

creates new forms of power with specific characteristics: the need of transparent subjects, the participation of patients to the power that aims to take control on their own body, and the growing porosity between the private and public sectors. First applied to the analysis of sexuality, the concept of biopower is nowadays highly relevant to analyze this new turn in medicine practices that involve the full cooperation and transparency of patients.

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MULTIPLE SCLEROSIS—NEW CHANCES?

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Summary: The treatment of multiple sclerosis as an autoimmune disorder has benefited for several years from the progresses of biotherapeutics. Since the mid-1990s, interferon beta has been proposed as a valuable treatment for certain MS patients due to its immunomodulator properties, followed shortly after by the registration of the polypeptide glatiramer acetate. More recently, monoclonal antibodies have been developed to target selective components of the immune response and provide a selective immunosuppression that could treat the disease with an acceptable safety profile. Natalizumab was the first of these monoclonal antibodies, and other monoclonal antibodies such as rituximab or alemtuzumab, originally developed in oncology, have since been repositioned for autoimmune disorders such as MS. However, these molecules, which are very selective in their targets, often do not appear so favorable during development, and their safety profile could significantly limit their use. More recently, the development of monoclonal antibodies has refocused more on targeting proteins that play critical roles in the pathophysiology of MS, notably on the specific processes of neurotoxicity: these antibodies are now in early clinical development and may bring new avenues in the treatment of MS.

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SAFETY INFORMATION TODAY AND HOW CAN WE IMPROVE TOMORROW?

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Summary: Ever since “modern” pharmacovigilance started in the early 1980s, it has gone through changes of various pace introduced by new concepts (eg, CIOMS I-V), development of science and methodologies (eg, pharmcoepidemiology), technology (eg, databases), or regulatory requirements (eg, risk management, new legislation). Over the period of time, methods of data collection and analysis became easier, which is helpful, taking into account the fast-growing world’s population. However, everyday general medical practice did not change much despite great progress in sciences. Large safety data are accessible from organized databases in regulatory bodies, industry, medical insurance, and other organizations, facilitating their analysis and aggregate evaluation, but in many situations, actions are still triggered by the assessment of causal associations based on medical judgment performed on individual cases or case reports. The future of pharmacovigilance should be based on well-thought-through risk management combined with risk minimization activities, which will reflect preceding appropriate benefit/risk assessment. This can be delivered by adequate training in clinical pharmacology, which will include good prescribing practices and the development of regulatory science either within clinical pharmacology or as a separate discipline. In addition, the broad understanding of important safety information

collected and assessed from population data and in large databases should grow and facilitate data-driven scientific decision making.

Clinical pharmacology has an important role at present and in the future by providing curricula for HCPs across the world, teaching appropriate prescribing, risk management/minimization concepts, and contributing to the increase in protection of public health and individual patient safety by being much more prominent in the HCP training and clinical practice.

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THE POISONS CENTRES NETWORKS—TOXICOSURVEILLANCE

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Summary: Every day, European poisons centers (PC) assess poisoning risks of thousands of exposures to toxic agents and give advice for best-practice medical treatment, triggered by telephone calls from medical staff, patients, or caregivers. PC are continuously registering all exposure cases in local databases and are analyzing these data to detect or verify unusual poisoning events (often involving several or many patients) and trends of poisoning.

By this method of toxicovigilance, for example, the Swiss PC detected series of unexpected breathing disorders caused by regular intended use of 1 of 3 waterproofing spray products in 2003 and, more recently in 2012, the GIZ-Nord Poisons Centre in Germany discovered a Ciguatera poisoning series (14 patients) generated by contaminated seafood (Red Snapper) purchased in local supermarkets. In some of these events, the toxic products identified were removed from shops within hours, after notifications of PCs to retail, competent regional, or national authorities, prevented many more poisonings.

In the past, unexpected poisoning risks that might have been caused by rare exposures and very rare notification to PC may have been missed if only single cases were notified to PC, and the cases could not be validated with sufficient quality. Today, networks of PC facilitate exchange of observations, case reports, and related toxicologic knowledge to rapidly confirm new or unusual poisoning risks. With help of conveniently new communication tools, several PC networks have been founded or intensified in Europe in the last decade. The European Association of Poisons Centres and Clinical Toxicologists forms the most powerful and Europe-wide expert network.

In 2011, the Public Health Project “Alert System for Health Threats” (ASHT, sponsored by the European Commission and the 7 project partner organizations) had designed and tested a surveillance system that can collect a vast number of exposure cases reported to PC in real time. This system facilitates the timely concomitant analysis of all cases submitted to detect unusual and hidden poisoning risk in a more sensitive way in the near future.

In conclusion, toxicosurveillance of population poisoning risks, enabled by PC’s toxicovigilance, has played an important role in detecting unexpected poisonings, especially poisonings caused by intended use of unsafe products in the past, and will play an even more important role in the future powered by rapidly reacting PC networks.

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THE RELEVANCE OF CLINICAL WORKPLACE LEARNING AND ASSESSMENT IN CP&T

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