



**Theft and laundering of medicines: early results of the AIFA project.
The Herceptin case**

The investigation currently in progress on the case involving the theft and subsequent recycling of different packages of HERCEPTIN, a medicine for hospital use indicated in the treatment of breast and gastric cancer (MAH: Roche Registration Limited) was started by AIFA and Carabinieri NAS (Military Police Command for health protection) as a result of a report filed by a UK wholesaler for anomalies detected in some packages of HERCEPTIN, purchased from the Italian wholesaler Farmaceutica Internazionale S.r.l. and bound to Germany. In particular, the anomalies concerned a discrepancy between the batch numbers indicated on the primary and the secondary packaging.

Following a first check, some of the concerned batch numbers emerged to match some batch numbers registered in the theft-medicines database, developed as part of the project launched in collaboration between AIFA, Farmindustria, Asso-Ram (trade associations) and Carabinieri NAS, with the support of the Italian Ministry of Health, aimed at sharing and analyzing data and information on this constantly growing phenomenon.

Following the verifications performed by Carabinieri NAS, further elements came into light: Farmaceutica Internazionale S.r.l. registered address, in fact, appears to have been already closed down since December 2013 and other products, such as HERCEPTIN, currently undergoing further investigation, turned out to have been exported in parallel trade from Italy to the UK by the same wholesaler.

The Italian MA Holders, on the other hand, have declared they never supplied the Italian wholesaler with their products; many of these medicines, in fact, are directly distributed to

hospital facilities by the MAHs, without any intermediation by wholesalers who therefore, disregarding rare exceptions, have no access to certain medicines.

As such, AIFA immediately liaised with UK regulatory Agency (MHRA) in order to verify whether other wholesalers might have purchased medicines by Farmaceutica Internazionale S.r.l..

Subsequent deepenings threw light further additional elements, as for example the involvement of other actors in this “suspicious process”. With regard to the European Alert System, the German authorities initially issued a “not urgent warning” report, indicating as “suspected counterfeit medicine” the batches of HERCEPTIN received by the English wholesaler, followed by the communication spread through the Rapid Alert System.

Confirming once more its commitment in the contrast against the different typologies of outlining pharmaceutical crimes, AIFA, in close cooperation with the Carabinieri NAS, considers a priority task to carry on any useful deepening on the matter, availing – also through the consolidated collaboration with the MHRA and with other European authorities such as EMA and Paul-Ehrlich Institut – of UK wholesalers’ support in the identification of Italian distributors operating unlawfully to the detriment of European patients, whose interests the (national) health authorities are committed to protect.

AIFA calls on all hospitals that had been robbed in 2013-2014 to submit any available information on the stolen medicines, via e-mail medicrime@aifa.gov.it or fax +39.(0)6.5978.4496, in order to enable the Agency to provide additional support to the ongoing Carabinieri NAS investigation.