AGENZIA ITALIANA DEL FARMACO

Tutela Ricerca e Sviluppo per la Salute

Availability of medicinal product: the Italian perspective

Carla Cantelmo

51° Emacolex meeting, 15-17 May 2019, Warsaw

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>

Availability of strategic medicinal products

- The two issues identified at European level as “main roots for shortages” should refer to two different situations, linked to different actors and macro-phenomena:
  - manufacturing shortages (due to problems of drug manufacturers), often related to the non-profitability of low price / old medicines,
  - distribution unavailability (due to distribution operators), often related to "parallel trade“.

Definitions

- **distributive unavailability**, due to disruptions in the distribution chain
- **production shortages**, due to manufacturing problems.

Distributive unavailability 1/2

- The unavailability is due primarily to economic factors related to the distribution network.

- Over the years, several strategies for combating this type of distortion have been proposed and implemented, and even the (definitely unlikely) imposition of an "average European price" comparable enough to discourage the export to more profitable markets has been from time to time mentioned in the discussion.

Distributive unavailability 2/2

- The involvement of all stakeholders in a process of “enforcement of existing rules” could be the best approach, whilst with respect to production shortages, regulatory action could be the right priority.

- Italy has had a positive experience with the “ad hoc technical forum”, and the involvement of all stakeholders in an “operative working group” targeting the issue allowed to reach good short-term results.

Production shortages

- Production shortages are related to manufacturing problems of individual companies rather than of the system as a whole.

- The imposition on marketing authorization holders of “contingency plans” and risk-management activities for “essential/critical medicines” at a risk of shortage, should be considered.

- The intervention should be at regulatory level.

Public Service Obligation (PSO) 1/3

- The new definition of PSO provides that «*medicines that were subjected to specific measures to prevent or limit states, even temporary, of shortage or unavailability on the market in the absence of viable therapeutic alternatives, cannot be subtracted to the distribution and the sell on the national territory*».

- The infringement of the obligations laid on wholesale distributors is subject to administrative sanctions, without prejudice of the penalties which may apply.

Article 1, no. 18, Directive 2001/83/EC

Public Service Obligation 2/3

- MAHs must notify to the National Authority (AIFA) in advance any forthcoming shortage, as well as any temporary or definitive marketing interruption.
- AIFA monitors the signals related to failed supplies, as for art. 46 of EC Directive 2001/83 as amended.
- When a report concerning the failed supply of a medicinal product to a pharmacy or a complaint by a patient/citizen for the lack of a medicine are submitted, AIFA has preliminarily to check whether such product is currently in short supply or temporarily unavailable in the distribution network.

Public Service Obligation 3/3

- In case the product is not listed in the shortage register published on AIFA's website, it is supposed to be regularly supplied in the distribution network.
- AIFA has to verify whether the MA Holder failed to comply with the PSO obligations.
- AIFA weekly report on medicines under shortages highlights all situations where an alternative to the medicine under shortage is not available on the Italian market.

Italian measures

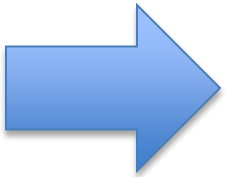
In order to prevent shortages, AIFA is studying how to oblige the MAH to keep sufficient stocks of the medicinal product and to supply it also with import in order to fulfill the national need:

1) Longer term of notification;
2) Contract clauses for reimbursed MPs;
3) Sanctions;
4) Other additional measures.

1) Longer term of notification

By the law decree 30 April 2019, n. 35, the obligation laid down at article 23a, par. 2, of Directive 2001/83, to notify the competent authority of that Member if the product ceases to be placed on the market **no less than two months** before the interruption in the placing on the market of the product, has been restrictively implemented and the term has been brought at **four months.**

no less than
2 months



4 months

2) Contract clauses for reimbursed MPs

- A discussion as to how to grant a continuity in the supply of strategic medicinal products for which Italy grants reimbursement through the national health system was recently raised.

- Italy is now evaluating the possibility of introducing in all negotiations for the price and reimbursement of MPs an explicit provision related to art. 81, par. 2, and art. 23a, par. 2, of Directive 2001/83 in order to **enhance the involvement of MAH in the administration of shortages**.

3) Sanctions

- In case of an **infringement of the contractual obligations** (see contract clauses for reimbursed MPs), the MAH may be sanctioned with penalties depending on the company revenue.

- 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 €.

4) Other additional measures

- In specific cases, pharmaceutical companies have been authorized with specific resolutions to and supply them to the Italian health structures. **import medicines no longer authorized in Italy.**

- The **Chemical-pharmaceutical Military Plant of Firenze took up the manufacture of a series of drugs in short supply** (for which the MA was no longer active) and for rare diseases on a named patient basis.

- In cases when the medicine availability was particularly limited, AIFA issued and published on its website specific communications addressed to Healthcare Professionals to **restrict the use of the product to particular categories of patients who had no adequate alternative therapy**.

Call for Common Approach

- How your country is tackling with shortages?
- Are there any **legislative or administrative measures to be implemented** or under evaluation?
- Alignment is welcome among MSs with regards to **term of notification** and **sanctions**.
- Coordination with HMA/EMA task force on availability of authorised medicine for human and veterinary use.

Thank you for your attention!

CONTACTS

t +0033 06 5978 4564
email c.cantelmo@aifa.gov.it
www.agenziafarmaco.gov.it