Italian Regulatory Affairs News

20th May, 2019

- Human Medicines
- Veterinary Medicines
- Homeopathic Products
- Medical Devices
- Diagnostics
- Food Supplements
- PMC (Medical Surgical Aids)
- Biocides
- Plant Protection Products
- Cosmetics
Drug expenditure and consumption data available in open format

The Italian Medicine Agency has published the drug expenditure and consumption data for pharmacy sales and direct purchases in an open data format to allow free consultation, use and distribution by everyone, with the sole obligation of reporting their source.

Data refers to year 2016 and 2017 and include year and month the data refer to, region, reimbursement class, ATC class, number of packs sold in the hospital channel (including direct distribution and hospital drugs sold in public pharmacies), hospital expenditure as per drug traceability flow (before VAT including direct distribution and hospital drugs sold in public pharmacies), number of packs sold in the pharmacy channel, pharmacy expenditure with public price (including VAT).

The relevant operational manual is also available.
Class A and H: update January 2019

To allow for the prescription by active substances, the Italian Medicines Agency has updated the tables containing the list of medicines in class A on an active ingredient and trade name basis.
The list of medicines in class A dispensed by the National Health Service includes medicines in the transparency list of the AIFA updated until 15 January 2019, medicines covered by patent protection, as well as medicines whose patent protection has expired but for which there is no provision for substitution. The tables do not set maximum prices for reimbursement.
The prescriptions on active ingredient basis by health professionals is laid down in Article 15, paragraph 11-bis of the Law Decree of 6 July 2012, no. 95, enacted with amendments into Law 7 August 2012, no. 135.
Medicine prices are net of the temporary reduction by law established by the AIFA Decision dated 3 July 2006 and of the further reduction of 5% according to AIFA Decision 27 September 2006 (in case this has not be suspended because of the 5% Pay-back) and the reduction provided for by article 11, section 9, of D.L.78/2010 enacted as amended into Law 30 July 2010, no. 122.
AIFA clarifies on product information transmission

In a communication published on their official website, the Italian Medicine Agency has requested MA holders to transmit the product information proposed for MA release, variation or renewal of medicinal products without including links to business websites or to website not previously authorised by AIFA. In case the Summary of Product Characteristics, Patient information Leaflet and Labelling are drafted using commonly used and consulted but unofficial websites, the deletion of any form of information contamination is exclusive responsibility of the MA holders transmitting them to the Agency.

European Regulatory Updates

EMA, new director wanted

The European Medicine Agency has started the search for its new executive director in view of the conclusion of the second term of Guido Rasi next year. The notice of vacancy published in the European Gazette (C 165 of 14/05/2019) underlines that the ideal candidate should have management experience, with knowledge of European pharmaceutical legislation and experience in medicine, pharmacology, veterinary preferably acquired in a national, European or international public administration involving contacts with the pharmaceutical industry, as well as communication and negotiations skills. The candidates must be European nationals, graduated preferably in medicine, pharmacy or veterinary and with a 15-year professional and management experience. The knowledge of the official European languages is also required. The Executive Director will be appointed by the Management Board of EMA on the basis of a list drawn up by the European Commission, after having made a statement to and answering questions from the European Parliament. Selection will be carried out in English and/or French. Applications may be submitted online by 13 June.
International Regulatory Updates

FDA publishes quality report

The US Regulatory Agency FDA published a report providing an overview on quality of drugs and biologicals intended for the US market, with special focus on the GMP compliance and product quality. Overall, the picture of US industry in terms of quality is good.

The report highlights the presence of over 4,500 manufacturing sites, 50% of which manufactures OTCs, homeopathics and other products not requiring any approval by the Agency. The number of the latter is increasing. Moreover, the report underlines that almost 1,350 manufacturing sites were inspected for quality in 2018. The inspections covered 30% of the sites registered at the Agency; most of them were carried out outside the country. Finally, the report attempts a product quality estimate through the analysis of reports from industry, healthcare providers, patients and consumers, including complaints, alert reports, vigilance reports and biotechnology product deviation reports. Recall and drug shortage data were also taken into account.

India, new measures against corruption

The Indian department of Pharmaceuticals has appointed a new vigilance responsible officer in the frame of a series of measures aimed at stopping corruption.

According to the Indian legislation, the vigilance officers of the various departments are appointed by a government commission and are never selected in the department itself. Their work of prevention of corruption and malpractice consists in the improvement of rules and procedures, in monitoring the organisation more subjected to corruption and in carrying out inspections in search of systems failures.

The new officer will serve for 3 months.
The European Committees

Committee for Medicinal Products for Human Use (CHMP)
Last meeting: 23-26 April 2019
Next meeting: 27-29 May 2019

The Committee for Advanced Therapies (CAT)
Last meeting: 15-17 April 2019
Next meeting: 22-24 May 2019

Paediatric Committee (PDCO)
Last meeting: 23-26 April 2019
Next meeting: 27-29 May 2019

The Committee for Orphan Medicinal Products (COMP)
Last meeting: 15-17 April 2019
Next meeting: 21-23 May 2019

The Committee for Risk Assessment in Pharmacovigilance (PRAC)
Last meeting: 13-16 May 2019
Next meeting: 11-14 June 2019

Committee for herbal Medicines (HMPC)
Last meeting: 14-16 January 2019
Next meeting: NA

Committee for Medicinal Products for Veterinary Use (CVMP)
Last meeting: 15-17 April 2019
Next meeting: 21-23 May 2019

Committee on Biocides (BPC)
Last meeting: 25 February - 1 March 2019
Next meeting: 24-28 June 2019
The Italian Commissions

Open-AIFA:
Next meeting: 14 June 2019

AIFA Board of Directors
Last meeting: 20 September 2018
Next meeting: NA

Technical Scientific Advisory Commission
Last meeting: 8-10 May 2019
Next meeting: 5-7 June 2019

The Committee for prices and reimbursement
Last meeting: 15-17 April 2019
Next meeting: 21-23 May 2019

The Technical Health Committee-Advertisement
Last meeting: 7 May 2019
Next meeting: 28 May 2019

Veterinary Commission
Last meeting: 25-26 March 2019
Next meeting: 21-22 May 2019

Relevant deadlines

31 May 2019
Deadline for all bodies and enterprises authorised to the production, manufacture, use and marketing of narcotic substances as well as medicinal products containing narcotic substances, included in tables I and II to transmit a communication to the Ministry of Health on the estimate of quantities to be imported in 2020 (art. 66, comma 2 of Presidential Decree 309/90).

International Meetings

29-31 May 2019
London
Regulation of Electrical, Electronic and Software Devices

www.topra.org
New headquarters for Di Renzo Regulatory Affairs

Two thousand square meters on four floors, and almost 100 employees.

This is the new face of Di Renzo Regulatory Affairs.

After more than 30 years spent in our historical headquarters of Viale Manzoni, as of 6th May 2019 the Company has moved to the headquarters in Via dell’Arco di Travertino 11, in Rome, to gain more space for our increasing international and dynamic vocation.

The new headquarters are free-standing, modern, sunny and surrounded by greenery, and perfectly embody the values of quality, organisation, dynamism and internationalisation that Di Renzo Regulatory Affairs has been carrying forward as its own project since its foundation.

The new headquarters bind the architectonic and functional aspect – taking care of the staff well-being – with the standards of efficiency and quality of our consultancy services.

The vocation of the company is that of further widening the relationship with institutions and international companies of the pharmaceutical and regulatory sector, always ensuring more and more extended competence to Italian clients as well.

In fact, we believe that new challenges represent a dynamic incentive to perfect our how-to-be and widen our know-how. Because knowledge is a process and not just information.