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India prepares pharmacovigilance guidelines

The Indian government set up a committee in late February to prepare pharmacovigilance guidelines that will set out adverse drug reaction reporting requirements for pharmaceutical companies, in a move that could see pharmacovigilance made mandatory in India.

"The government is attempting to bring India on a par with other developed nations," said Tony Verghese and Sherill Pal of J. Sagar Associates. "Typically, the only adverse drug reaction reports filed in India are those arising at the clinical trial stage. Once the drug is sold to the general public, such reports are rarely filed."

Once the guidelines for the implementation of pharmacovigilance have been drafted, they will be released for public consultation before being finalised.

"India's drug regulator, the Central Drugs Standard Control Organisation, has also introduced a National Program, called the Pharmacovigilance Program of India ('PvPI')," explain Dr Milind Antani and Anay Shukla of Nishith Desai Associates. "The PvPI is being implemented in phases. Thus, there is possibly a gap in adverse event data collection."

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Scope of French Sunshine Act expanded following challenge

The French Council of State ('Conseil d'Etat') annulled, on 24 February, some of the provisions of the French Sunshine Act, which imposes disclosure obligations on healthcare companies, following legal action by the French Medical Board and a non-profit organisation against the law's implementing decree and its explanatory circular.

The decision of the Council expands the scope of the French Sunshine Act's disclosure obligations as follows: firstly regarding the decree implementing the Bertrand law, the Council cancelled the limitation on the obligation of transparency for companies that manufacture or sell non-corrective eye lenses, cosmetic products and tattooing products, and secondly cancelled the exclusion to the obligation of transparency, contained within the explanatory circular, for the salary of a healthcare professional.

Following the decision companies that manufacture or sell non-corrective eye lenses, cosmetic products and tattooing products will now need to declare all the conventions signed with healthcare professionals, and the salary given by companies to healthcare professionals will need to be declared.

"The decision of the Council was a victory for some MPs, the French Medical Board and the non-profit organisation," said Olivier Lantrès, Partner at Fieldfisher. "However, from our perspective, we consider that the Council's decision makes the current transparency system more complex and uncertain, which is already a major burden for companies acting in the Life Science sector." However Daniel Kadar, Partner at Reed Smith believes that "In terms of transparency, this may be interpreted as an improvement. However, there is obviously a need to clarify how to implement the transition to the new regime after the decision of the Council in terms of reporting of remunerations, but also to lay out the reporting obligations of other affected companies."

The consequences of the Council's decision are being analysed by the French government, which will need to take appropriate measures to comply with the decision. As yet it is not known when the new decree and circular will be published. However, explains Pierre Desmarais, Lawyer at Desmarais Avocats, "The cancellation of the decree and the interpretative circular is retroactive. So in theory, companies would have to publish information on all the contracts that were not under the scope of the provisions struck down by the Council's decision."

MHRA sees rise in complaints about drug adverts on internet

The UK's Medicines and Healthcare Products Regulatory Agency (MHRA) published on 24 February its 'Delivering High Standards in Medicines Advertising' report, which states that the amount of complaints received by the MHRA regarding drug adverts fell from 283 to 193 between 2013-2014, but reports a rise in the proportion of complaints about adverts for prescription only medicines (POMs) to the public online.

"Due to increasing guidance from regulators (and the putting in place of adequate internal policies and processes), pharma has become more active online; hence it can be expected that the proportion of 'online' complaints will continue to rise," said Eveline Van Keymeulen, Associate at Allen & Overy. "Although the prohibition of advertising POMs to the public is widely understood and respected in the pharma industry, many of the complaints (e.g. in relation to botulinum toxin products) relate to promotion of the product by others (such as clinics offering treatments)," adds Tim Worden, Partner at Taylor Wessing.

The MHRA notes that many complaints related to ads on platforms such as Twitter; no complaint resulted in corrective action by the MHRA. Helen Cline, Legal Director at Pinsent Masons, concludes that "companies need to be cautious to ensure they deploy social media compliantly as regulatory authorities such as the MHRA are already stepping up their monitoring programs and will impose sanctions on non-compliant companies."