Follow-up and Non-urgent Information for Quality Defects

	ITALIAN MEDICINES AGENCY – (AIFA) *Prot.*		
1.	To: (see list attached, if more than one)		
2.	Recall Number Assigned: **German RA of 19.08.2020**	3.	National reference Number
4.	Product: **NEUPRO** 4 mg/24 h 28 patches **VIMPAT** 100 mg 56 film-coated tablets **BRIMICA GENUAIR** 340 mcg/12 mcg inhalation powder 60 doses **RASILEZ** 300 mg 28 film-coated tablets	5.	Marketing Authorisation number: **For use in Humans**
6.	Brand/Trade name: **NEUPRO** 4 mg/24 h 28 patches **VIMPAT** 100 mg 56 film-coated tablets **BRIMICA GENUAIR** 340 mcg/12 mcg inhalation powder 60 doses **RASILEZ** 300 mg 28 film-coated tablets	7.	INN or Generic Name:
8.	Dosage form:	9.	Strength:
10.	Batch number (and bulk, if different): NA		
14.	Marketing Authorisation holder: NA		
15.	Manufacturer[1]: NA	16.	Contact Person: NA

[1] The holder of an authorisation to under Article 40 of Directive 2001/83/EC and Article 44 of Directive 2001/82/EC and the holder of the authorisation on behalf of whom the Qualified Person has certified the batch for release in accordance with Article 51 of Directive 2001/83/EC or Article 55 of Directive 2001/82/EC, if different

17. SUBJECT

Background information

On 19th August 2020 Germany issued two Rapid Alert Notifications (Ref. n. DE_BW_01_RAS 290_2020 and DE_BW_RAS 291_2020) about a suspected falsification of some packages of VIMPAT and NEUPRO, detected at the parallel distributor ACA Mueller ADAG Pharma AG (ACA) in Germany, which show differences in the bollino labels. The packages are in Italian livery and have been sold by an Italian operator, that has purchased them from a non-authorized wholeasaler.
After investigation, a list of the products exported have been identified, including further medicinal products as Brimica Genuair and Rasilez. The packages were quarantined at the parallel importers warehouses and recalls were issued for medicines that have already been distributed on the market.

PROPOSED ACTION

In 2019 AIFA widespread a guide describing the essential characteristics of genuine Bollini labels which should and could be checked by the parallel importers within their incoming goods inspection, in order to prevent the distribution of falsified medicines through the parallel distribution channel. Following that, several cases of falsified bollino labels have been reported, probably due to the increased attention and control operated by distributors thanks also to the guidance tool.
Now, it would consider useful to widespread the updated guide attached to this NUI.

The new guide has two major changes:

- The name of the medicinal product and the MAH on the bollino label are reported in red color instead that black;
- The vertically serial number on the unremovable intermediate layer of the bollino is now centered relating to the space reserved for it.

These features are present on the bollini labels of the medicinal products on the market, but were not specified in the previous guide version.
It is also considered useful to remember that the Italian bollino label has always to be present on the outer carton of exported medicines of Italian origin. Furthermore, the exported packages should bear a "bollino" with a nullification mark (e.g., an "ESPORTAZIONE" stamp or a cross over the barcode). For medicines classified as hospital product (class H), the packs distributed should have the bollino with the specific wording "Confezione Ospedaliera/Ambulatoriale" stamped on the label, in order to invalidate reimbursement out of the hospital channel.

If there be any anomalies with regard to the offer of medicinal products with bollini labels showing different features from those described, please contact the writing office at the e-mail address medicrime@aifa.gov.it, to allow any check to ascertain the legitimacy of the products.

22.	From (issuing Authority): **AIFA – Italian Medicines Agency**	23.	Contact person: **Dr. Domenico Di Giorgio,** **medicrime@aifa.gov.it**
24.	Signed: Domenico Di Giorgio	25. 26.	Date: 07.10.2020 Time: