AGENZIA ITALIANA DEL FARMACO

Tutela Ricerca e Sviluppo per la Salute

Update about the Italian measures on availability of medicinal product

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Public Declaration of transparency/interests*

The view and opinions expressed are those of the individual presenter and should not be attributed to AIFA

Interests in pharmaceutical industry	NO	Current	From 0 to 3 previous years	Over 3 preavious years
DIRECT INTERESTS:				
1.1 Employment with a company: pharmaceutical company in an executive role	x	☐	☐	☐ mandatory
1.2 Employment with a company: in a lead role in the development of a medicinal product	x	☐	☐	☐ mandatory
1.3 Employment with a company: other activities	x	☐	☐	☐ optional
2. Consultancy for a company	x	☐	☐	☐ optional
3. Strategic advisory role for a company	x	☐	☐	☐ optional
4. Financial interests	x	☐	☐	☐ optional
5. Ownership of a patent	x	☐	☐	☐ optional
INDIRECT INTERESTS:				
6. Principal investigator	x	☐	☐	☐ optional
7. Investigator	x	☐	☐	☐ optional
8. Grant or other funding	x	☐	☐	☐ optional
9. Family members interests	x	☐	☐	☐ optional

*Carla Cantelmo, in accordance with the Conflict of Interest Regulations approved by AIFA Board of Directors (25.03.2015) and published on the Official Journal of 15.05.2015 according to EMA policy /626261/2014 on the handling of the conflicts of interest for scientific committee members and experts.

N.B. < I am not receiving any compensation>

Definition agreed by EMA-HMA

- '*A shortage of a medicinal product for human or veterinary use occurs when supply does not meet demand at a national level*.
- The definition applies to all shortages that are already affecting or that are expected to affect one or more EU member states in the future.
- It applies to prescription and non-prescription medicines alike.

Italian measures

- In order to prevent shortages, there have been introduced by law some measures in order to enforce the power of AIFA to prevent shortages:

  - The block of exportation;
  - A longer term of notification;
  - The informative note;
  - The contract clause.

The block of exportation

- The block of exportation has been introduced by the law decree 30 April 2019, n. 35, converted in law n. 60/2019, which gives AIFA the power to adopt a temporary block of exportation when it is necessary to preempt or limit situations of shortages or unavailability.

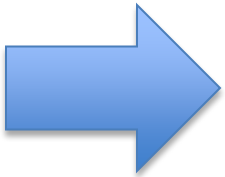
The block of exportation

- Since now, AIFA has adopted three block of exportation (Sinemet, Questran, Famotidine), in order to protect public health, preempt shortages and guarantee an assortment of medicines sufficient to meet the needs of care on the national territory.

Longer term of notification

- By the law decree 30 April 2019, n. 35, converted in law n. 60/2019, the term of notification has been prolonged:

no less than
2 months



4 months

Sanctions

- In case of **violation of the term for the notification of the shortage**, it is applicable an administrative sanction consisting in a fine between 3.000 € to 18.000 €.

Informative note

- AIFA has published an informative note for AIC owners about communications on shortages or temporary and permanent unavailability of medicinal products.
- In the note it is stated that the interruption of commercialization, temporary or definitive, determines a state of shortage of a medicinal product when supply does not satisfy the demand at national level.

Informative note

- Without prejudice of the obligation of the holder of the AIC, as per article 105, paragraph 4, of the legislative decree n. 219/2006 (Implementing Art. 81 Dir. 2001/83), to provide within 48 hours, at the request of pharmacies, including hospitals, a medicine that cannot be found in the regional distribution network, the MAH must adopt the appropriate organizational and logistic measures to ensure the fulfillment of its supply obligations for the entire period of interruption of marketing.

Informative note

- The communications from the MAH concerning the temporary or definitive interruption of the marketing of a medicinal product or any other information element that may have direct or indirect relevance to current or incumbent shortages or to anticipate the occurrence of a shortage of their own medicine, must contain specific information.

Contract clauses for reimbursed MPs

- Italy has introduced in all negotiations for the price and reimbursement of MPs an explicit provision related to art. 13 of the Law Decree no. 35/2019, in which the MAH, without prejudice of the rules about the selling off of the stocks, commits itself to keep a continuous supply in order to fulfill the patient's needs.

Sanctions

- In the event of a breach of contractual obligations, the marketing authorization holder can be sanctioned with provisions according to the company's revenue.

Other initiatives

- AIFA has the leadership of the focus area on **supply chain** which will be part of the strategy of the National Authorities' Network.

- In the EU context AIFA has proposed:
  - Shortages risks management plan
  - Transparency of movement of goods
  - Analysis of EU market developments

Other initiatives

In the agenda of the **ICMRA Summit 2019** hosted by Italy in Rome during next 28-30 October:

- A session is dedicated to the Regulatory science and harmonised approach with a speech by FDA on the opportunity of the Collective Knowledge Management to reduce Drug Shortages

Thank you for your attention!

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