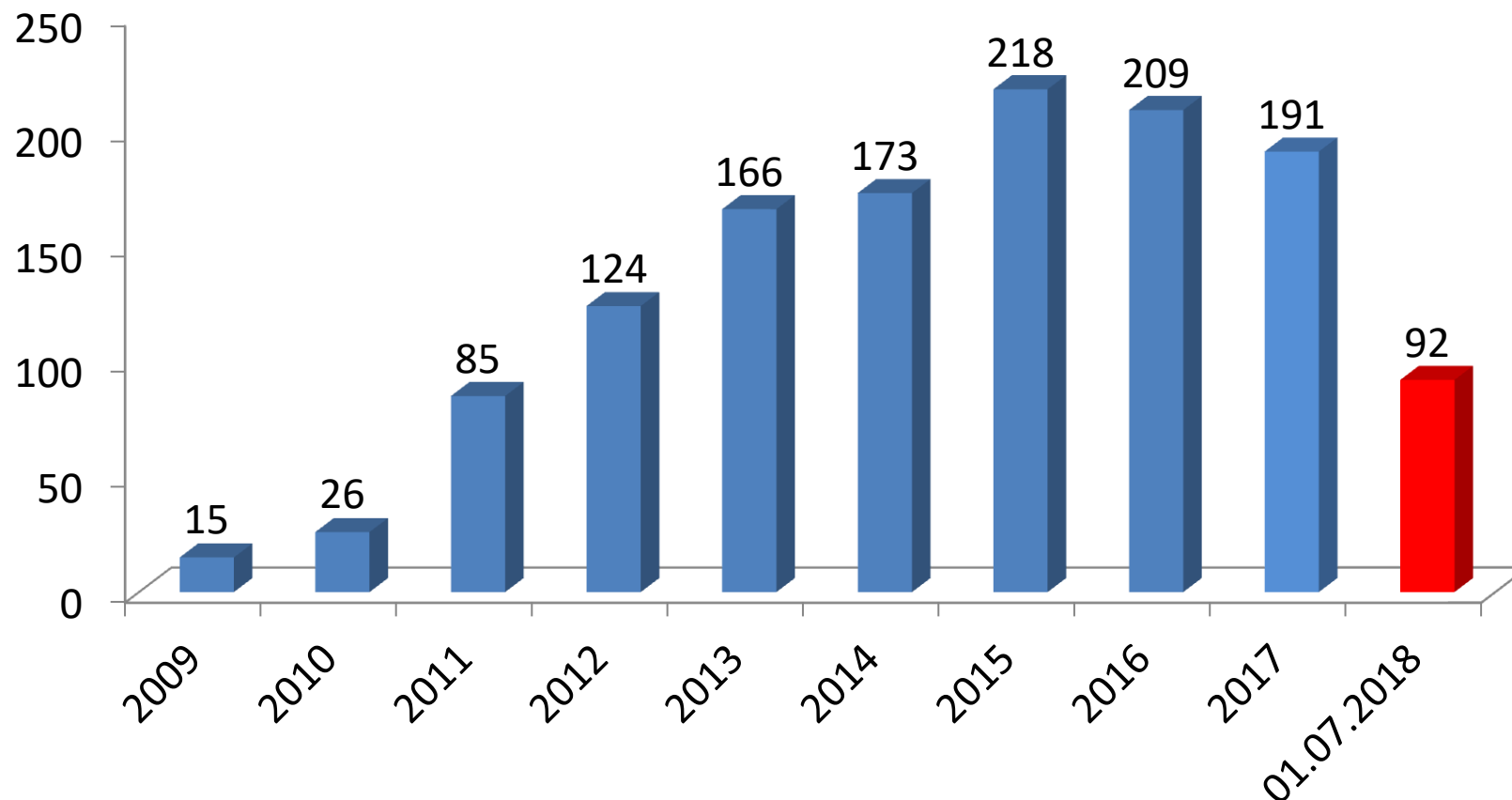


# Results of the Voluntary Harmonisation Procedure 2009 – 1.7.2018

HMA's Clinical Trials Facilitation  
Group

Status 1.7.2018

# No. of initial VHPs per submission year

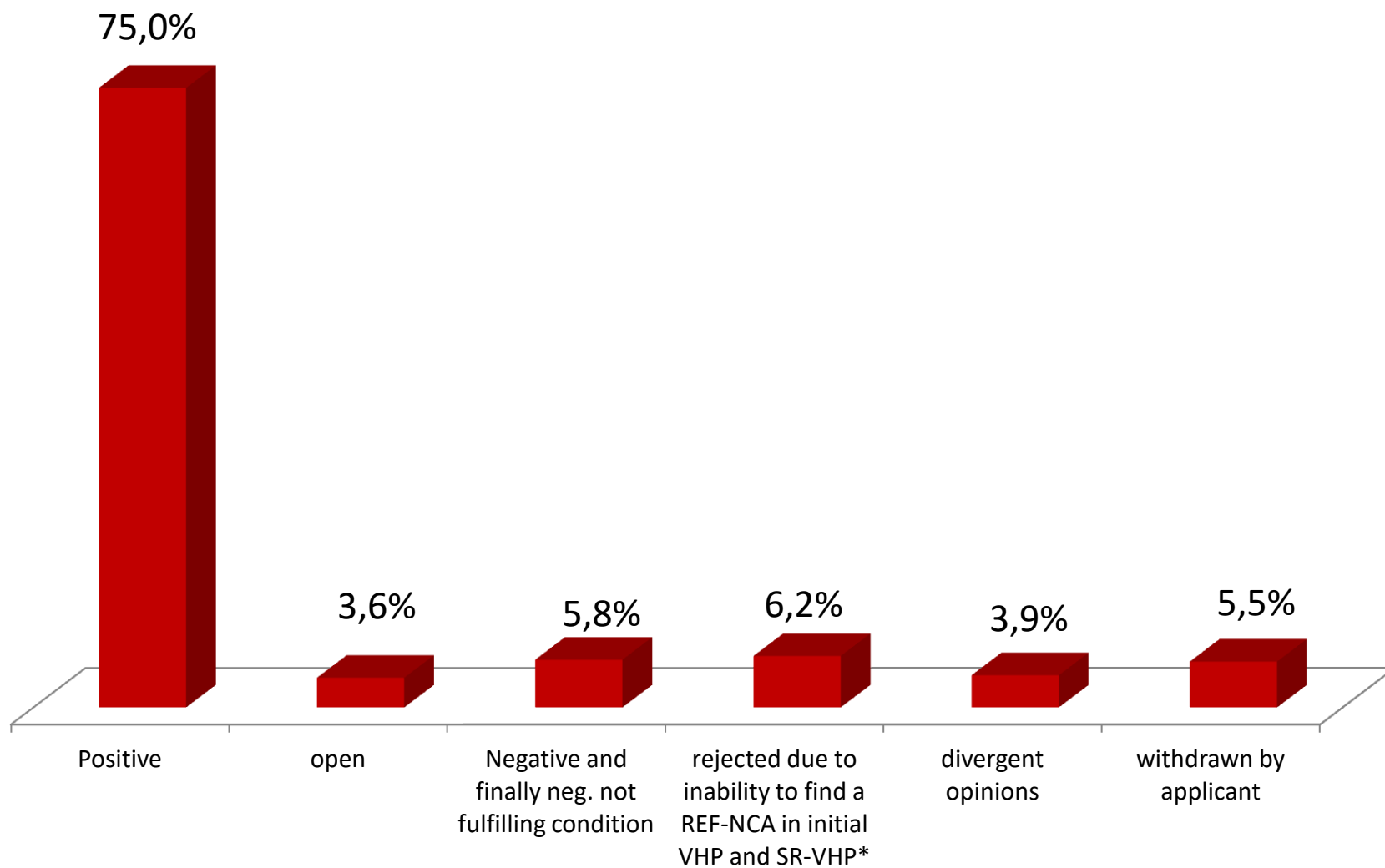


The graph depicts evaluable Voluntary Harmonisation Procedures excluding 11 procedures from the pandemic influenza situation in 2009

2013 to 2017

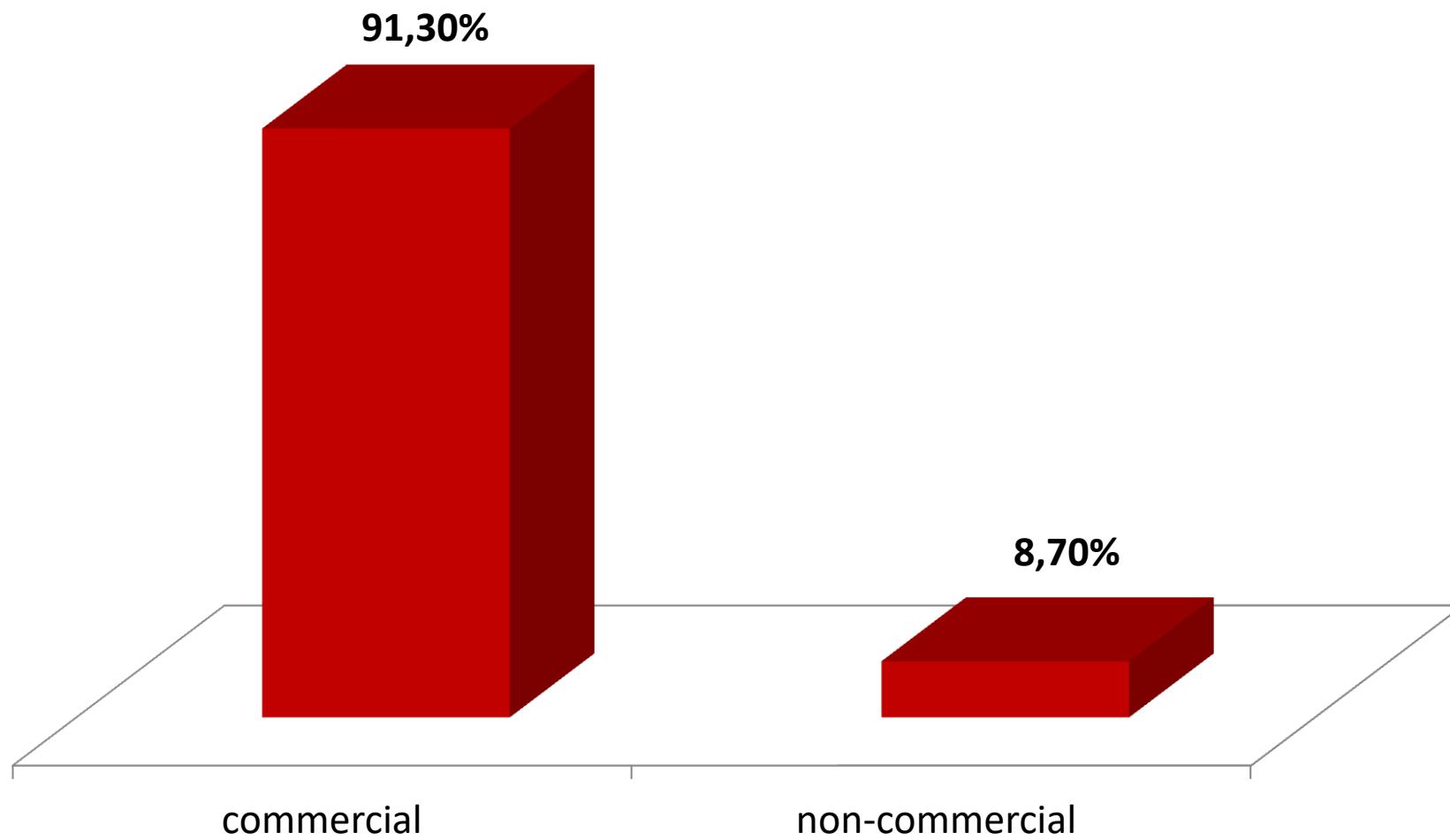
16-23% of all multinational clinical trials in Europe underwent a VHP before they were submitted to the National competent authorities

## Percentages of VHP decisions from 3/2009 to 1.7.2018



\*rejection to participate in 2nd waves (SR-VHP (18)) and cases where no REF-NCA (63) was found

## Distribution of commercial / non-com. Sponsors in VHP



# Distribution of regions/countries of VHP sponsors

<b>Country of Sponsor</b>	<b>Number of Voluntary Harmonisation Procedures</b>
<b>United States of America</b>	<b>511</b>
<b>SWITZERLAND</b>	<b>211</b>
<b>Germany</b>	<b>175</b>
<b>UNITED KINGDOM</b>	<b>95</b>
<b>FRANCE</b>	<b>87</b>
<b>DENMARK</b>	<b>61</b>
<b>BELGIUM</b>	<b>54</b>
<b>SWEDEN</b>	<b>34</b>
<b>SPAIN</b>	<b>18</b>
<b>ITALY</b>	<b>11</b>
<b>AUSTRIA</b>	<b>12</b>
<b>NETHERLANDS</b>	<b>12</b>
<b>IRELAND</b>	<b>12</b>
<b>CANADA</b>	<b>10</b>
<b>JAPAN</b>	<b>7</b>
<b>ISRAEL</b>	<b>5</b>
<b>AUSTRALIA</b>	<b>4</b>
<b>CZECH REPUBLIC</b>	<b>4</b>
<b>SINGAPORE</b>	<b>3</b>
<b>LUXEMBOURG</b>	<b>2</b>
<b>NORWAY</b>	<b>2</b>
<b>PORTUGAL</b>	<b>1</b>

**The total number of different sponsors is 314**

Status 5.9.2018

# **Applicants with 10 to more than 100 VHP submissions**

**F.Hoffmann-La Roche**

**AbbVie Deutschland GmbH & Co. KG**

**Gilead Sciences Inc.**

**Amgen Inc**

**Merck KGaA**

**Actelion Pharmaceuticals Ltd**

**AstraZeneca AB**

**Eli Lilly and Company**

**Novo Nordisk A/S**

**Incyte Corporation**

**Genentech, Inc.**

**Novartis Pharma Services AG**

**Eisai Ltd.**

**Bristol-Myers Squibb International Corporation**

**EORTC**

**Regeneron Pharmaceuticals, Inc.**

**GlaxoSmithKline Research & Development Ltd.**

**Millennium Pharmaceuticals, Inc**

**MedImmune, LLC**

Status 5.9.2018

# Member States joining the VHP

mean of Member States per Voluntary Harmonisation Procedure (Without SR-VHP) n=1069	7
min	2
max	22

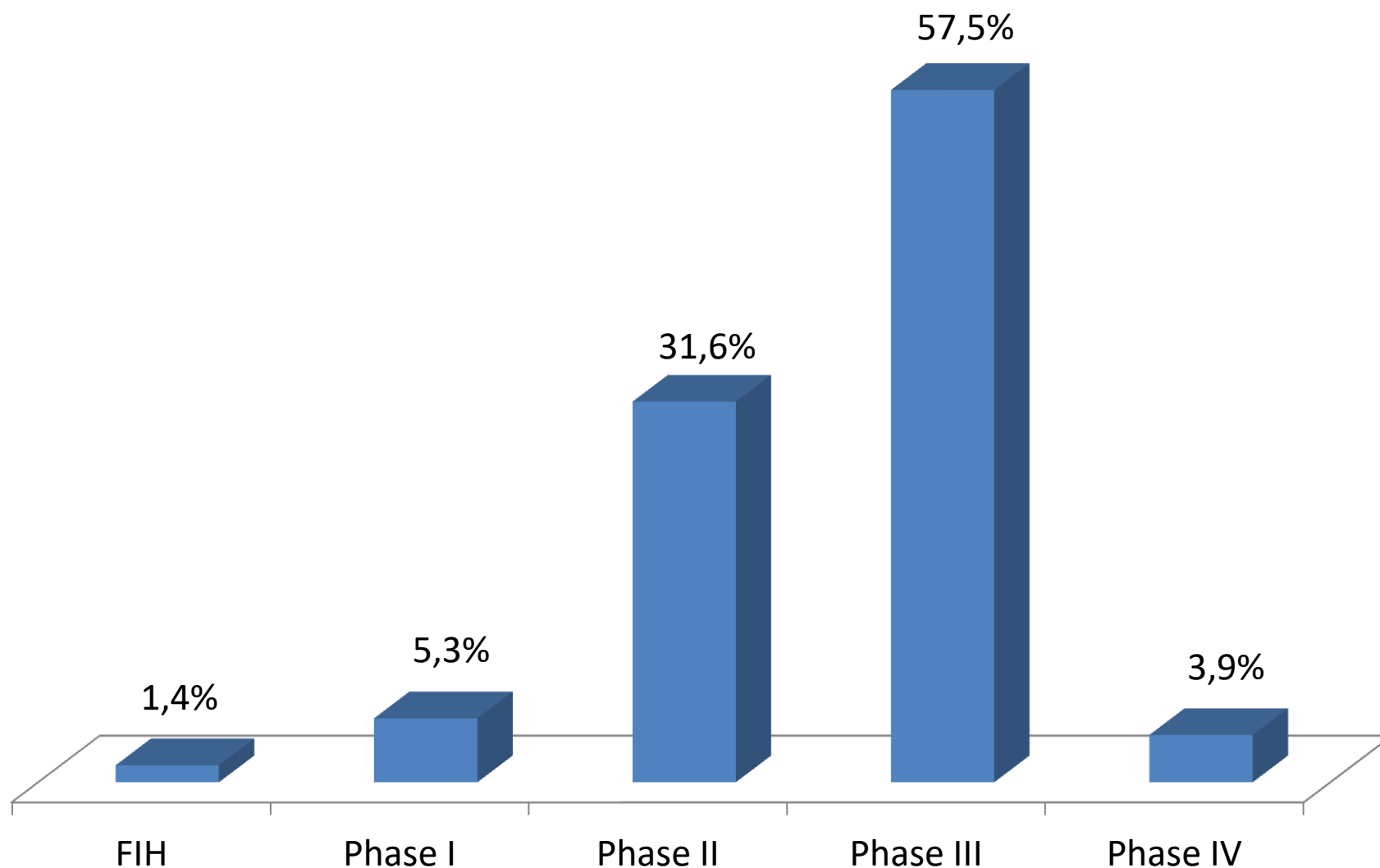


# Distribution of IMPs

## 1.7.2018

Group IMP	Percentage
Chemicals	51,0
Biologicals	49,0

# Distribution of VHPs by phase of the clinical trial

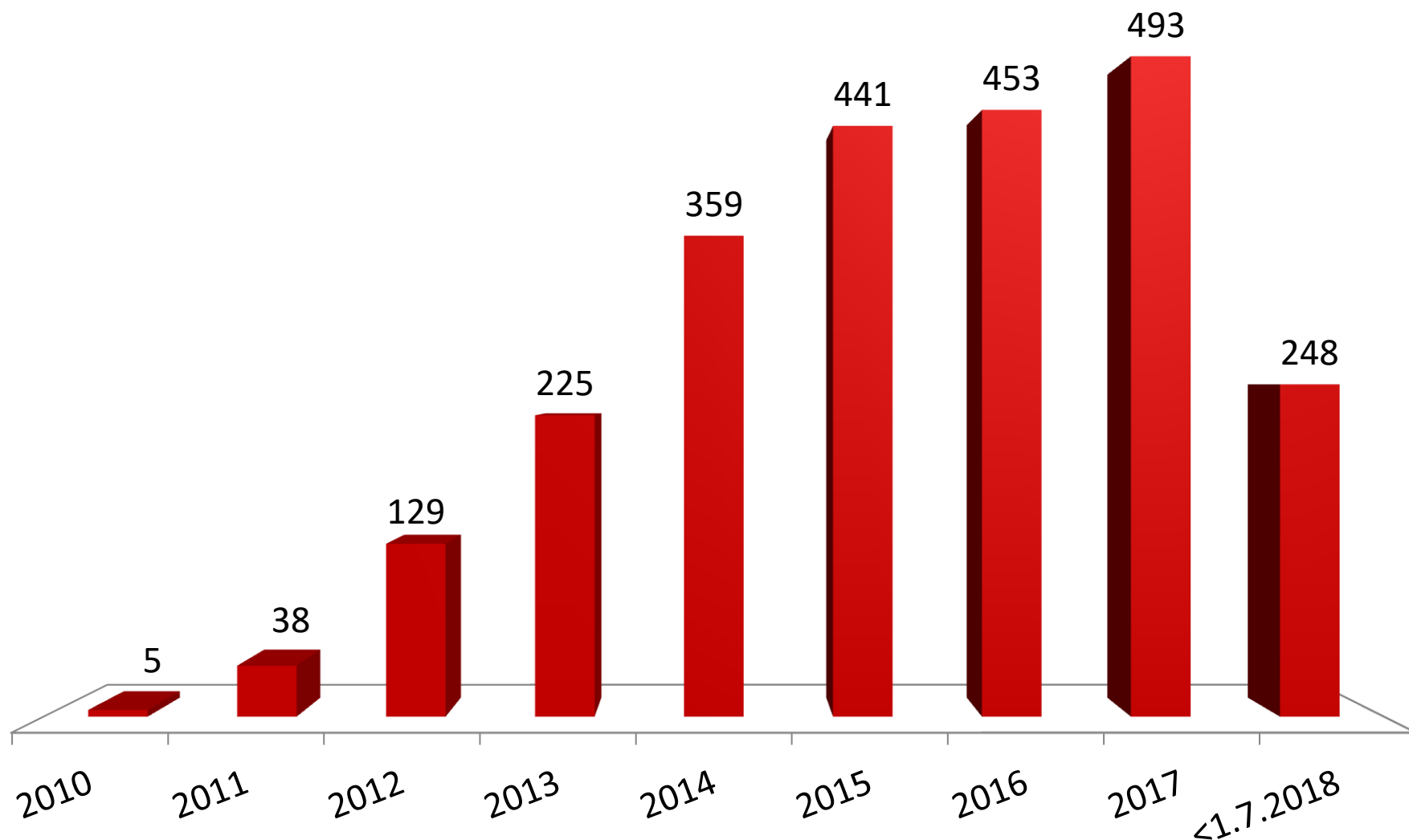


# Status of the IMP

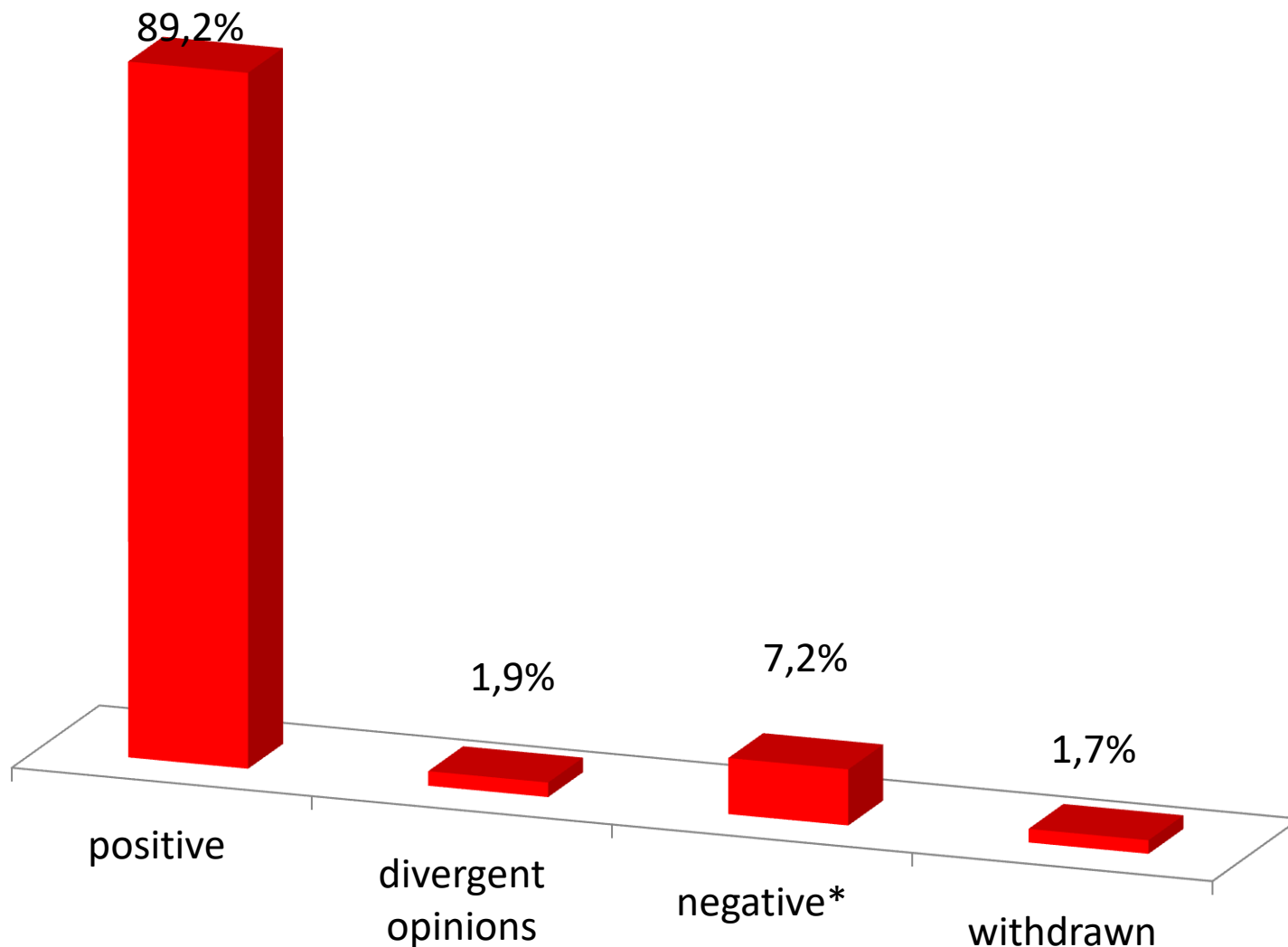
Status 5.9.2018

Status marketing authorisation	Percentage
authorised	18,4%
non-authorised	81,6%

# Numbers of VHP-Substantial Amendments 2009 – 1.7.2018



# Percentages of VHP SA decisions from 3/2009 to 01.07.2018



\* Some case s , where the REF-NCA was lost and no replacement found

questions / comments can be sent via  
mail to

[VHP-CTFG@VHP-CTFG.eu](mailto:VHP-CTFG@VHP-CTFG.eu)