• Human Medicines
• Veterinary Medicines
• Homeopathic Products
• Medical Devices
• Diagnostics
• Food Supplements
• PMC (Medical Surgical Aids)
• Biocides
• Plant Protection Products
• Cosmetics
Italian Regulatory Updates

Transparency: update January 2019

The new transparency list of medicines included in the list of equivalent drugs (Law 178/2002) is available with the corresponding reference prices updated at 15th January 2019, including the reduction in accordance with the AIFA Determination of 3 July, 2006, the further reduction of 5% according to AIFA Determination of 27 September, 2006 and article 9, paragraph 1, of the Law no. 31 of 28 February 2008 (Pay-back) and paragraph 9 of article 11 of the Legislative Decree 78/2010 enacted with amendments by Law no. 122 of 30 July 2010. The list is available in Excel and CSV format, on active ingredients and trade names basis.

Italian expense balancing for 2017

The Italian Medicine Agency has announced the imminent publication in the Official Gazette of the decree on the balancing of the pharmaceutical expense for 2017. All concerned companies shall pay the amounts indicated in the decree no later than 15th February 2019. The decree is part of the procedures required to comply with the provisions of article 1, comma 582 of Law 30 December 2018 no. 145: “State estimated budget for the financial year 2019 and the multi-annual budget for the period 2019-2021”.
AIFA survey on DEA

The Italian Medicine Agency has requested all MA holders of medicinal products authorised by national or European mutual recognition or decentralised procedure to urgently transmit the names of their medicinal products containing the excipients diethanolamine (DEA) and/or diethanolamide from fatty acids from coconut oils (coconut oil DEA). The Agency has also requested the quantities of these excipients for each authorised formulation.

The information shall be submitted within 21st January 2019 at dietanolammina@aifa.gov.it

New forms to access AIFA 5% fund

The Italian Medicine Agency has informed that new forms are in force for the request to access the national AIFA fund 5% (5% fund) as of 11th January 2019. The forms are to be filled in and submitted electronically at 648. fondo5@aifa.gov.it. The fund allows the use of orphan drugs for rare diseases and of drugs under authorisation for severe and particular disease, reimbursed by the Italian National Health Service. The Agency has reminded that the requests are individual for each single patient, and that shall be submitted by the reference centres reporting the reason of the request, the patient’s clinical report, the proposed therapeutic plan, and the costs expected for the treatment.

Release changes for veterinary GMP certificates

The Italian Ministry of Health has informed that the release of Good Manufacturing Practice certificates for medicinal products and/or active pharmacological ingredients (API) for veterinary use shall be only granted to pharmaceutical forms and/or APIs whose production can be proved in the last three years.

The new conditions for the release aim at releasing GMP certificates only to companies actually manufacturing pharmaceutical forms of medicinal products and/or APIs for human use.
Food control data published for 2017

The Italian Ministry of Health has published a report including the data of the official controls on food and drinks for 2017. The controls ensuring the conformity of the products with the provisions in force to prevent public health risks and protect consumers, are carried out at any stage of the manufacturing, processing, distribution, storage, transport, marketing and administration. In 2017 more than 47,000 samples of food, drinks and materials intended to come into contact with food were withdrawn, for a total of almost 120,000 analyses; non conformities were 0.88%, quite all concentrated in meats and meat products and in dairy products, mostly microbiologic issues (presence of Escherichia coli, Salmonella, and Listeria monocytogenes). Moreover, more than 175,000 manufacturing sites were controlled for a total of more than 490,000 inspections, that found deviations for 22.50%. The controls involved food products, regardless their origin, intended for the national market as well as those intended to be shipped in other Member States of the EU or to be exported to Third Countries.

Control of Indian manufacturing site

The Italian Medicine Agency has requested MA holders to check the presence of the Indian manufacturing site Jubilant, Plot No. 18, 56, 57&58, KIADB Industrial Area, Nanjangud, Mysore, 571 302, India in the registration dossier of medicinal products authorised for the Italian market as supplier of active substances/intermediates. Only companies with a positive feedback shall inform the Agency within 23rd January 2019, indicating the MA number, the authorisation procedure and any information on the marketing on the national territory. Companies are also requested to indicate the presence of alternative manufacturing sites of active substances/intermediates, if any.
New regulations for veterinary drugs

New regulations on veterinary medicinal products and medicated feed were published on 7th January 2019 in the Official Gazette of the European Union no. L 4:


The new regulations promotes a proper use of veterinary medicinal products and medicated feed, simplify and reduce the administrative burden, enhance the internal market and favour an increased availability of veterinary medicinal products, ensuring at the same time a maximum level of protection to public health, animals, and environment.
EMA launches new public consultations

The European Medicine Agency has launched two new public consultations. The first concerns the revision of its guideline on the evaluation of human medicines indicated for the treatment of bacterial infections. Stakeholders can send their comments by 31st July 2019.

The second regards a discussion paper on the use of patient registries for regulatory purposes. The consultation will be open up to 30th June 2019 and a final submission of the document to the relevant EMA committees is expected by the end of 2019.
The European Committees

Committee for Medicinal Products for Human Use (CHMP)
Last meeting: 10-13 December 2018
Next meeting: 28-31 January 2019

Committee for Risk Assessment in Pharmacovigilance (PRAC)
Last meeting: 14-17 January 2019
Next meeting: 11-14 February 2019

The Committee for Advanced Therapies (CAT)
Last meeting: 6-8 December 2018
Next meeting: 23-25 January 2019

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

Paediatric Committee (PDCO)
Last meeting: 11-14 December 2018
Next meeting: 29 January – 1 February 2019

Committee for Medicinal Products for Veterinary Use (CVMP)
Last meeting: 4-6 December 2018
Next meeting: 22-24 January 2019

Committee on Biocides (BPC)
Last meeting: 15-19 October 2018
Next meeting: 25 February - 1 March 2019

The Italian Commissions

Open-AIFA:
Next meeting: 13 February 2019

The Committee for prices and reimbursement
Last meeting: 17-19 December 2018
Next meeting: 29-31 January 2019

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

The Technical Health Committee-Advertisement
Last meeting: 9 January 2019
Next meeting: 28 January 2019

Technical Scientific Advisory Commission
Last meeting: 14-16 January 2019
Next meeting: 4-6 February 2019

Veterinary Commission
Last meeting: 19-21 November 2018
Next meeting: 22-23 January 2019
<table>
<thead>
<tr>
<th>Date</th>
<th>Location</th>
<th>Event</th>
<th>Website</th>
</tr>
</thead>
<tbody>
<tr>
<td>28 January 2019</td>
<td>London</td>
<td>A Practical Guide to Writing Risk Management Plans (RMPs)</td>
<td><a href="http://www.management-forum.co.uk">www.management-forum.co.uk</a></td>
</tr>
<tr>
<td>29 January 2019</td>
<td>London</td>
<td>A Practical Guide to Producing and Maintaining the PSMF</td>
<td><a href="http://www.management-forum.co.uk">www.management-forum.co.uk</a></td>
</tr>
<tr>
<td>29-30 January 2019</td>
<td>London</td>
<td>EC Medical Devices Vigilance System and Post Marketing Surveillance</td>
<td><a href="http://www.management-forum.co.uk">www.management-forum.co.uk</a></td>
</tr>
<tr>
<td>30 January – 1° February 2019</td>
<td>Chesham</td>
<td>Leadership and Strategic Management in Regulatory Affairs</td>
<td><a href="http://www.topra.org">www.topra.org</a></td>
</tr>
</tbody>
</table>