Update about blister cutting in parallel import in the Italian case-law

Carla Cantelmo

61° EMACOLEX Meeting – Antwerp 3-5 April 2024

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	☒	☐	☐	☐ mandatory
1.2 Employment with a company: in a lead role in the development of a medicinal product	☒	☐	☐	☐ mandatory
1.3 Employment with a company: other activities	☒	☐	☐	☐ optional
2. Consultancy for a company	☒	☐	☐	☐ optional
3. Strategic advisory role for a company	☒	☐	☐	☐ optional
4. Financial interests	☒	☐	☐	☐ optional
5. Ownership of a patent	☒	☐	☐	☐ optional
INDIRECT INTERESTS:				
6. Principal investigator	☒	☐	☐	☐ optional
7. Investigator	☒	☐	☐	☐ optional
8. Grant or other funding	☒	☐	☐	☐ optional
9. Family members interests	☒	☐	☐	☐ optional

*Carla Cantelmo, in accordance with the Conflict of Interest Regulation approved by AIFA Board of Directors (Resolution n. 37 dated 13/10/2020)

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

Italian regulation

- According to national provisions (Ministerial Decree of August 1997), parallel import medicines must have a valid marketing authorization issued by the competent regulatory authority in their country and be identical or essentially similar to a medical product that already has marketing authorization in Italy. Following verification of the requirements set out by the Ministerial Decree, the AIFA will issue a parallel import licence with a specific marketing authorization code, so individual batches can be imported into Italy from the EU/EEA country.
- With reference to the possibility of "repackaging", of which the cutting of blister constitutes a specification, the Ministerial Decree (art. 2) simply requires that takes place in an establishment duly authorized for this purpose by the Ministry (now by AIFA), recipient of specific communication, provided "within the limits and forms established by current legislation".

Blister cutting in parallel import

- In application of the EMA Guidelines concerning the cutting of blisters and the Commission communication COM (2003)839, AIFA published the "instructions for filling the application form", whose annex states that: "*The cutting of blisters is not recommended by the Agency. This procedure must be essential in order to ensure effective market access. Parallel distributor must properly explain and prove by documents: the reasons underlying the cutting of the blisters is required (i.e. the required size pack is not authorized/marketed on foreign market(origin country); no risk of alteration of the quality of MPs*".
- According to AIFA, parallel import could be grant on a case by case basis:

- **only** if cutting blister is stritcly necessary, due to the risk of alteration of the quality of MPs;
- **only** if the corresponding pack size is not authorized in the State of exportation, due to the fact that there aren't other options to import the product in Italy.

Background

- **FACTS (I):** Pricetag AD applied for a parallel import authorization in order to import the MP "*Arlevert 20 mg/40mg tablette, 100 tabletten*" from Germany to Italy. The company filed the form and specified that "*MP will be commercialized in Italy after cutting blister and repackaging in pack of 20 tablets*". AIFA verified that in Germany it was commercialized the required pack (20 tablets) and denied the request, taking into account that the applicant didn't give evidence of the reasons requiring the blister cutting and the absence of risks for health of that practice.

- **FACTS (II):** Pricetag AD applied for a parallel import authorization in order to import the MP "*Arlevert 20 mg/40mg tablette, 50 tabletten*" from Hungary to Italy. Also in this case, AIFA denied the request for the same reasons.

- Pricetag deferred the two refusal to the Administrative Court of 1° instance.

The parallel importer position

- AIFA, in evaluating whether to release the AIP should have only considered relevant profiles to the protection of public health, i.e. verifying according to the provisions of the Ministerial Decree 29 August 1997 that repackaging with cutting of the blister did not alter the original condition of the medicine, having instead to abstain from aspects of nature purely commercial and economic referring to the applicant's choice.
- The importer would have full freedom to choose, on the basis of commercial logic, the "pack size" of the medicine to be imported from packs available on the local market, adapting it to the pack claimed to be the reference medicine in Italy, even if both exist the following conditions:
  - in the country of origin the exact correspondent in terms of "pack size" of the medicinal product is on the market, therefore the package with the exact same number of dosage units
  - adaptation to the packaging of the corresponding medicinal product authorized in Italy must necessarily involve cutting the blister

The judgement of the Administrative Court (1)

- In the Court's opinion the specificity of the relevant discipline derives from the need to reconcile the aspects of economic-commercial protection, common to any type of goods, with those of health protection, intrinsic to the type of goods in question, which implies the need to not be able to ignore compliance with the presupposition regulation on the marketing of medicinal products. For this reason, parallel import is subject to authorization released for each medicine on the basis of a procedure that has been seen be "simplified" compared to that necessary for placing the product on the market product. The rationale for this simplification lies precisely in the fact that the imported product has already had a marketing authorization in the Member State of origin e in the destination one.
- The EMA in the information referred to, which despite having no value regulatory, however, they constitute an expression of discretionary technical evaluation of the highest regulatory authority on the subject, carries out a sort of graduation between repackaging operations, starting from their qualification as "changes to the medicine".

The judgement of the Administrative Court (2)

- EMA takes care of graduating the different types of modifications of the drug due to repackaging, resulting in “changes in the language of the labeling and package leaflet to comply with the requirements of legislation on medicinal products” are permitted, while all other different repackaging operations are generally not recommended. This, however, does not allow the Court to believe that these are absolutely not permitted, but only that an activity will be carried out for them from time to time investigation and evaluation to verify whether there are no risks for the consumer safety and health. In the aforementioned information, the EMA therefore requires that applications for "replacement of packaging" is attached by the subsistence applicant of the objective necessity of this operation to allow effective access to the market. In these cases, the request must be “carefully evaluated on a case-by-case basis” for ensuring compliance with the regulatory provisions on medicines to protect safety of patients. Therefore, cutting the blister, although not recommended, can nevertheless be done from time to time deemed acceptable and therefore permitted, where it is not jeopardized the original state of the product and the proposals of the parallel distributor comply with the marketing authorization conditions.

The judgement of the Administrative Court (3)

- As part of this assessment, given that as reiterated by the EMA itself, the Authorities involved in the authorization procedure parallel imports do not have jurisdiction over trademark protection, the aspect relating to market accessibility must be taken into account by them consideration ("taken into account") in the context of the procedural preliminary investigation activity. Satisfaction of the market accessibility criterion is one of the aspects to consider when weighing the interests involved in procedure for the purposes of the final administrative determination. However, even this investigative element can only be considered, given the institutional purposes of the EMA and AIFA, through the lens of interest public to the protection of the health and safety of final consumers and certainly not purely from the economic aspect of protecting ownership of the brand. In this sense the need for repackaging in order to access the market assumes importance having always aimed at this public interest and functions attributed to the Authority, certainly integrating a further positive element into the evaluation of the relevant application for the AIP and so on, not because it constitutes a limit to the trademark owner's power of opposition, but because he is a respondent to the public interest in placing that particular drug on the market.

The judgement of the Administrative Court (4)

- It follows that, on the other hand, one cannot automatically be considered unacceptable AIP application exclusively because this condition is not satisfied; referring the mere question of market accessibility to the relationships between the owner of the brand and importer and to another and different private level.
- AIFA in this case does not appear to have carried out the necessary preliminary assessment, limiting itself to provision burdened with insisting on the unacceptability of the justification provided to support the need to cut the blister for effective access to the market, thus ending up stopping its evaluation at only one of the elements instructors provided (rectius "not provided") by the applicant, without clarifying whether the repackaging implemented through cutting the blister may also result only by its very nature or by the methods with which it is carried out in the present case the risk of altering the original state of the product or in any case of the differences that could cause even a potential harm to health public.

The Appeal' reasons

In both cases, AIFA appealed the judgments in front of the High Administrative Court on the following grounds:

- misinterpretation and misapplication of the legal rule/framework, due to the fact that it bears to the applicant is required to provide a proper justification for the request of blister cutting;
- the evaluation of the justification in order to allow the blister cutting is strictly connected to health and safety requirements due to pursue public health;
- incorrectness of the sentence, in the part in which required AIFA to assess the risk to public health, even in the event that cutting the blister would not have been necessary for the market, as it is based on essentially economic choices.

The Judgment of Court of Appeal (1)

- In both cases, the Court of Appeal confirmed the decisions of the Court of first instance, stating that: "*The plea is unfounded because, as the first court well recalled, the ECJ and the Commission have intervened several times on the subject of parallel importation of medicines for human use, affirming -also with reference to this market- the principle of free movement of goods*".
- The Court of Appeal further observed that:
  - the Court of first instance has not exceeded the limits of its jurisdiction;
  - the alleged absence of one of the two authorization requirements for parallel import application, including that of verifying the necessity or otherwise of the blister cut for the market, alleging economic choices cannot in itself justify- in the absence of a health risk assessment - the refusal to import the MP.

The Judgment of Court of Appeal (2)

- The alleged absence of one of the two authorization requirements (AIP) including verifying whether or not it is necessary to cut the blister for the market, allegedly responding to economic choices, cannot ex se justify – in the absence of an assessment of health risks – the refusal to import the drug. Hence the validity of the complaint of lack of preliminary investigation, accepted by the first judge, referring the question inherent to the accessibility of the product to the market to reports of a predominantly private nature.
- The aim of European legislation is essentially inspired by a logic of maximum protection of public health, so that in the absence of clarification if the repackaging carried out by cutting the blister pack may entail the risk of alteration of the original state of the product, even if only potential, for public health, the appeal must be dismissed. Therefore AIFA should have justified and motivated its refusal by pointing out the risks, even if only potential, that the cutting of the blister could have on public health.

How to manage this situation?

- AIFA is currently managing how the better improve the statements of the Court, thinking about publishing a new public notice for applicant.
- Increase of blister cutting parallel import applications.
- Increase of administrative burden taking into account the case-by-case approach required.
- A EU common approach on the matter shall be desirable.

Thank you for your attention!