ORDER
on approval of mandatory monthly reporting of placement on the market in Romania and of sales of medicinal products for human use, respectively, by authorised wholesale distributors/importers/manufacturers

(Published in the Official Gazette of Romania, Part I, no. 210 of 13/04/2013)

On seeing Approval Report no. EN 3.787 of 11 April 2013 of the Pharmaceutical Directorate of the Ministry of Health,

Taking into account provisions of:

- Law 95/2006 on healthcare reform, Title XVII – The medicinal product, as amended;
- Government Decision no. 734/2010 on the organisation and operation of the National Agency for Medicines and Medical Devices, as amended,

based on Art. 7 (4) of Government Decision no. 144/2010 on the organisation and functioning of the Minister of Health, as amended,

the Minister of Health hereby issues the following Order:

Art. 1. - (1) On this Order coming into force, at the end of each month, wholesale distribution units of medicinal products, authorised importers and manufacturers shall submit to the National Agency for Medicines and Medical Devices a report on trade operations performed, *parallel import* included, respectively on distribution of medicinal products outside Romania, in other EEA member states, performed with medicinal products in their portfolio.

(2) The final purpose of reporting is to ensure traceability of medicinal products throughout the distribution chain, from manufacturing and/or distribution to the level of community pharmacy, hospital pharmacy, drugstore, to assess the propriety of on-prescription/off-prescription medicinal product release, to detect falsified products and prevent their entry into the authorised distribution network, to combat illegal parallel circuits for medicinal product sale, and respectively warrant rapid recall of non-compliant product batches or in case of health emergencies.

Art. 2. – The report submitted to the National Agency for Medicines and Medical Devices – the Pharmaceutical Inspection Department contains the following, as required:

a) The List of medicinal products for human use entered in /exited from stocks of wholesale importers/distributors authorised in accordance with Order of the Minister of Health no. 312/2009 on approval of Regulations for manufacturing/importation authorisation of manufacturers and importers of medicinal products for human use, including investigational medicinal products and grant of the good manufacturing practice certificate to manufacturers of medicinal products for human use and/or active substances, as amended, and with Order of the Minister of Public Health no. 1964/2008 on approval of the Norms on the set up, organisation and operation of wholesale distribution units of medicinal products for human use, for various types of import/wholesale distribution activities stating the amounts, manufacturing batches, supplier(s) and recipient(s) of medicinal products, as well as the identification data of respective fiscal documents (number, batch, date of the invoice and/or of delivery notification);

b) The List of medicinal products for human use exited from the inventory of Romanian manufacturers authorised in accordance with Order of the Minister of Health No. 312/2009, as amended, stating the amounts, manufacturing batches, recipient(s) of the respective products, as well as the identification data of respective fiscal documents (number, batch, date of invoice and/or delivery notification).

Art. 3. - (1) The report is forwarded in electronic format, accompanied by the statutory declaration of the legal representative of the reporting company on conformity of submitted data.

(2) The first reporting necessarily contains the Romanian distributor/importer/manufacturer's product stock at the time of report drafting.

(3) The tabulated form and the Guideline for its filling in (also specifying the e-mail address for submission of the report) are part of the Annex which is integral part of this Order.

Art. 4. – Non-compliance with provisions of this Order are sanctioned in accordance with provisions of Law 95/2006 on healthcare reform, as amended.

Art. 5. – This Order is to be published in the Official Gazette of Romania, Part I.

Minister of Health,
Gheorghe-Eugen Nicolăescu

Bucharest, 11 April 2013.
No. 502.

ANNEX

GUIDELINE
on filling in the table concerning monthly electronic reporting of medicinal products distributed by wholesale distributors/importers/manufacturers

For more efficient reporting and data processing, the following recommendations concerning the manner of filling in the table of medicinal products distributed must be taken into account.

Manner of reporting:

- the report is submitted on CD as well as to the following e-mail address: raportaremedicamente@anm.ro; the CD is accompanied by a statutory declaration of the reporting company's legal representative, on compliance of data submitted with the actual status;
- the report is only submitted in .xls format;
- only standard Latin script is used, font: Times New Roman, size 10;
- consistency of the filling-in manner throughout the reports is taken into account (for example, the same name of the distributor/manufacturer/importer is used in all reports);
- separately from the table, contact data of the person who has filled in each report is provided (name, telephone number, e-mail address);
- each report includes all medicinal products in the reporting company's own portfolio, provided in two separate tables, one for OTC products and the other for on-prescription products; in case of one product elimination from the portfolio, this is reported until the remaining stock is used up;
- the monthly report is submitted until the 25th day of the following month and replaces the previously required biannual reporting.

Manner of table columns completion is as follows:

- Name of distributor/importer/manufacturer: the type of unit to be selected from the filter provided; the name does not include the acronym related to legal trade form. i.e. "SRL", "SA", or "+SC" mention.
- The trade name of the product: to be filled in with the exact name as per the NAMMD Index of medicinal products (http://www.anm.ro/app/nom1/anm_list.asp).
- Pharmaceutical form: to be filled in with the exact name as per the NAMMD Index of medicinal products (http://www.anm.ro/app/nom1/anm_list.asp).
- Strength: to be filled in with the exact name as per the NAMMD Index of medicinal products (http://www.anm.ro/app/nom1/anm_list.asp).

- Type of packaging: to be filled in under "number and type of primary packaging in a secondary packaging x number of units or amount per unit" (e.g. 5 vials x 10 ml, 3 blisters x 20 tablets, 1 tube x 10 g, 2 pre-filled syringes x 2 ml).

- Marketing Authorisation Holder: to be filled in the exact name as per the NAMMD Index of medicinal products (http://www.anm.ro/app/nom1/anm_list.asp).

- Stock available on 01.MM.2013: the stock of product is declared for each batch, each time providing the product identification data (name of the distributor/importer/manufacturer, trade name of the product, pharmaceutical form, strength, packaging type, Marketing Authorisation Holder, batch, supplier).

- Batch: each cell comprises one single batch. The next line is filled in for a different batch, each time specifying the product identification data (name of the distributor/importer/ manufacturer, trade name of the product, pharmaceutical form, strength, packaging type, Marketing Authorisation Holder).

- Supplier: does not include acronym related to legal trade form. i.e. "SRL", "SA", or "SC" mention.

- Entered amount in: digits only.

- Series and number of purchase invoice: one single invoice to be filled in, as "series/number".

- Date of purchase invoice: the date to be provided as "dd.mm.yyyy".

- Exited amount out: digits only.

- Recipient: does not include acronym related to legal trade form. i.e. "SRL", "SA", or "SC" mention.

- Unit type: one of the following is selected: Wholesale distributor, Open pharmacy, In-house pharmacy, Drugstore, Other persons authorised for medicinal product release to the public (e.g. medical clinics, dialysis centres etc.).

- Country of recipient residence: full name of recipient country of residence to be filled, no abbreviations allowed.

- Series and number of delivery invoice: identification data to be provided for one single invoice, as "series/number".

- Date of delivery invoice: the date to be provided as "dd.mm.yyyy".

- Stock on exit date: digits to be used only; stock available at the end of the month corresponding to each medicinal product batch becomes initial stock for the next month.

Product identification data								Input				Output						
Distributor	Medicinal product trade name	Pharm. form	Strength	Packaging type	Marketing Authorisation Holder	Stock available on 01.MM. 2013	Batch	Supplier	Amount entered	Series and number of purchase invoice	Date of purchase invoice	Amount exited	Recipient	Unit type	Country of recipient residence	Batch and number of delivery invoice	Date of delivery invoice	Stock on exit date