

Regulatory Affairs

BfArM probes pelargonium risks

A total of 20 suspected cases of liver-related side-effects linked to pelargonium-containing herbal medicines has led Germany's federal institute for drugs and medical devices, BfArM, to launch an investigation.

The regulatory agency said that over the past six months it had received an increasing number of reports of hepatotoxicological side-effects. "Due to this increase in the frequency of reports – and against the background of these medicines' stated indications – we feel it is necessary to evaluate further the hepatotoxicological risk from using pelargonium medicines," BfArM stated.

Within four weeks, the agency wants answers to a number of questions it has sent to relevant parties.

BfArM is demanding a list of all known liver-related side-effects that have been linked to the herbal medicine, "independent of any assessment of causal relationship". Affected companies should supply numbers, descriptive analyses and a causal assessment of the reported cases.

Furthermore, BfArM wants details of hepatotoxicological reactions that have arisen during pre-clinical work and clinical trials, as well as from epidemiological and observational studies.

The regulatory agency has also enquired whether companies intend to take "independent measures" in light of their experiences.

Earlier this year, Germany's federal union of pharmacists, ABDA, warned that Spitzner Arzneimittel's Umckaloabo pelargonium medicine might cause liver damage. The pharmacists' body urged consumers who had taken the herbal bronchitis remedy to watch out for side-effects such as rashes, itching or "unspecific pain", and to report any such symptoms to their pharmacist or doctor (*OTC bulletin*, 18 August 2011, page 18).

ABDA noted that Germany's spontaneous pharmacovigilance system had received 145 reports of side-effects linked to Umckaloabo as of June 2011.

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Third-Quarter Results

J&J's OTC sales hit new low in US

US sales at Johnson & Johnson's OTC & Nutritionals business have more than halved over the past two years, as the closure of McNeil Consumer Healthcare's Fort Washington manufacturing plant and the firm's subsequent efforts to improve production quality have taken their toll.

Turnover in the US was just US\$332 million (€242 million) in the third quarter of this year, which was 24.2% lower than in the same period a year earlier, and 54.6% down on the third quarter of 2009 when sales stood at US\$732 million.

The US decline pushed down worldwide sales at the OTC & Nutritionals business by 5.0% to US\$1.05 billion. The fall would have been worse but for a positive currency effect of 4.4%, which partially offset a 9.4% operational decline.

In September, Johnson & Johnson boosted its US OTC business by taking full control of its consumer healthcare joint venture with Merck & Co in Canada and the US (*OTC bulletin*, 14 October 2011, page 1).

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Trading Update

Omega withdraws full-year guidance

Omega Pharma has withdrawn its full-year forecast because there are “too many uncertainties to provide a specific, quantified guidance” in the current economic climate.

The move by the Belgian company followed a third quarter in which its sales edged up by just 1% to €202 million. Omega said the “difficult conditions” in certain Southern European markets had hit sales in its Western Europe region while problems in Russia had hampered turnover in Emerging Markets.

Strong gains in Belgium and France had produced the rise in third-quarter sales, Omega noted, adding that although the fourth quarter was expected to be “relatively stronger than the third”, the company was no longer comfortable sticking with its previous guidance of €927 million for full-year sales (*OTC bulletin*, 18 August 2011, page 12).

Omega performed best in France, where sales jumped up by 21.8% to €42.7 million.

Omega could soon return to private ownership, after Marc Coucke, the firm's chief executive officer, made a takeover bid through his investment firm Couckinvest (*OTC bulletin*, 14 September 2011, page 1).

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Regulatory Affairs

French industry wants more education

Educating French consumers and healthcare professionals about self-medication, creating a logo to clearly identify medicines for self-medication, and introducing a more liberal approach to umbrella branding are among the proposals suggested by France's OTC industry association, AFIPA, to improve the country's self-medication market.

Outlining its proposals at the association's first Self-Medication Forum in October, AFIPA urged the French authorities to launch a communication campaign to inform the public about good self-medication practice. The association also wants pharmacy and medicine students to study specific modules relating to self-medication.

AFIPA also suggested creating a specific logo for self-medication medicines to encourage consumer trust and to avoid the misuse of certain medicines by clearly identifying products that should be used for self-medication.

According to AFIPA, the French authorities should consider allowing certain treatments for chronic conditions – such as migraine or cystitis – to be sold without prescription. The industry association called for a mutual-recognition system that would allow medicines switched from prescription-to-non-prescription status elsewhere in Europe to qualify for the same status in France.

Furthermore, a data-protection period of three years should apply for the first company to qualify for a prescription-to-non-prescription switch for a certain medicine, the association suggested.

Another change demanded by AFIPA was replacing the denomination “insufficient therapeutic value” – which is used to describe dereimbursed medicines – with the term “submitted for individual care”. The current label had negative connotations, the association pointed out, which created the “harmful” impression that dereimbursed medicines were ineffective.

AFIPA's president, Pascal Brossard, acknowledged that self-medication was making slow progress in France. However, he said recent government policies to dereimburse certain products and to reduce public healthcare spending (*OTC bulletin*, 30 September 2011, page 12) would accelerate the development of the OTC market.

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Distribution Agreements

BioGaia signs up Victus in Venezuela

BioGaia's probiotic drops and tablets will soon be available in Puerto Rico and Venezuela, after the Swedish firm signed an exclusive distribution agreement with Victus.

Victus would sell the products under the BioGaia brand name, said BioGaia, adding that launches were expected in 2012.

The two companies have worked together since 2001, when Victus started to buy BioGaia's probiotic culture with *Lactobacillus reuteri* Protectis for use in its Glutapak-R products. BioGaia pointed out that Glutapak-R was "successfully" marketed by Victus in most Latin American countries.

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