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Microbiological methods applied during the post marketing quality surveillance of products dispensed by Belgian pharmacists

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The Laboratory of the Belgian Pharmaceutical Association (APB) is assigned to carry out the post marketing surveillance of all medicinal drugs dispensed in Belgian community pharmacies. With over 1000 analyses each year, the APB Laboratory supports the pharmacist in its legal responsibility to dispense medicines of high quality. The APB Laboratory samples specific groups of (non-)medicinal products and pharmacists can also report quality defects for which specific testing may be done. Various chemical and biological tests are performed on both raw materials and finished products. For the microbiological analysis of pharmaceutical products all current pharmacopeial methods are used. Examination of non-sterile products is done by microbial enumeration tests for total aerobic microbial counts (TAMC) and total yeast and mold counts (TYMC), in addition to the tests for specified microorganisms. Sterile products are analyzed using filtration techniques or a direct inoculation method. Endotoxin testing of injectable therapeutics can be achieved by a qualitative (gel-clot) or quantitative (chromogenic) method. Compared to medicines, products such as dietary supplements are differently regulated and controlled. Systematic analysis of these products such as for medicines can reveal prominent quality defects. The Biology Platform of the APB Laboratory performed comparative studies of herbal products including teas and demonstrated some non-conformities: TAMC and TYMC were exceeded and/or *Escherichia coli* was present. When a product is non-compliant, the APB Laboratory contacts the marketing authorization holder (MAH) and suggests changes in the analytical file or patient information leaflet. If necessary, a recall from the market can also be organized in concertation with the Belgian health authorities. In addition to our post marketing surveillance, the laboratory offers under its brand name Phasius customized services and solutions for different stakeholders in the health sector including hospital pharmacies and pharmaceutical industry. Complementary to European programs by health authorities, the APB Laboratory provides a unique system of quality control of the products dispensed in Belgian community pharmacies. In this context, microbial enumeration and identification tests, sterility testing and endotoxin assays are particularly important in the achievement of our mission.

Biography

Sofie Clais has completed her PhD in Pharmaceutical Sciences at the University of Antwerp in 2015. She is Platform Manager Biology at the Laboratory of the Belgian Pharmaceutical Association, which is assigned to carry out the post marketing quality surveillance of all medicinal drugs dispensed in Belgian community pharmacies.

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