPN opinion will be necessary).

The cooperation agreement between the HCA and the NIPN has been in place for more than 10 months and appears to be going smoothly, with information and opinions being exchanged in a timely manner.

Latest consumer protection cases

The cooperation agreement between the HCA and the NIPN has led to an increase in the number of consumer protection cases against pharmaceutical companies and other healthcare suppliers. HCA investigations are usually preceded by NIPN proceedings. As mentioned above, if the NIPN refuses to grant marketing
authorisation for a pharmaceutical product, claims regarding the product's therapeutic effects or disease prevention qualities cannot be made, and the HCA will not have to carry out further investigations regarding their validity. For example, in the case against HYD Cancer Research and Drug Development, such claims led the HCA to impose a Ft30 million (€96,000) fine.

This is the same for food supplements and foods for special medical purposes that are regulated by the NPIP. The non-authorisation of these products clearly determines the legal scope of any subsequent promotional communication, which reduces the HCA's investigative burden.

The HCA also investigates the commercial practices of pharmaceutical companies to ensure that promotional communications are in line with pharmaceutical law. In this regard, compliance with the summary of pharmaceutical product characteristics receives particular attention. However, as these issues require medical expertise, the HCA requires the NIPN's opinion during the course of such proceedings. In a recent case, the HCA imposed a Ft10 million (€32,000) fine on Sager for claims used in promotional communications that were not in line with the applicable summary of product characteristics.

Role of CPA

While the HCA is generally responsible for consumer protection cases if competition is materially affected by an alleged infringement, in certain exceptional cases the Hungarian Consumer Protection Authority (CPA) is responsible and its related procedural rules apply. This can have a significant effect – for example, while the maximum fine that the HCA can impose is 10% of a company's annual net turnover, the maximum fine that the CPA can impose is only 5% of the company's annual net turnover.

The CPA may be responsible for cases if the alleged infringement relates only to information contained on the label or package or in the instructions for use, which is often the case for medical devices. The CPA may also be responsible for a number of other cases – for example:

- when prohibited communications have been issued regarding investigational products; and
- when the alleged infringement relates only to information obligations pertaining to the therapeutic effects or safety of a product (eg, if the company has failed to provide the necessary information).

Comment

The high number of consumer protection cases relating to the pharmaceutical and healthcare industries can be attributed to their outstanding public importance and the fact that consumers in these markets are considered exceptionally vulnerable. For this reason, the Hungarian legal framework provides for three authorities (the HCA, the NIPN and the CPA) to investigate commercial practices in these markets. Each authority can initiate proceedings and subsequently transfer the case to the competent authority.

In light of this framework, companies should prepare and carry out their commercial practices in these fields with the utmost care and attention to ensure that they follow the applicable regulatory rules.

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