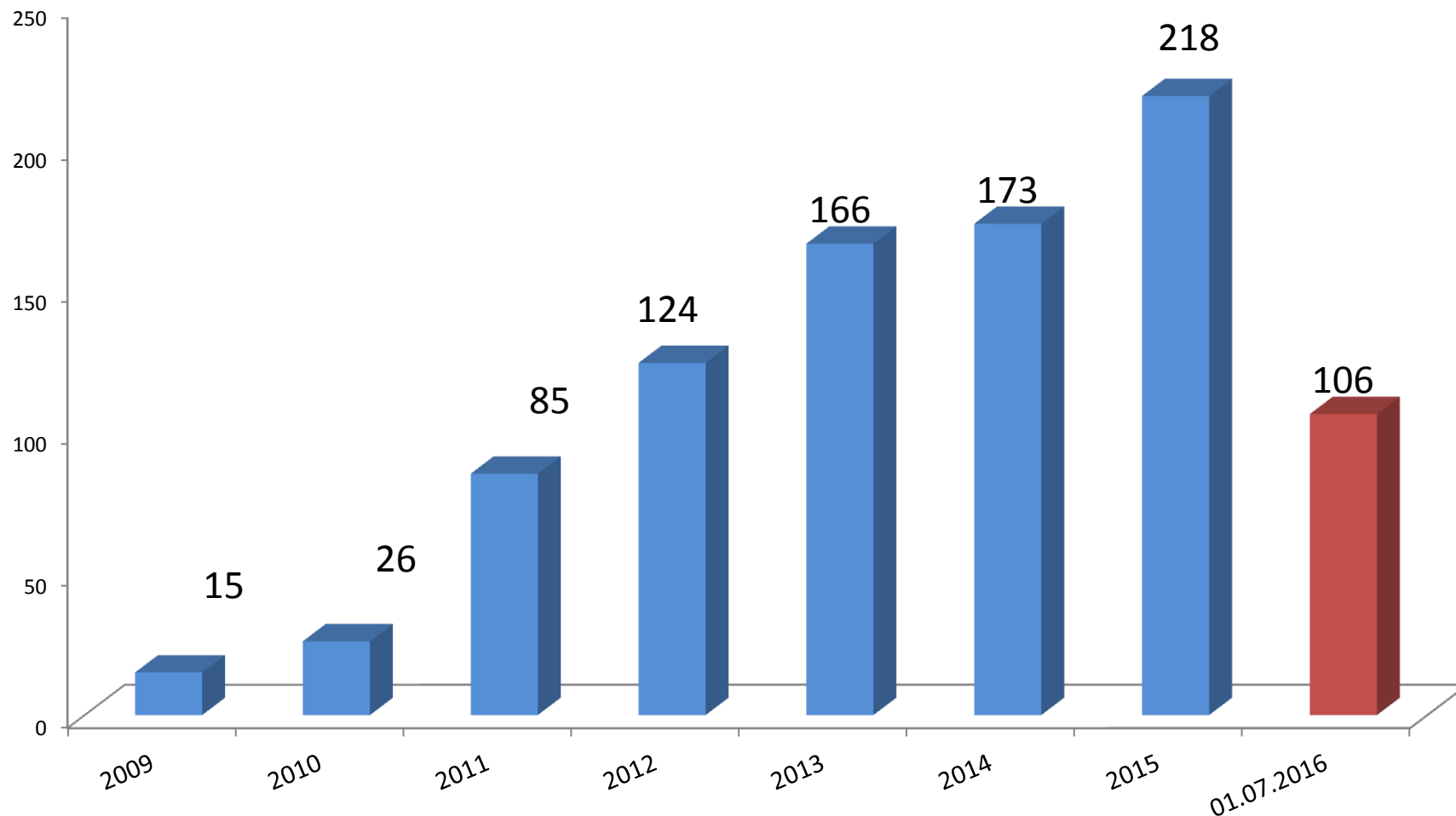


Results of the Voluntary Harmonisation Procedure 2009 –2016

HMA's Clinical Trials Facilitation
Group

Status 1.7.2016

No. of VHPs per submission year



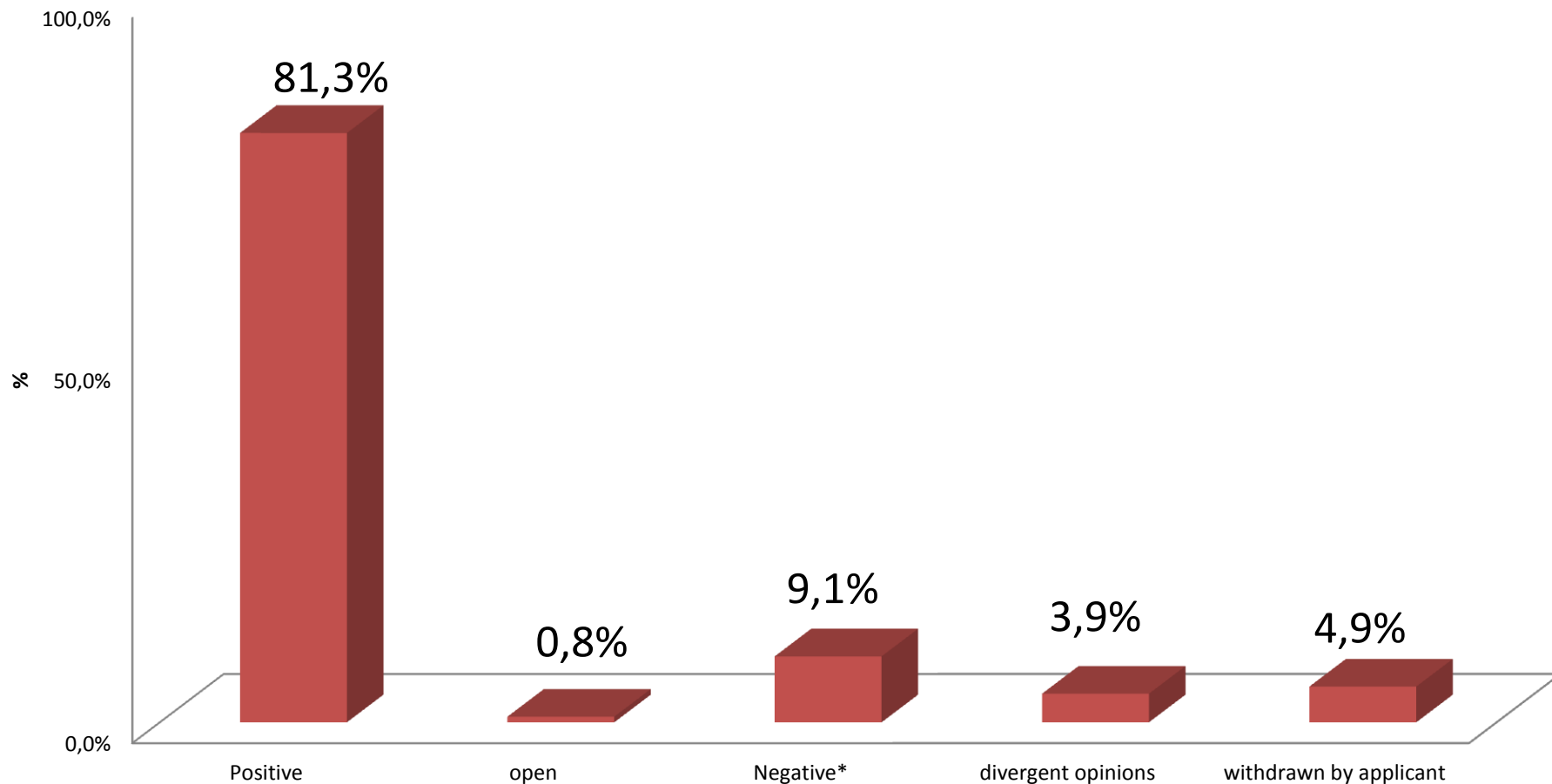
The graph depicts evaluable Voluntary Harmonisation Procedures excluding 11 procedures from the pandemic influenza situation in 2009

2013; 2014 & 2015

17-22% of all multinational clinical trials in Europe underwent a VHP before they were submitted to the National competent authorities

Status 1.1.2016

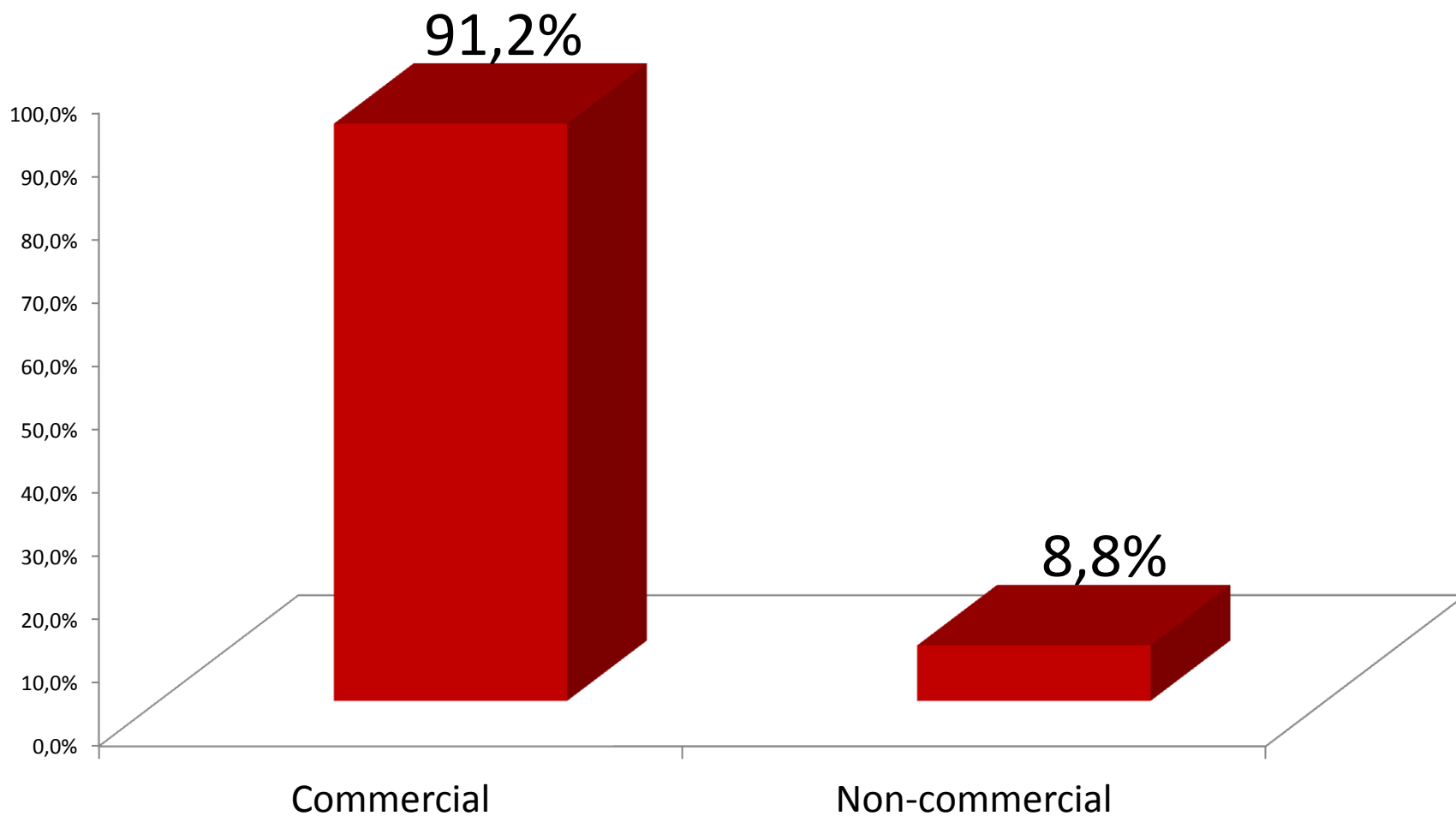
Percentages of VHP decisions from 3/2009 to 01.07.2016



*including rejections to participate in 2nd waves and 20 cases where no REF-NCA was found

The graph depicts evaluable Voluntary Harmonisation Procedures excluding 11 procedures from the pandemic influenza situation in 2009

Distribution of commercial / non-com. Sponsors in VHP



Distribution of regions/countries of VHP sponsors

Country of Sponsor	Number of Voluntary Harmonisation Procedures
United States of America	320
SWITZERLAND	134
Germany	113
UNITED KINGDOM	62
FRANCE	56
DENMARK	40
BELGIUM	39
SWEDEN	32
SPAIN	12
AUSTRIA	7
NETHERLANDS	7
IRELAND	7
ITALY	5
CANADA	5
CZECH REPUBLIC	4
ISRAEL	4
AUSTRALIA	3
SINGAPORE	3
LUXEMBOURG	2
NORWAY	2
JAPAN	2
PORTUGAL	1

The total number of different sponsors is **221**

Status 1.1.2016

Member States joining the VHP

mean of Member States per Voluntary Harmonisation Procedure	6
min	2
max	21

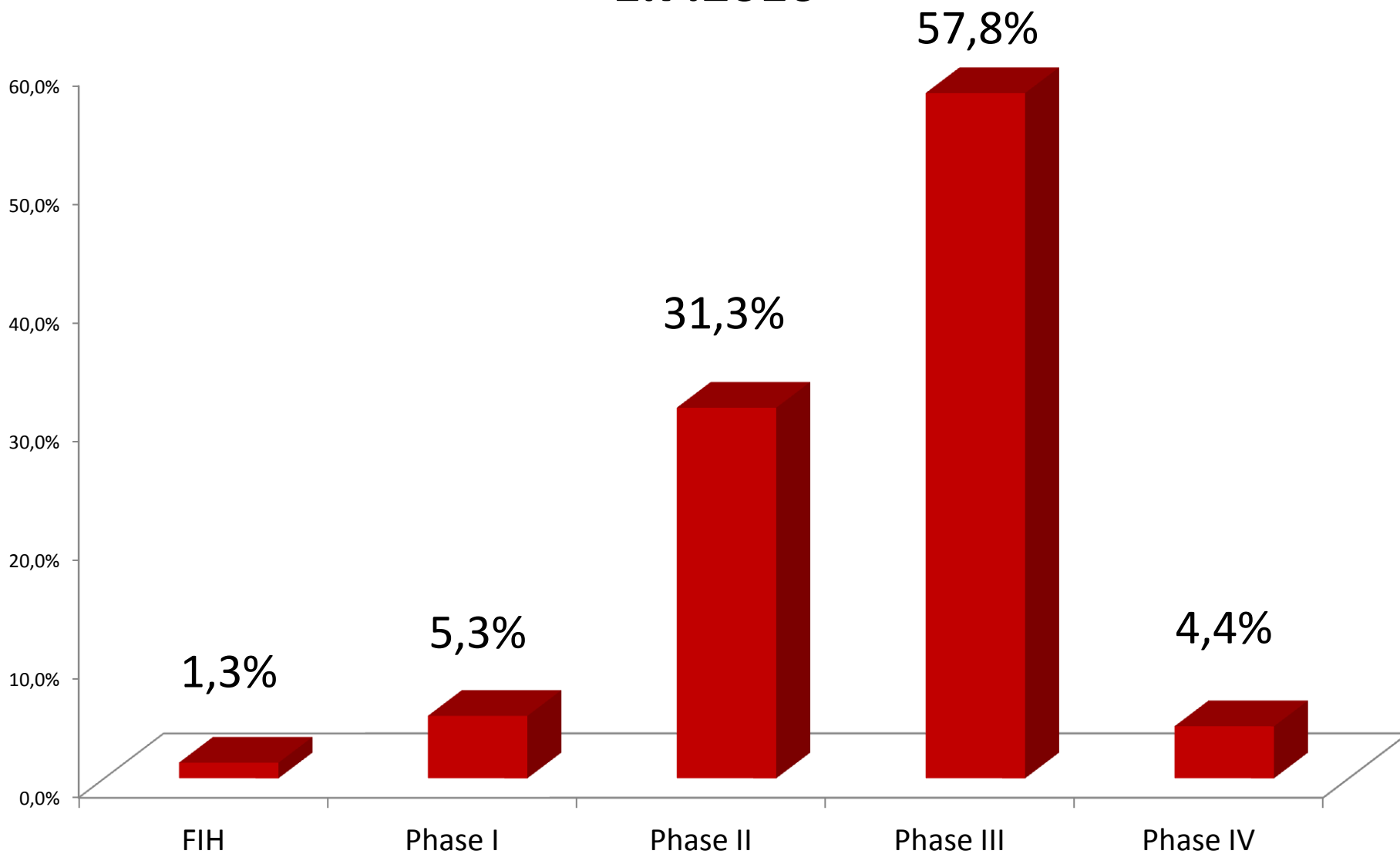
Distribution of IMPs

1.7.2016

Group IMP	Percentage
Chemicals	47,0
Biologicals	53,0

Distribution of VHPs by phase of clinical trial

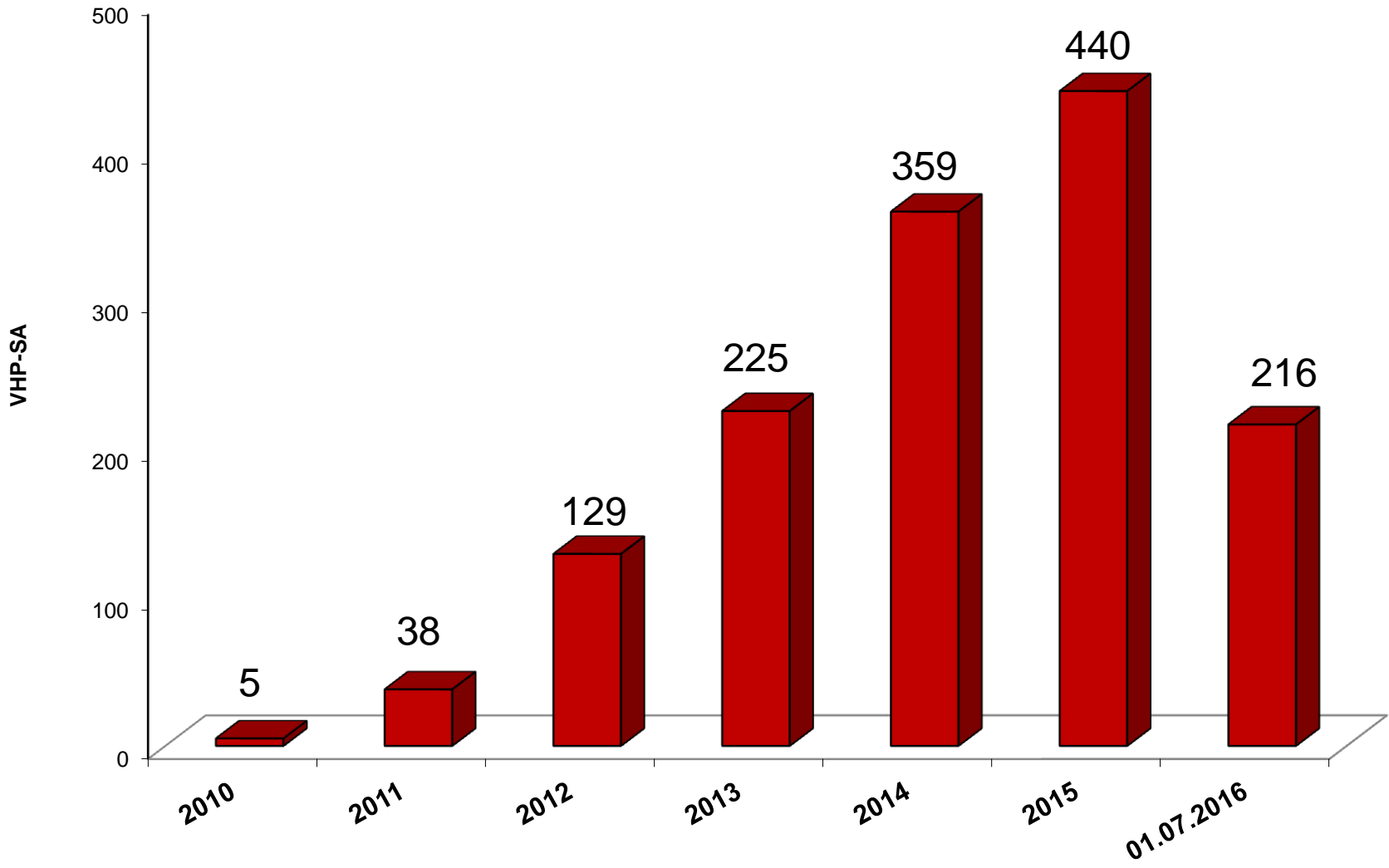
1.7.2016



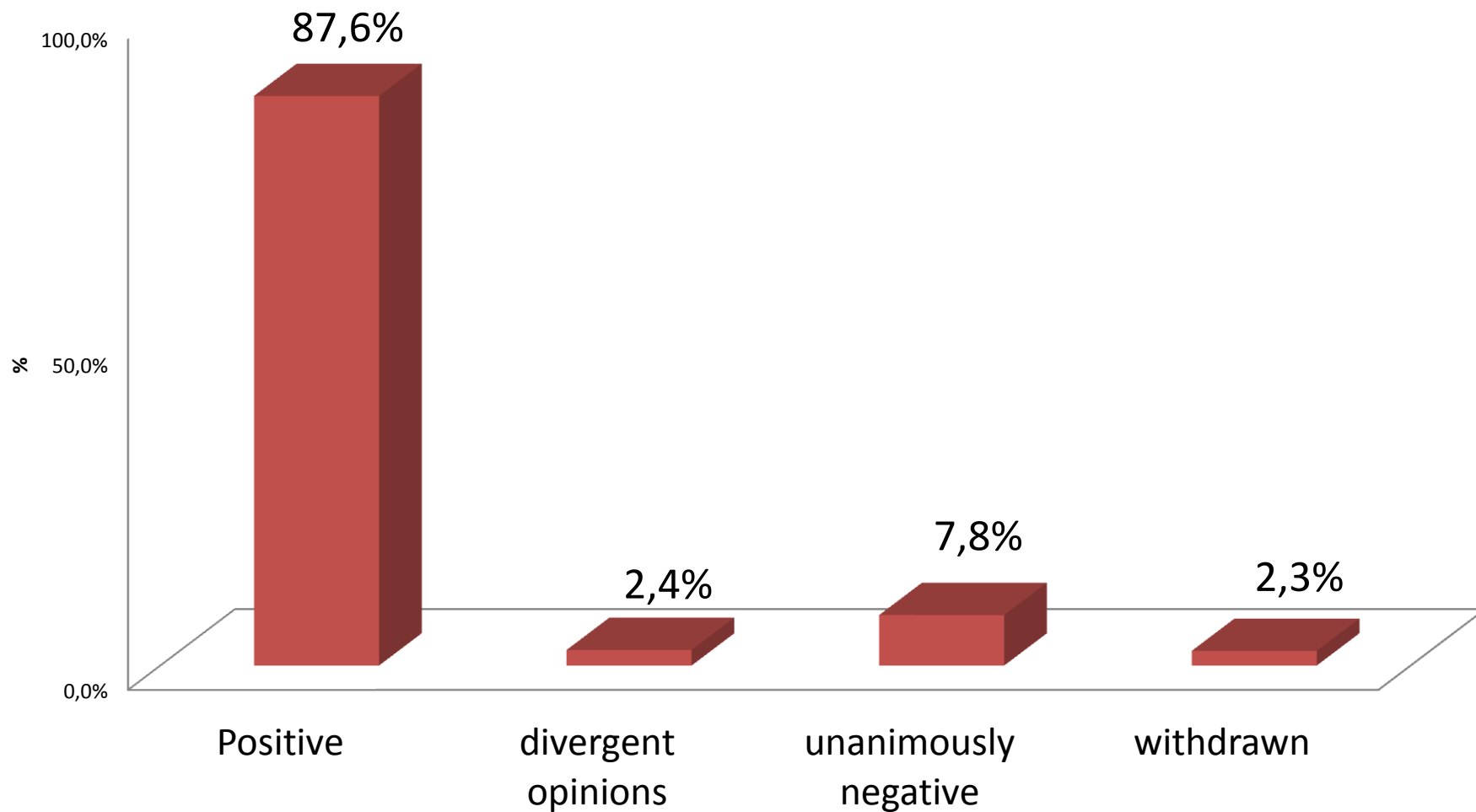
Status of the IMP

Status marketing authorisation	Percentage
authorised	18%
non-authorised	82%

Numbers of VHP-SA 2009 - 1.7.2016



Percentages of VHP SA decisions from 3/2009 to 01.07.2016



questions / comments can be sent via
mail to

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