

Emergency treatment in Lombardy: a new methodology for the pre-Hospital Drugs management on Advanced Rescue Vehicles

Elisa Perego¹, Federica Balzarini², Marco Botteri³, Stefania Favetti³, Alberto Zoli³, Giuseppe Maria Sechi³, Anna Odone², Carlo Signorelli², Guido Francesco Villa³

¹Università degli Studi Mediolanensis; ²School of Hygiene and Preventive Medicine University Vita-Salute San Raffaele-Milan; ³AREU [Lombardy EMS Regional Agency] – Milan

Summary. *Background and aim of the work:* The main objectives of our work were the regional harmonization and standardization of pharmaceutical supplies on MSA in Lombardy. *Methods:* The retrospective investigation was articulated in 2 phases: the first was the collection of data in every area of the Region (2012), the second was the analysis and elaboration of the information retrieved. *Results:* Beginning with 24 common drugs used by 8 AATs out of 12 an evaluation of the chemical-therapeutic characteristics was performed. The temporary list, including over 80 drugs classified in more than 25 therapeutic groups, was finally reduced to provide bags that were easier to handle but at the same time complete. Between October and November 2014, the proposed supply, including 71 formulations and approved by the Technical Board of AREU, officially entered into force. At the same time, the working group followed the same procedure to define the standard equipment for the Region's helicopters, with only 58 formulations for relatively reduced weight allowed on board. *Conclusions:* In conclusion, we can state that, thanks to the support of experts, of the literature review, and thanks to the practical experience of the members of the AREU working groups and thanks to the documents coming from AIFA and EMA, the first operative regional project of unified pharmacological supply for MSA was delivered.

Keywords: Emergency Medical System, drug supplies, drugs management, datasheet for emergency treatment

Introduction

Emergencies present the most critical issues of medical management and play a crucial role within the evaluation of the quality of the entire national health system. The peculiarity of the pre-Hospital Emergency Medical System (EMS - AREU Lombardy) has led to a deviation from the conventional medical disciplines, highlighting the need of integrating professional experience, promptness of intervention, emotional management and the selection of the best, strictly evidence-based, available and suitable drugs.

The equipment present in Advanced Rescue Vehicles (MSA) has always been variable (until 2012) and based on operative protocols and local regulations (1, 2). Despite the standard minimal compulsory require-

ments of the drugs, the incomplete specificity of these guidelines led to different choices in the same Region, with each AAT choosing the best drug according to their needs. The lack of standardized regional guidelines and the diversity of the supplies in terms of devices and drugs on MSA (due to the different pharmaceutical registers present in each trust in Lombardy), led to treat patients (with the same needs) by different drugs.

In order to reach the objective a feasible methodology was developed in Lombardy to standardize the drugs and to provide concrete benefits: the answer was the "harmonization and standardization" of rescue management, starting from the standardization of the drug supplies.

The harmonization process was necessary to decrease the differences of drug supplies and protocols in

the Region, and presented several advantages:

- Unified management of the resources
- Draft guidelines and homogenous protocols
- Optimization of the medical services
- Economic benefits (monitoring of costs and consumption) and less bureaucracy for every province

In this paper we have analyzed the situation of the EMS in Lombardy (until 2012). In particular we have focused on MSA, Advanced Ambulances and Medical Rescue helicopters, where the drug supply is available, along with anesthesiologists and experienced critical nurses (ER and Intensive Care Area).

Objectives of The Study

The main objectives of our work were the regional harmonization and standardization of pharmaceutical supplies on MSA in Lombardy.

To reach our goals we proceeded step by step as follows.

- Collection of qualitative and quantitative data on the use of drugs in the AATs in Lombardy (2012)
- Retrospective analysis of the situation in Lombardy
- Evaluation of the drugs already used by the different AATs and analysis of the characteristics of the potentially suitable ones
- Draft of a preliminary list (2013)
- Building a new ad hoc datasheet for emergency treatment
- Final list of medical equipment and drug supplies, common for the whole region
- Approval of the final list of medical supplies by the AREU Committee (2014).

The final results include the implementation of a standard drugs protocol in the pre-Hospital context.

Materials and methods

The retrospective investigation was articulated in 2 phases: the first was the collection of data in every area of the Region (2012), the second was the analysis and elaboration of the information retrieved. The information obtained allowed us to study both the qualitative aspect of the drugs, and the corresponding volumes.

To realize this study, AREU set up a Working Group (GdL) made of different professionals, who are involved with territorial emergencies every day. Practical skills developed from experiences of Chiefs of AAT, doctors, nurses, pharmacists, together with the information found in the literature, produced concrete and common solutions.

The data gathered for the first drafting of the list allowed us to highlight the drugs used in more than one AAT. This initial list was then extended to include the drugs potentially suitable to cover all kinds of emergencies. After that, minor and superfluous drugs were excluded.

This methodology produced a number of advantages, although this approach was more time-consuming: the drugs were analyzed several times by all standards; the goal of this project being the harmonization, and not the creation of an ex-novo list. The evaluation of the equipment considered: efficacy, risk-benefit ratio, side effects, route of administration, onset of action, availability, storage, storage conditions and costs. Information was retrieved from the literature, AIFA and EMA official communications (3,4,5,6) and working group members' experience. This particular strategy, which was based on a number of criteria, produced an integrated network of information and concrete results that did not neglect the requirements of the single provinces.

After the common list was drafted, an ad hoc data sheet of the selected drugs was prepared. The role of this sheet was two-fold: first, to provide the medical team with the right choice in a short time, second, to improve the training of the professionals (didactical purpose). The layout of the sheet was simple and clear, and each file was divided in five sections.

The information provided was: general, such as the name of the active ingredient, concentration, commercial name, therapeutic group, indications and contraindications, and instructions for the preparation of the drug. Moreover, the mLs needed for the right dose and the speed of infusion according to the patient's weight was provided for a selection of drugs in order to drastically reduce the risk of dosage mistakes. Table 1 is an example based on the epinephrine data sheet.

It was also considered appropriate to highlight the precautions to be kept in mind before proceeding with the administration and potential side effects, listed

from the most frequent to the least frequent ones. Finally, storage conditions were included in the tables. The terms and sentences reported in the data sheet were the result of discussions aimed at finding standard clear and general sentences.

Concerns regarding drug administration to specific target populations were considered: pediatric, elderly, pregnant or breastfeeding women. Table 2 is the example of a data sheet.

Results

Beginning with 24 common drugs used by 8 AATs out of 12, an evaluation of the chemical-therapeutic characteristics was performed. The aim was

to create a temporary list which could be useful and increasingly complete. Substances like infusion solutions and disinfectants were also included, as they are extremely helpful during medical rescue.

The temporary list, including over 80 drugs classified in more than 25 therapeutic groups, was constantly reviewed and finally reduced to provide bags that were easier to handle but at the same time complete. A particularly important role was attributed to the comparison of drugs of the same group in terms of effectiveness, safety, onset of action and costs.

Between October and November 2014, the proposed supply, including 71 formulations and approved by the Technical Board of AREU, officially entered into force (document number 99 – “List of drugs MSA”). The further step of the validation of the equipment was

Table 1. Infusion speed – epinephrine data sheet

Infusion 5 mg in 50 mL	Dose mcg/kg/min	0,02 - 0,10 mcg/kg/min								
		0,02	0,03	0,04	0,05	0,06	0,07	0,08	0,09	0,10
	Weight kg	InfusionspeednessmL/h								
	30	0,4	0,5	0,7	0,9	1,1	1,3	1,4	1,6	1,8
	40	0,5	0,7	1,0	1,2	1,4	1,7	1,9	2,2	2,4
	50	0,6	0,9	1,2	1,5	1,8	2,1	2,4	2,7	3,0
	60	0,7	1,1	1,4	1,8	2,2	2,5	2,9	3,2	3,6
	70	0,8	1,3	1,7	2,1	2,5	2,9	3,4	3,8	4,2
	80	1,0	1,4	1,9	2,4	2,9	3,4	3,8	4,3	4,8
	90	1,1	1,6	2,2	2,7	3,2	3,8	4,3	4,9	5,4
	100	1,2	1,8	2,4	3,0	3,6	4,2	4,8	5,4	6,0

Table 2. Data sheet of “Lysine acetyl salicylate”

Lysine acetyl salicylate	
Concentration	500 mg/2,5 mL
Commercial Name	Flectadol®
Group	Antiaggregants of platelets. Antithrombotics [Antiinflammatory, anti-pyretics, analgesics]
Indications	Acute coronary syndromes. (in particular STEMI) if administration of ASA per os not possible [hyperthermia, painful syndromes]
Contraindications	Known hypersensitivity. Esophageal varices. 3rd trimester pregnancy. Association with methotrexate. Do not administer when <16 years old.
Preparation	
Dilution	Dilution in SF, RA, RL, G 5%
Administration	
Bolo	125 mg EV (80 - 150 mg)
Precautions	Asthma. Peptical ulcer. Esophageal varices. Viral infections in children. Chronic urticaria. Chronic rhinitis. Gout. Kidney and hepatic failure. Thrombocytopenia. Coagulopathies. Crohn Disease. Ulcerative colitis.
Possible relevant side effects	Anaphylactoid reaction. Gastralgia. Asthmatic crisis.
Storage	
T ≤ 20°C	

Table 3. New medical equipment supplies for the MSAs of Lombardy

N.	Drug	Formulation	Administr.	Storage	Group
1	Acetilsalicilato di lisina	fl 500 mg / 2,5 ml	ev	2	Antiaggregant
2	Acido acetilsalicilico	cp 100 mg / blst	os	1	Antiaggregant
3	Acido tranexamico	fl 500 mg / 5 ml	ev	2	Antifibrinolytic
4	Adenosina	fl 6 mg / 2 ml	ev	5	Antiarrhythmic
5	Adrenalina	fl 1 mg / 1 ml	ev	5	Circulation
6	Adrenalina	fl 5 mg / 5 ml	ev	4	Circulation
7	Aloperidolo	gtt 10 mg / 1 ml	os	1	Central Nervous System
8	Amido idrossietilico 6%	sol 500 ml	ev	2	Colloids/Infusions
9	Amiodarone	fl 150 mg / 3 ml	ev	3	Antiarrhythmic
10	Atropina	fl 0,5 mg / 1 ml	ev	4	Circulation
11	Beclometasonedip	0,8 mg / 2 ml	inal	1	Respiratory
12	Betametasonone	fl 4 mg / 2 ml	ev	2	Steroids
13	CaCl ₂	fl 1 g / 10 ml	ev	2	Electrolytes
14	Carbomix®	sosp 50 g / polv	os	1	Antidote
15	Clorfenamina	fl 10 mg / 1ml	ev - im	2	Antihistamines
16	Clotiapina	fl 40 mg / 4 ml	ev - im	1	Central Nervous System
17	Diazepamos	gtt 5 mg / 1 ml	os	1	Sedation/hypnotics
18	Diazepamrett	mcls 5 mg / 2,5 ml	rett	2	Sedation/hypnotics
19	Diazepamev - im	fl 10 mg / 2 ml	ev - im	2	Sedation/hypnotics
20	Diltiazem	fl 50 mg / 5 ml	ev	2	Antihypertensive
21	Dopamina	fl 200 mg / 5 ml	ev	2	Circulation
22	Eparina sodica	fl 5000 UI / 1 ml	ev	2	Anticoagulants
23	Esmololo	fl 100 mg / 10 ml	ev	2	Antihypertensive
24	Fentanyl	fl 100 mcg / 2 ml	ev	4	Narcotic/Analgesics
25	Fisiologica	sol 10 ml	ev	5	Cristalloid/Infusions
26	Fisiologica	sol 100 ml	ev	1	Cristalloid/Infusions
27	Fisiologica	sol 250 ml	ev	1	Cristalloid/Infusions
28	Fisiologica	sol 500 ml	ev	2	Cristalloid/Infusions
29	Flumazenil	fl 0,5 mg / 5 ml	ev	2	Antidote
30	Furosemide	fl 20 mg / 2 ml	ev	5	Diuretics
31	Glucosio 5%	sol 250 ml	ev	1	Solution for Infusion
32	Glucosio 33%	sol 10 ml	ev	5	Antidote
33	Ibuprofene	fl 400 mg / 3 ml	im	2	Minor Analgesics
34	Idrocortisone	fl 1000 mg / 10 ml	ev	2	Steroids
35	Insulina rapida	fl 1000 UI / 10 ml	ev	1	Antidiabetic
36	Ketamina	fl 100 mg / 2 ml	ev -im	2	Sedation/Hypnotics
37	Labetalolo	fl 100 mg / 20 ml	ev	2	Antihypertensive
38	Lidocaina 2%	fl 200 mg / 10 ml	ev	2	Antiarrhythmic/Local Anesthetic
39	Lormetazepam	gtt 2,5 mg / 1ml	os	1	Sedation/Hypnotics
40	Mannitolo 20%	sol 100 ml	ev	1	Diuretics
41	Metoclopramide	fl 10 mg / 2 ml	ev - im	2	Gastrointestinal

Table 3. New medical equipment supplies for the MSAs of Lombardy

N.	Drug	Formulation	Administr.	Storage	Group
42	Metilprednisolone	fl 40 mg / 1 ml	ev - im	2	Steroids
43	MgSO ₄	fl 1 g / 10 ml	ev	4	Electrolytes
44	Midazolam	fl 15 mg / 3 ml	ev - im	2	Sedation/Hypnotics
45	Midazolam	fl 5 mg / 1 ml	ev - im	2	Sedation/Hypnotics
46	Morfina	fl 10 mg / 1 ml	ev - sc	2	NarcoticAnalgesics
47	NaHCO ₃ 8,4%	sol 100 ml	ev	1	Electrolytes
48	Naloxone	fl 0,4 mg / 1 ml	ev - im - sc	3	Antidote
49	Nitroglicerina spray	spray sbl 18 ml	sbl	1	Antihypertensive
50	Nitroglicerina	fl 5 mg / 1,5 ml	ev	4	Antihypertensive
51	Noradrenalina	fl 2 mg / 1 ml	ev	2	Circulation
52	Ondansetrone	fl 4 mg / 2 ml	ev - im	2	Gastrointestinal
53	Ossitocina	fl 5 UI / 1 ml	ev - im	4	Obst-Gyn
54	Pantoprazolo	fl 40 mg / 10 ml	ev	3	Gastrointestinal
55	Paracetamolo	250 mg / supp	rett	2	Minor Analgesics
56	Paracetamolo	fl 1000 mg / 100 ml	ev	1	Minor Analgesics
57	Propofol	fl 200 mg / 20 ml	ev	3	Sedation/Hypnotics
58	Ranitidina	fl 50 mg / 5 ml	ev	2	Gastrointestinal
59	Ringer acetato	sol 500 ml	ev	4	Cristalloidinfusions
60	Ringer lattato	sol 500 ml	ev	4	Cristalloidinfusions
61	Rocuronio	fl 50 mg / 5 ml	ev	4	Musclerelaxant
62	Salbutamolo + Ipratropio	gtt 0,375% + 0,75%	inal	1	Respiratory
63	Salbutamolo solfato	fl 0,5 mg / 1 ml	ev	2	Respiratory
64	Salbutamolo spray	fl 100 mcg / puff	inal	1	Respiratory
65	Succinilcolina	fl 100 mg / 2 ml	ev	2	Musclerelaxants
66	Sufentanyl	fl 50 mcg / 1 ml	ev	2	NarcoticAnalgesics
67	Sugammadex	fl 500 mg / 5 ml	ev	2	Antidote
68	Symeticone	gtt 2 g / 30 ml	os	1	Gastrointestinal
69	Tenecteplase*	fl 10.000 UI / 10 ml	ev	1	Tthrombolytics
70	Urapidil	fl 50 mg / 10 ml	ev	2	Antihypertensive
71	Vecuronio**	fl 10 mg / 10 ml	ev	4	MuscleRelaxants

* Only for locations far from a Cardiological HUB; ** Until available in stock

the attribution of an ATC code (anatomical, therapeutic and chemical) to every active ingredient selected.

In what follows we report the drugs selected for the medical rescue and particularly for MSAs working in pre-hospital emergencies in the Lombardy Region.

At the same time, the working group followed the same procedure to define the standard equipment for the Region's helicopters.

For reasons related to space and relatively reduced weight allowed on board, a list with fewer drugs was

drafted, with only 58 formulations.

Several observations were made after the official lists were defined and the regional AAT acknowledged the work done. The most discussed drugs were: diazepam, single-dose microenemas for the selected dosages and lorazepam drops, to be substituted with bromazepam drops (substitution denied).

In both cases AREU justified their choices supporting the safety use of the drugs on children, waiting for a specific evidence of literature not yet established

for pediatric population.

Another request was the substitution, which was accepted, of i.v. esomeprazole (40 mg/10 mL), already in use, with i.v. pantoprazole (40 mg/10 mL).

Further issues concerned the availability of some drugs, as they are not included in some hospital registers. In particular, labetalole, that can be obtained from the International Pharmacy since it is not yet manufactured in Italy, and the association of salbutamole + ipratropium, proposed as commercial brand Breva® and Carbomix®, available upon request at the Poison Control Centre. Other reports have been performed regarding formulation of mannitol (already in use 18% instead of 20% as requested).

Discussion

The evaluation process was not simple: it was difficult to choose the number of drugs because during this selection, an invitation to tender was issued for new emergency backpacks. The prototypes being unavailable, it was hard to imagine how to prepare the equipment.

During the study, concerns regarding administration to specific target populations arose: pediatric and elderly populations, pregnant or breastfeeding women. The pediatric sector was particularly critical because, at the moment, evidence based on the literature does not include the safety profiles and effectiveness of drugs administered to this population. Considering the potential difficulties behind the creation of one supply suitable for both adults and children, with certainly different needs, it was agreed to treat only adults, with the future goal to study a specific list for the pediatric population.

For the elderly we had to take into consideration their fragilities and co-morbidities, thus resulting in polytherapy. In this regard, in the section “precautions” and “contraindications” of the drugs’ data sheet all the relevant information has been reported. Concerning pregnant and breastfeeding women, a literature review allowed us to identify which drugs could be safe and which ones, instead, ought to be avoided to prevent damage to the fetus or to the breastfed baby. The research has been carried out evaluating each trimester

of pregnancy. Some drugs were forbidden only during the 3rd trimester (e.g. lormetazepam, morphine, midazolam) others only during the 1st trimester (e.g. metoclopramide). Where data were incomplete or conflicting, the standard phrase “NO DATA AVAILABLE” was reported. The same research was performed on breastfeeding women: only 7 drugs out of 71 (beclomethasone, carbomix, insulin, magnesium sulphate, oxytocin, paracetamol and sugammadex) were found to be safe. The others have to be considered carefully. The draft results were retrieved and pooled in an Excel spreadsheet.

Guidelines concerning the storage of drugs were also discussed and provided: particular attention was needed because there are two different locations, the Station and the Car. An accurate evaluation of the literature was performed (5) (6). Storage conditions, chosen at the end of the analysis and discussion within the working group, reported these standard indications:

- “No particular precaution”
- “ $2^{\circ}\text{C} < T < 8^{\circ}\text{C}$ in refrigerator”
- “ $T \leq 15^{\circ}\text{C}$ ”, “ $T < 20^{\circ}\text{C}$ ”
- “ $T < 25^{\circ}\text{C}$ ”, “ $T < 30^{\circ}\text{C}$ ”.

The essential difference for the storage of the drugs in the locations mentioned was just a matter of organization: in the working Station all the drugs can be found in the medical cabinets or in the fridge, set at around 5°C to include both formulations requesting $T \leq 15^{\circ}\text{C}$ (epinephrine 1 mg/1 mL and epinephrine 5 mg/5 mL) and the ones requesting even lower temperatures, $2^{\circ}\text{C} < T < 8^{\circ}\text{C}$ (insulin, oxytocin, rocuronium and succinylcholine); in MSA we don’t have standard containers, but bags (backpacks), bags for infusions and a fridge. The backpack was used for the drugs not requesting any particular care, while all the others are stored somewhere else: six critical formulations must be stored inside the fridge, and the others in cases and thermal bags with temperatures $< 25^{\circ}\text{C}$ and $< 30^{\circ}\text{C}$. It was then essential to specify the exact location of each drug and to register the results in an Excel file.

At the end of the evaluation, most of the drugs in fact did not need particular arrangements, and could be stored at ambient temperature. Few formulations request lower temperatures ($T < 25^{\circ}\text{C}$), while only 5

(present in 6 formulations) needed a different storage, in the fridge, (insulin, oxytocin, succinylcholine, rocuronium, adrenaline).

An analysis of narcotics and analgesics was also performed. DPR n. 309 of 9th of October 1990, and further modifications (6)(7), that rule the use, was estimated to be too general for pre-hospital rescue, and did not take into the right consideration the problems deriving from extraordinary emergency situations. The lack of clear indications concerning the Working Stations and MSA made the extra-hospital area uncertain about the governance of these drugs. Major problems were related to tracking the narcotics, not always available and suitable according to the time imposed by the law, and the supply, most of all for the working stations far away from hospitals and not located in hospitals. Being aware of the concrete problems that rescue teams have to face, some solutions were submitted to the Central Narcotics Bureau.

The goal was to guarantee their immediate availability and at the same time their correct management and tracking, according to the law. For this reason, AREU prepared a regional standardized supply to be used as major analgesics that could be stored in the bags inside the MSA. It was proposed to store them in the Working Stations, inside a locked cabinet, with a form indicating the characteristics (type and quantity) of each substance stored both in the station and in the MSA.

Conclusions

The harmonization and standardization of the drugs needed in every MSA allowed us to draft a common supply of 71 drugs, in all the region. However, the process was not straightforward: major issues concerned the choice of some drugs, their safety profiles, the process of procurement and their dosage. The impact on the new equipment led to modifications at different levels, operational, organizational, educational and professional.

In conclusion, we can state that, thanks to the support of experts, of the literature review, and thanks to the practical experience of the members of the AREU working groups and thanks to the documents coming AIFA and EMA, the first operative regional

project of unified pharmacological supply for MSA was delivered.

Further development

There are still a few aspects that need to be clarified in future projects:

- Extension of the analysis to the paediatric population to identify safe drugs for this age group. In the list selected by AREU, indeed, few drugs can be guaranteed for children (paracetamol suppositories, diazepam 5 mg/2,5 mL, lormetazepam drops 2,5 mg/mL and ibuprofen vials 400 mg/3 mL); the situation is still uncertain and controversial for all the other drugs
- Optimization of the number of drugs: to simplify the supply and to handle the bags more easily (lighter backpacks), it is necessary to monitor and remove all the drugs that will not be used during the first year of the investigation and those that will be withdrawn from the market according to AIFA and EMA reports.

Proceeding in this direction we will be able to consolidate the EMS network and improve the management and organization of the rescue medical service.

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Disclosures

This article is based on previously conducted studies and does not involve any new studies of human or animal subjects performed by any of the authors. Ethics approval was not required for this review. The facts, conclusions, and opinions stated in the article represent the authors' research, conclusions, and opinions and are believed to be substantiated, accurate, valid, and reliable. However, as this article includes the results of personal

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Glossary

Definitions and abbreviations

AAT	= Territorial Agency Articulation (Articolazione Aziendale Territoriale)
AIFA	= Italian Medicines Agency (Agenzia Italiana del Farmaco)
AREU	= EMS Regional Agency (Azienda Regionale Emergenza Urgenza - Lombardia)
ATC	= Anatomical, Therapeutical, Chemical (Anatomico Terapeutico Chimico)
CT	= Technical Board (Collegio Tecnico)
DL	= Legislative Decree (Decreto Legge)
DM	= Ministerial Decree (Decreto Ministeriale)
DPR	= Decree of the President of the Republic (Decreto del Presidente della Repubblica)
EMA	= European Medicines Agency
GdL	= Working Group (Gruppo di Lavoro)
GU	= Official Gazette (Gazzetta Ufficiale)
MSA	= Advanced Rescue Vehicles (Mezzi di Soccorso Avanzato)
WHO	= World Health Organization (Organizzazione Mondiale della Sanità - OMS)
SOREU	= Regional Medical Dispatch Centre (Sala Operativa Regionale Emergenza Urgenza)

Acronyms Used In The Document

blst	= blister
dip	= dipropionato (dipropionate)
ev	= endovena (intra venous)
fl	= fiala (ampoule)
flac	= flacone (bottle)
g	= grammo (gram)
gtt	= gocce (drops)
im	= intramuscolare (intra muscle)
inal	= inalatoria (inhalation)
mcg	= microgrammi (micrograms)
mcls	= microclisma (micro enema)
mg	= milligrammi (milligrams)
mL	= millilitri (milliliters)
os	= "per via orale" (orally administered)
polv	= polvere per preparazioni iniettabili o infusioni (powder for injectable preparations or infusions)

puff	= erogazione calibrata per via aerea (calibrated provision for airway administration)
sbl	= sublinguale (sublingual)
sc	= sottocute (subcutaneously)
sol	= soluzioni per preparazioni iniettabili o infusioni (solutions for injectable preparations or infusions)
sosp	= sospensione orale (oral suspension)
supp	= supposta (suppository)
UI	= Unità Internazionale (International unit)
rett	= rettale (rectal)
T	= temperatura (temperature)
°C	= gradi Celsius (Celsius degree)

Conflict of interest: Each author declares that he or she has no commercial associations (e.g. consultancies, stock ownership, equity interest, patent/licensing arrangement etc.) that might pose a conflict of interest in connection with the submitted article

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Correspondence:

Dr Guido Francesco Villa

AREU (Lombardy EMS Regional Agency) - Milan,

Via Campanini 6, 20124, Milano - Italia

Tel: 0267129022

E-mail: gf.villa@areu.lombardia.it