



# INDIPENDENT MEDICINES INFORMATION CENTRE (IMIC):

## Valsartan Case

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4 Dicembre 2018

HMA WORKING GROUP OF  
COMMUNICATION PROFESSIONALS (WGCP)  
MEETING

# 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 previous years
<i>DIRECT INTERESTS:</i>				
1.1 Employment with a company: pharmaceutical company in an executive role	x	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> mandatory
1.2 Employment with a company: in a lead role in the development of a medicinal product	x	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> mandatory
1.3 Employment with a company: other activities	x	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
2. Consultancy for a company	x	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
3. Strategic advisory role for a company	x	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
4. Financial interests	x	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
5. Ownership of a patent	x	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
<i>INDIRECT INTERESTS:</i>				
6. Principal investigator	x	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
7. Investigator	x	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
8. Grant or other funding	x	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional
9. Family members interests	x	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> optional

\*Irene Cappuccio, in accordance with the Conflict of Interest Regulations approved by AIFA Board of Directors (25.03.2015) and published on the Official Journal of 15.05.2015 according to EMA policy /626261/2014 on the handling of the conflicts of interest for scientific committee members and experts.

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

# INTRODUCTION

2004

IMIC was established in Italy

Institutional law September 30<sup>th</sup> 2003, n. 269

- ❖ To provide written and/or verbal information or advice of DRUGS
- ❖ To provide service to health professionals such as general practitioners, specialists, pharmacists
- ❖ To provide service to the public
- ❖ To draw up information documents on issues emerging from the daily activity of the Pharmacy-line service.

How does



works?

free number 800571661 every day from Monday to Friday from 9 am to 13 am.

E-mail: [farmaciline@aifa.gov.it](mailto:farmaciline@aifa.gov.it)

Fax number: 06 5978 4807

# FUNCTIONS

01 Therapeutic indication

Pharmacokinetics

02

03

Formulation and composition

04 Generic and Brands

Dosage and adjustment

05

06

Contraindications

07

Special warning and precautions for use

Drug interactions

08

09

Pregnancy/lactation

10

Availability

Reimbursement and price

11

12

Clarification CTS-AIFA Notes

# STAFF



Pharmacists, specialists with proper knowledge for the resolution of doubts and the preparation of answers to request of clarifications about drugs

Every answer is codified by :

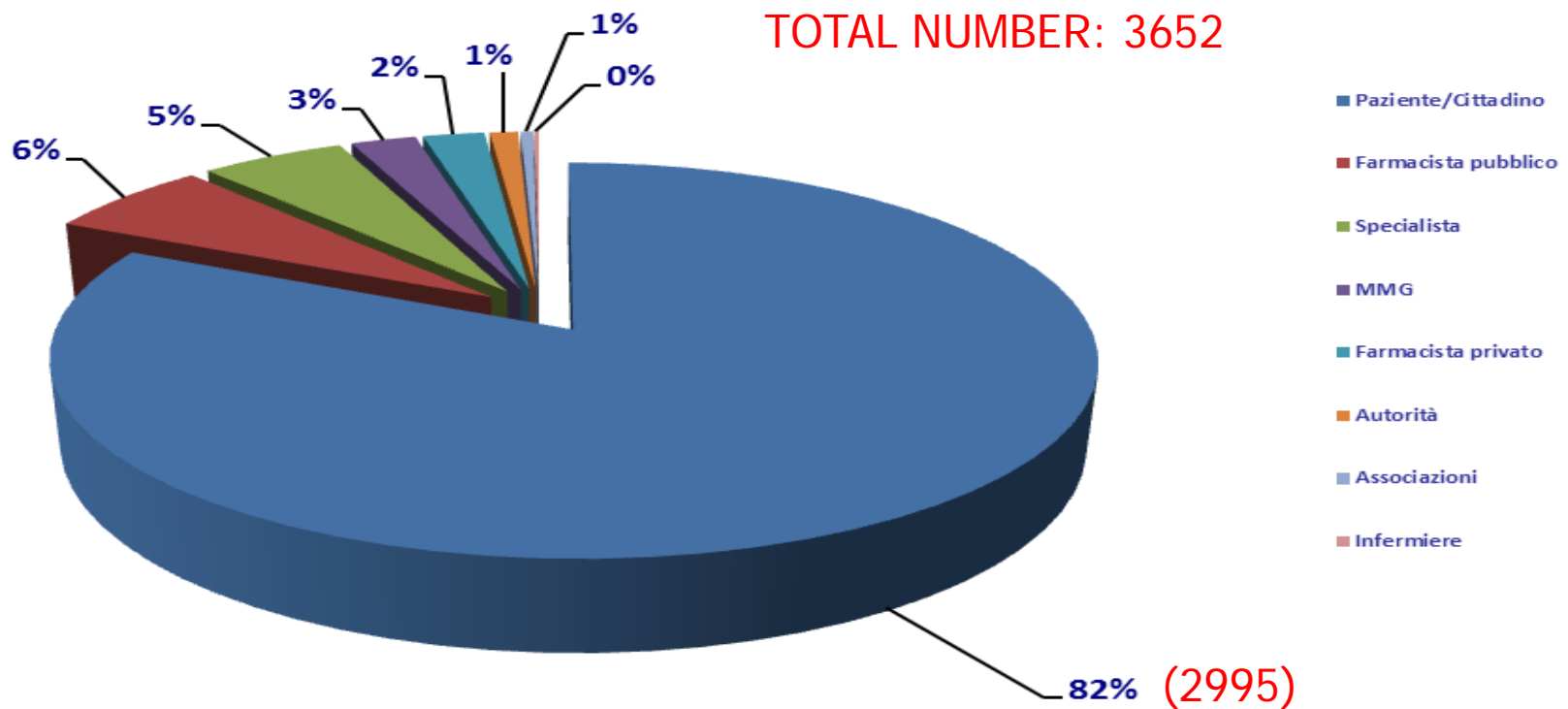
1. drugs
2. AIC code
3. type of question
4. ATC,...etc

and filed in a software



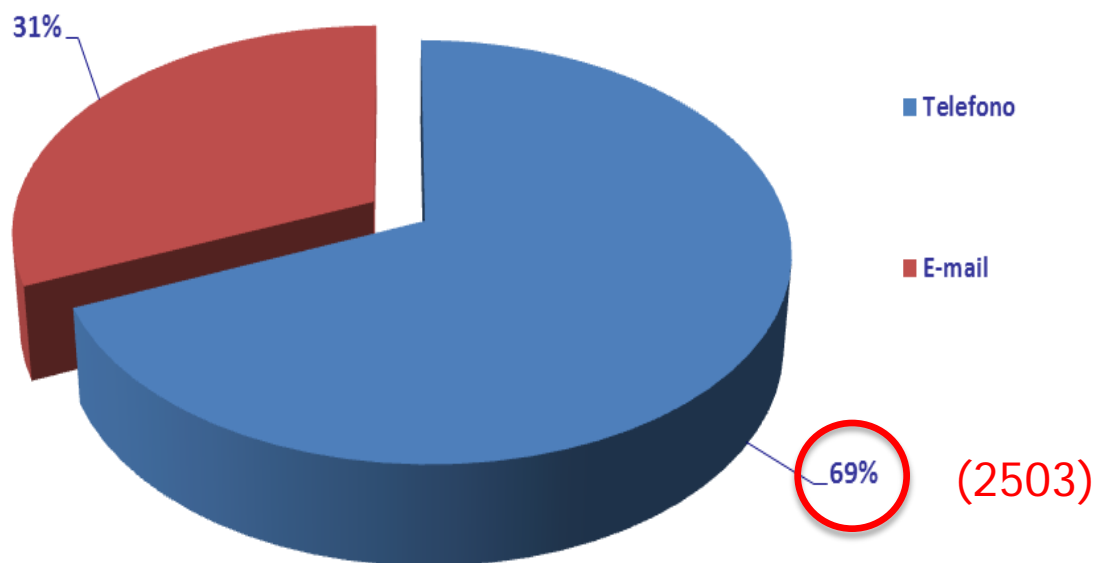
# ANSWERS TO THE QUERIES

Percentage distribution of the type of users:  
January-October 2018



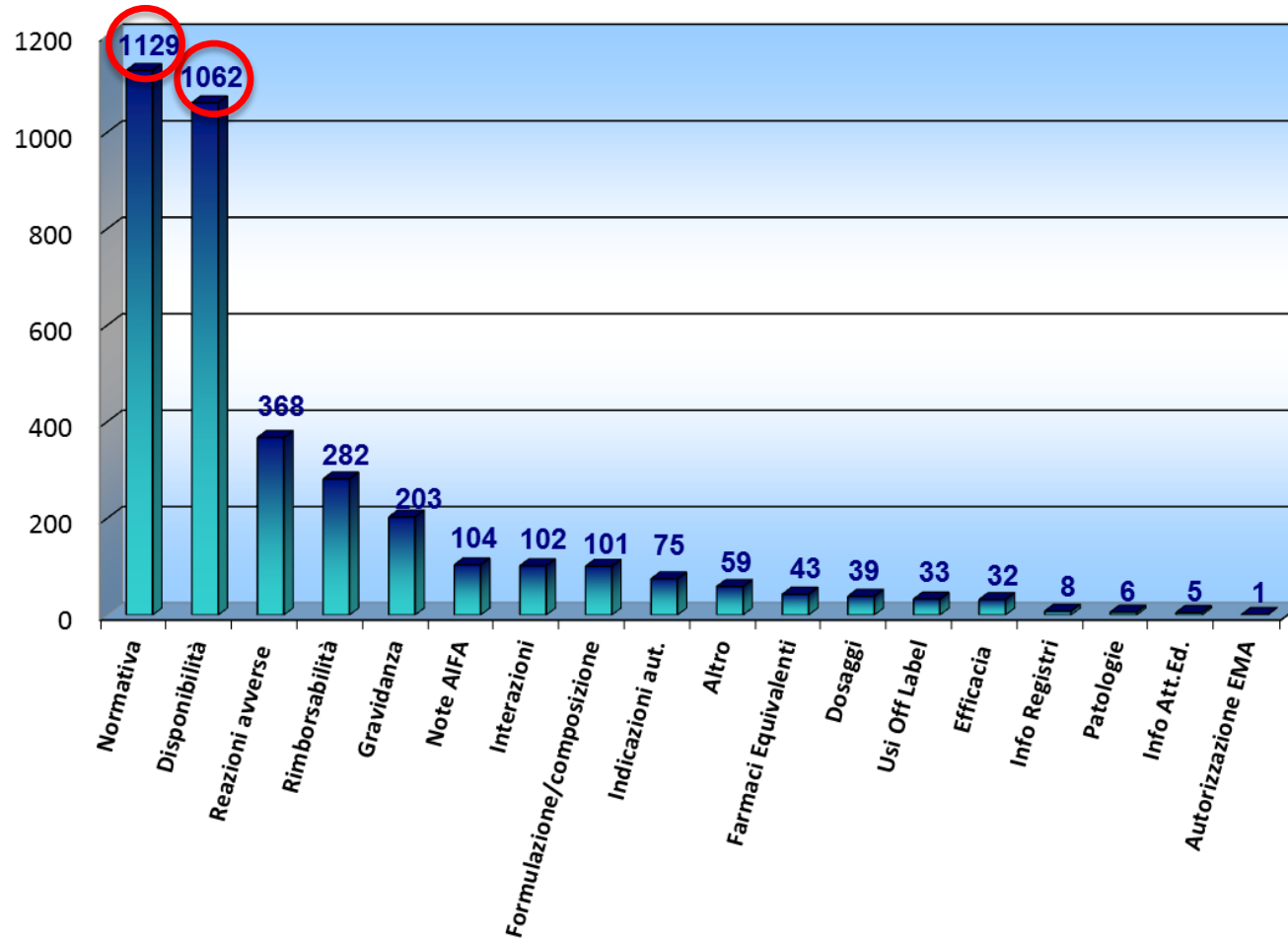
# ANSWERS TO THE QUERIES

Percentage distribution of the type of reception:  
January-October 2018



# ANSWERS TO THE QUERIES

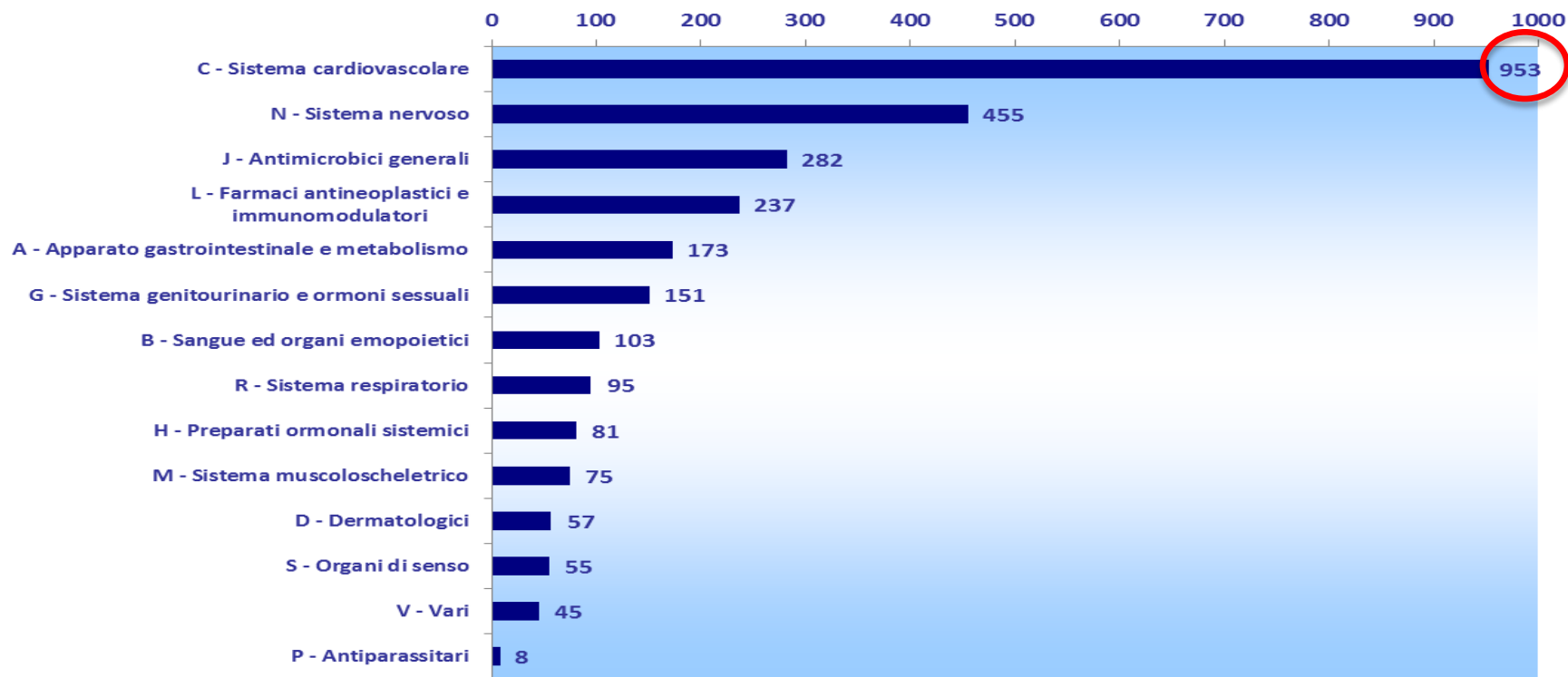
Distribution of the typology of queries: January - October 2018 Total questions: 3652





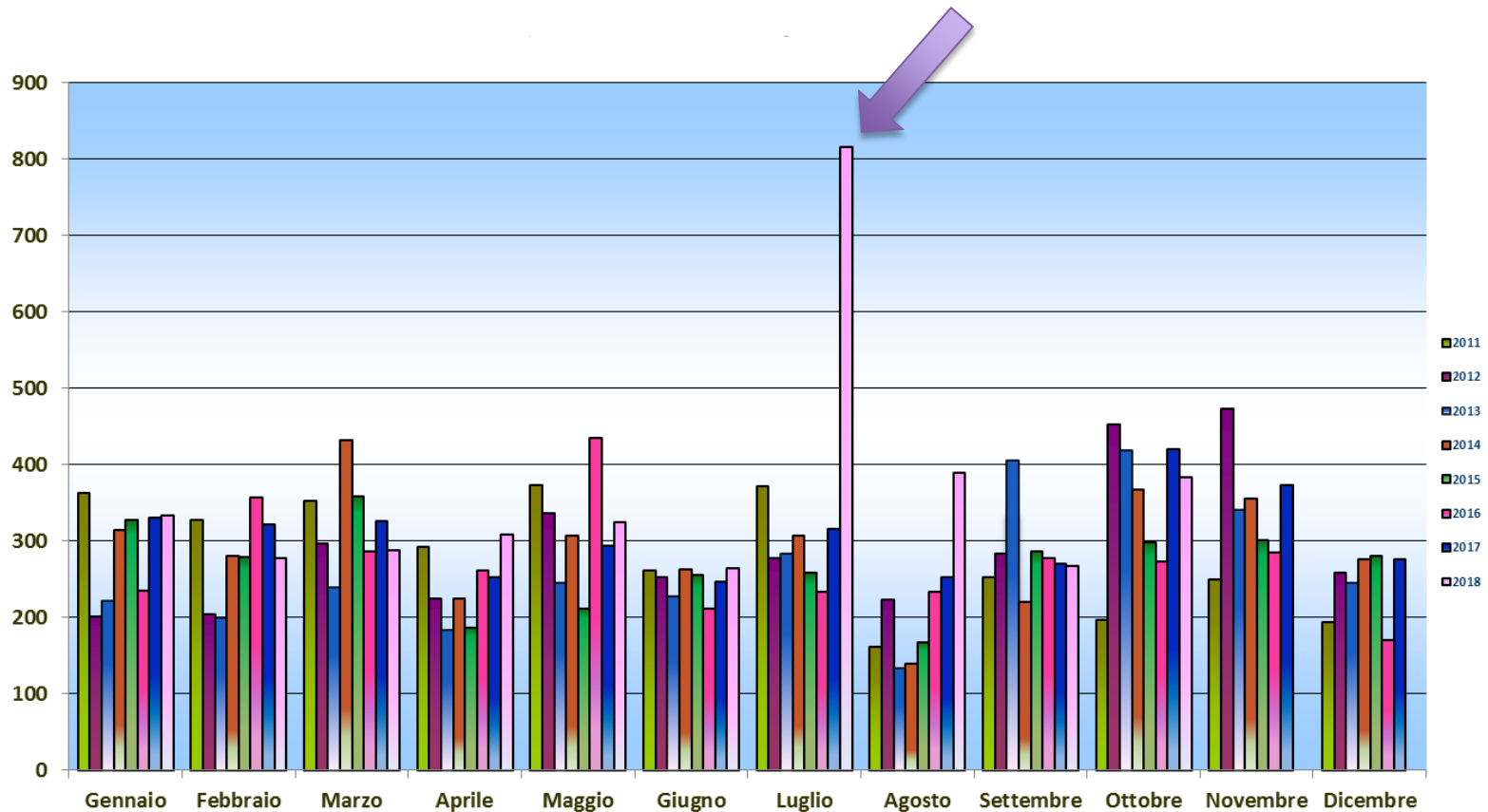
# ANSWERS TO THE QUERIES

Distribution of questions related to drugs according to the ATC system  
 January - October 2018 Total queries concerning drugs: 2770



# ANSWERS TO THE QUERIES

Monthly distribution of the number of questions.  
 Total: 3652



# RECALL OF VALSARTAN MEDICINES BY EMA.....



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

5 July 2018¶  
EMA/459276/2018¶

¶

EMA reviewing medicines containing valsartan from Zhejiang Huahai following detection of an impurity¶

Some valsartan medicines being recalled across the EU.¶

The European Medicines Agency (EMA) is reviewing medicines containing the active substance valsartan that is supplied by Zhejiang Huahai Pharmaceuticals, a company in Linhai, China.¶

The review was triggered after the company detected an impurity, N-nitrosodimethylamine (NDMA), in the valsartan active substance which the company supplies to manufacturers producing some of the valsartan medicines available in the EU.¶

NDMA is classified as a probable human carcinogen (a substance that could cause cancer) based on results from laboratory tests. The presence of NDMA was unexpected and is thought to be related to changes in the way the active substance was manufactured.¶

While the review is underway, national authorities across the EU are recalling medicines containing valsartan supplied by Zhejiang Huahai.¶

# PATIENTS WERE CONCERNED ABOUT.....



- ❖ "I learned the news only for one case and not from official sources. I think such important news had to be communicated through the public service organs, radio news broadcasts and more."
- ❖ "I learned that the drug in question has been withdrawn with serious accusations of damaging health ... I look for information and instructions if possible."
- ❖ "... Since when the affected batches have been on the market? "
- ❖ "I would like information on Valsartan recently withdrawn because it is contaminated with carcinogens. I would also like to know what kind of tumors or problems or symptoms the contaminant may cause."
- ❖ "I would like to receive information on the carcinogenic substance NMDA."
- ❖ "Is the drug Chinese?"

## .....and DOCTORS



“I am a doctor, I consulted a pharmacist about the lot numbers reported in the list of the batches were withdrawn.

How should I behave with patients?

I would like clarification on this.”

# CONCLUSIONS

- ❖ Poor information and limited use of information channel.
- ❖ Lack of trust about the quality of valsartan drugs not produced in Italy.
- ❖ Concern of the risks associated with prolonged medication intake.
- ❖ Incidence of cancer onset for the user.



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