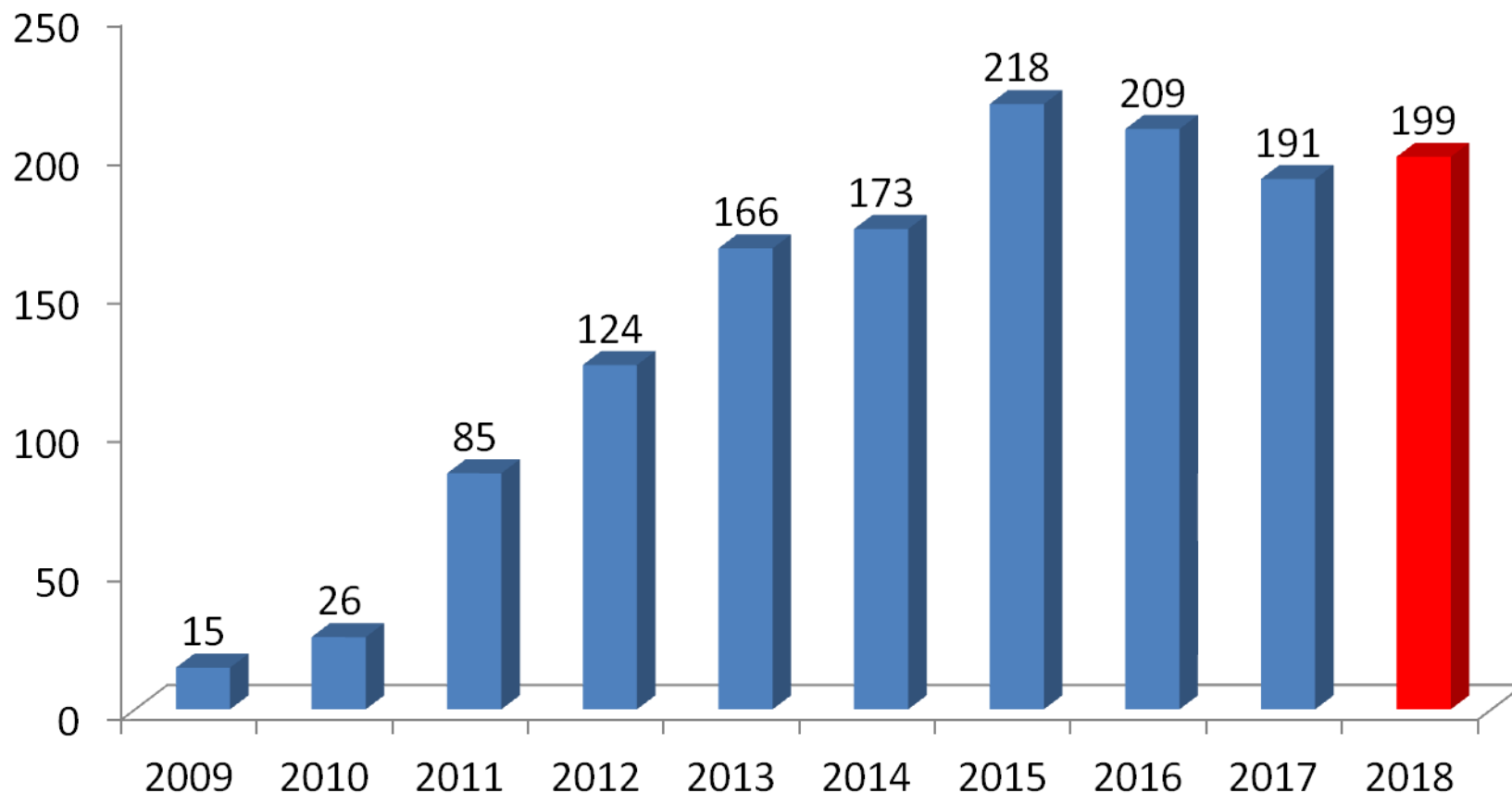


# Results of the Voluntary Harmonisation Procedure 2009 – 2018

HMA's Clinical Trials Facilitation  
Group

Status 1.1.2019

# No. of initial VHPs per submission year



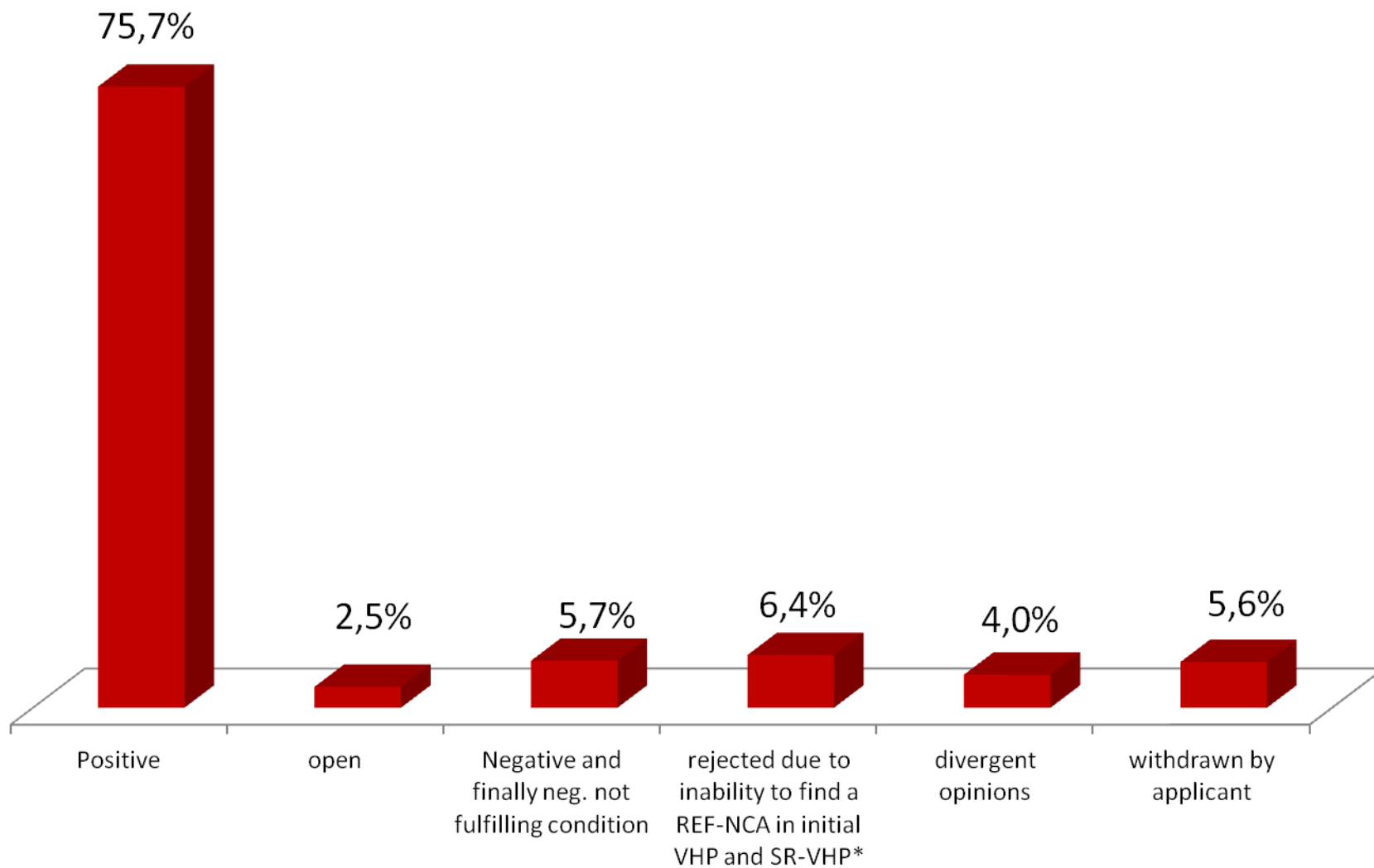
The graph depicts evaluable Voluntary Harmonisation Procedures excluding 11 procedures from the pandemic influenza situation in 2009

## **2013 to 2018**

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

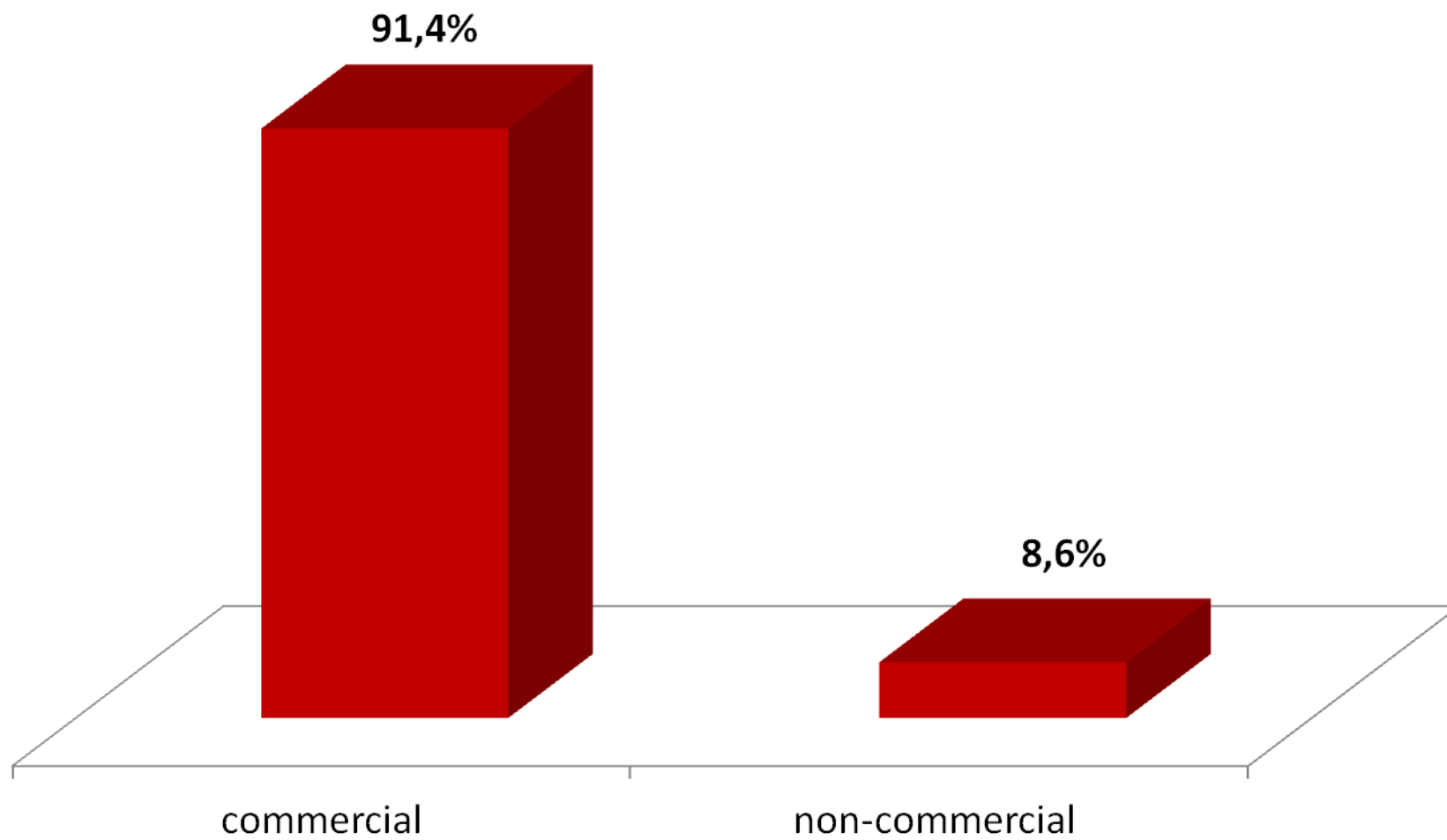
Status 1.1.2017

## Percentages of VHP decisions from 3/2009 to 1.2.2019



\*rejection to participate in 2nd waves (SR-VHP (21) and cases where no REF-NCA (70) 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>551</b>
<b>SWITZERLAND</b>	<b>222</b>
<b>Germany</b>	<b>188</b>
<b>UNITED KINGDOM</b>	<b>97</b>
<b>FRANCE</b>	<b>90</b>
<b>DENMARK</b>	<b>64</b>
<b>BELGIUM</b>	<b>56</b>
<b>SWEDEN</b>	<b>34</b>
<b>SPAIN</b>	<b>18</b>
<b>ITALY</b>	<b>11</b>
<b>AUSTRIA</b>	<b>13</b>
<b>NETHERLANDS</b>	<b>13</b>
<b>IRELAND</b>	<b>14</b>
<b>CANADA</b>	<b>11</b>
<b>JAPAN</b>	<b>7</b>
<b>ISRAEL</b>	<b>5</b>
<b>AUSTRALIA</b>	<b>4</b>
<b>CZECH REPUBLIC</b>	<b>6</b>
<b>SINGAPORE</b>	<b>3</b>
<b>LUXEMBOURG</b>	<b>2</b>
<b>Portugal, Taiwan, Ukraine, Iceland</b>	<b>1</b>

**The total number of different sponsors is 330**

**25 sponsors use VHP often >10-100 times**

Status 1.2.2019

# Member States joining the VHP

mean of Member States per Voluntary Harmonisation Procedure (Without SR-VHP) n=1243	7
min	2
max	22

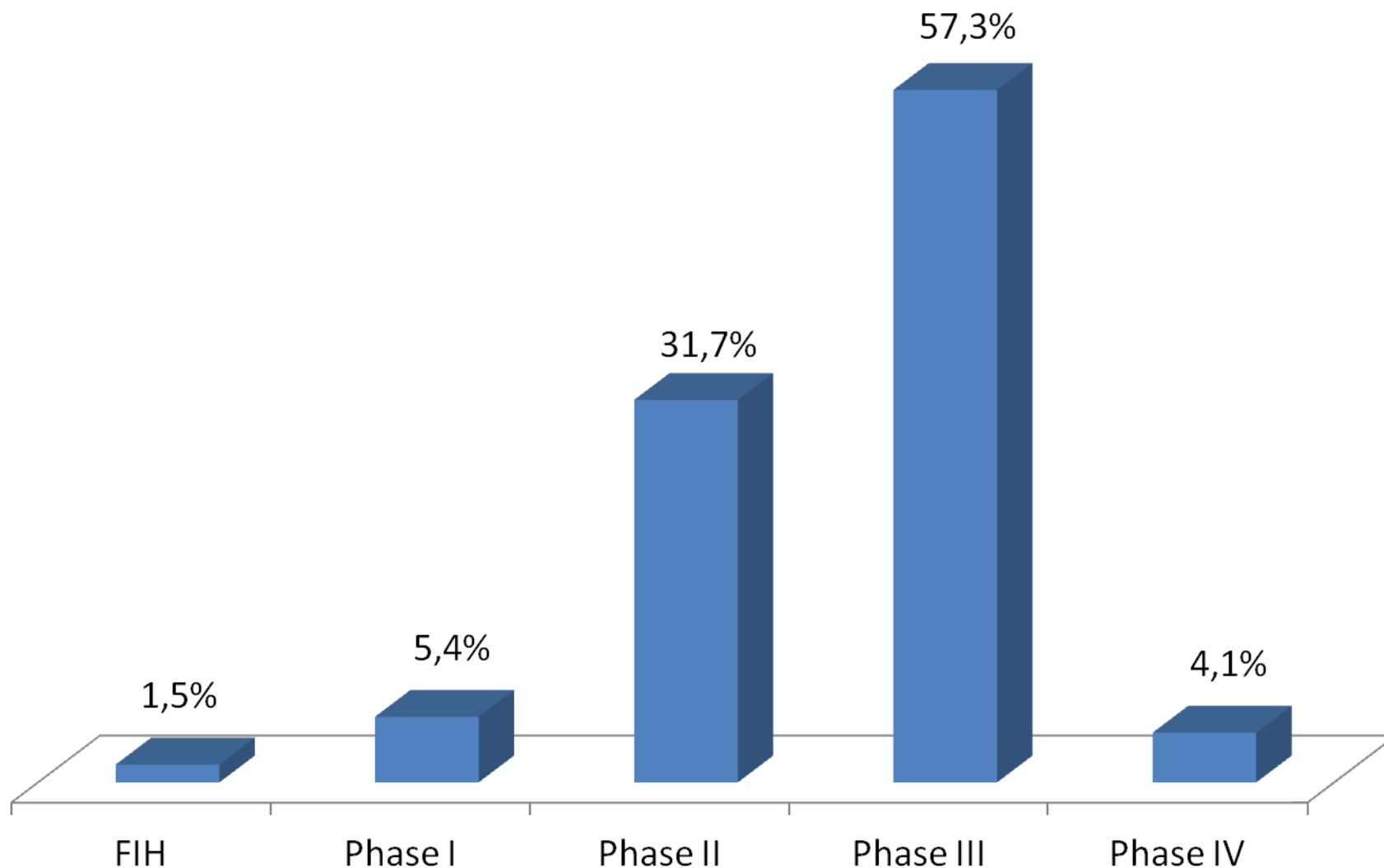
# Distribution of IMPs

## 1.2.2019

Group IMP	Percentage
Chemicals	51,0
Biologicals	49,0

# Distribution of VHPs by phase of the clinical trial

Status 1.1.2019

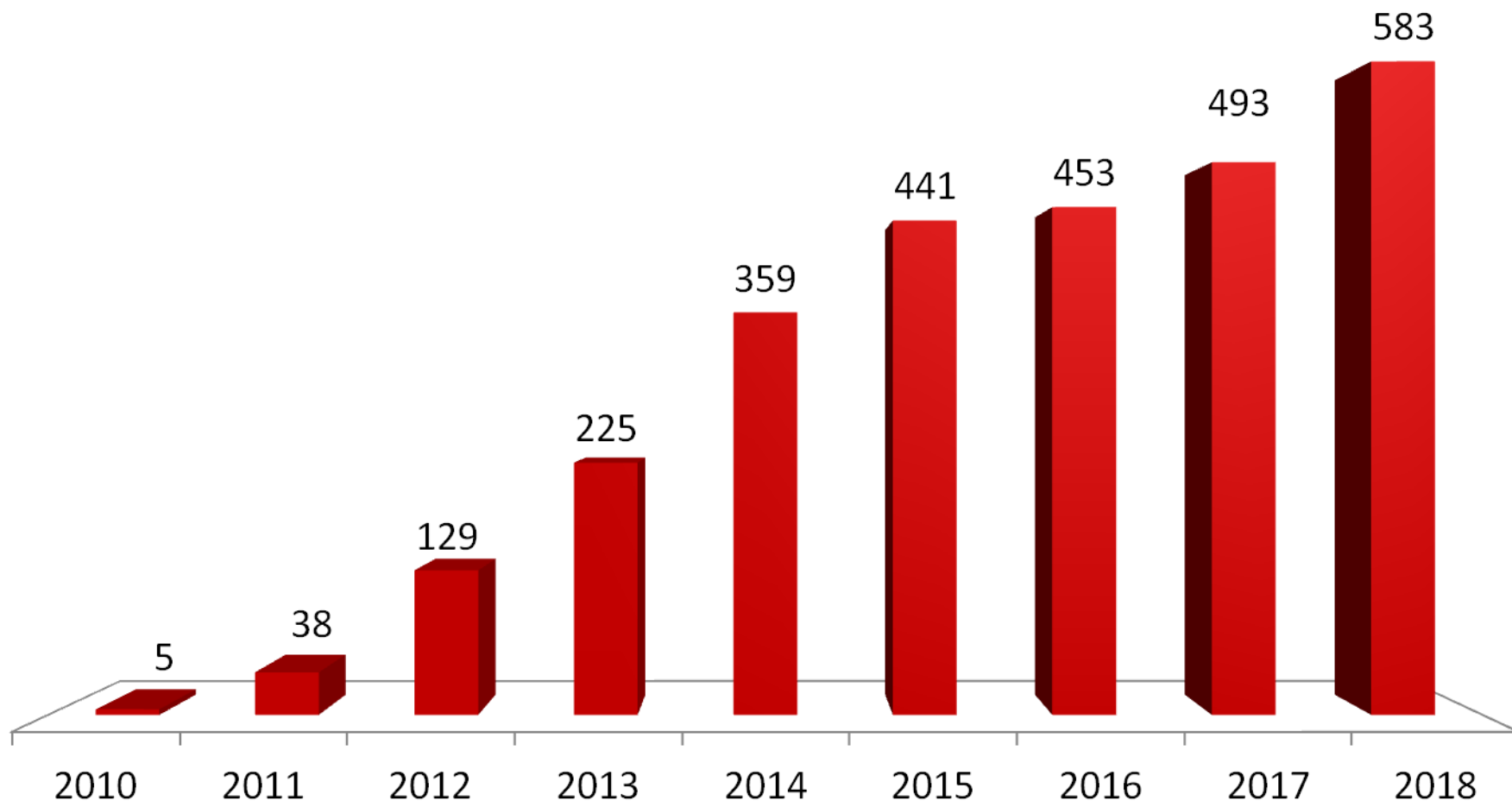


# Status of the IMP

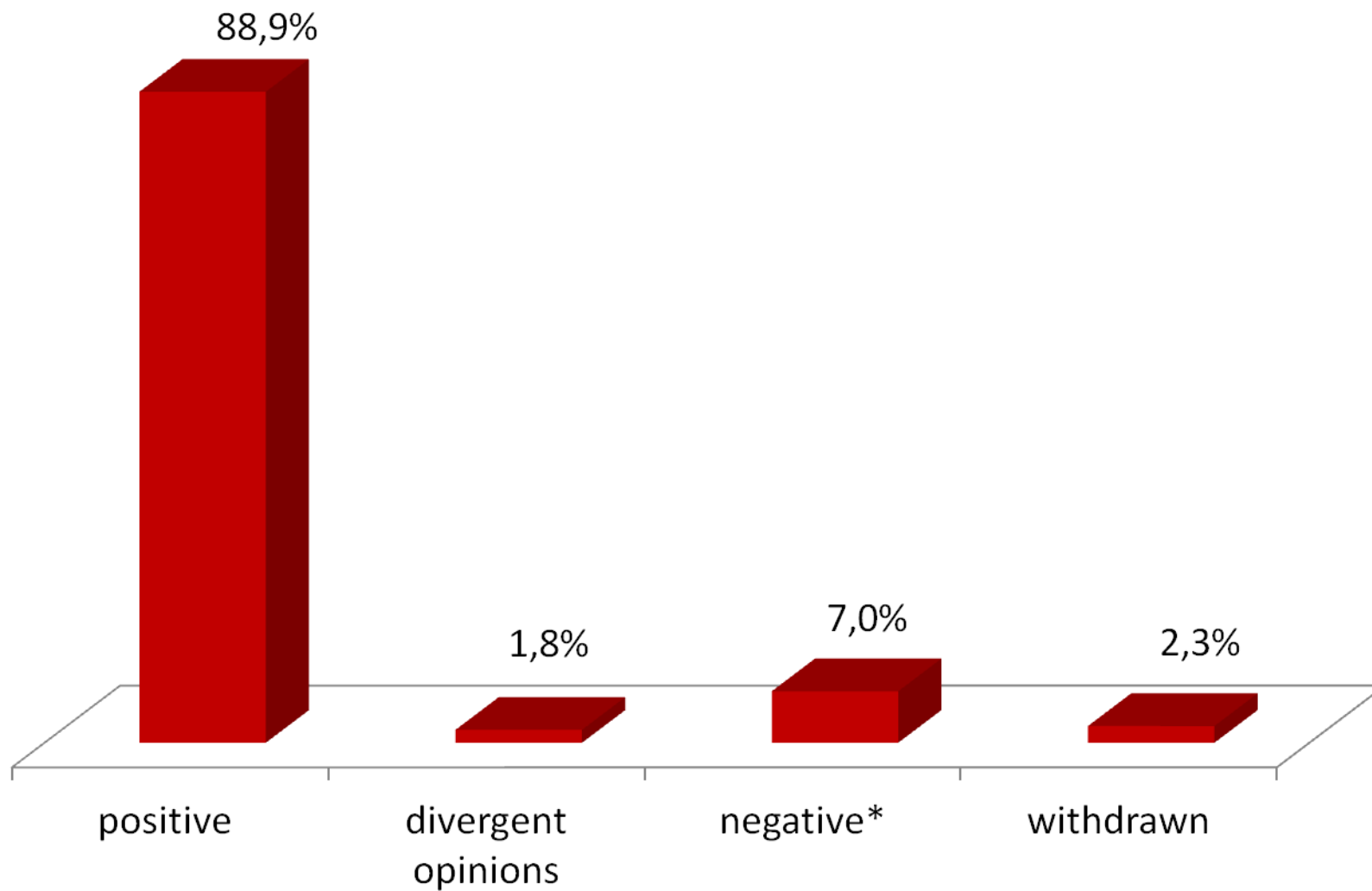
Status 1.1.2019

Status marketing authorisation	Percentage
authorised	19%
non-authorised	81%

# Numbers of VHP-Substantial Amendments 2009 – 1.1.2019

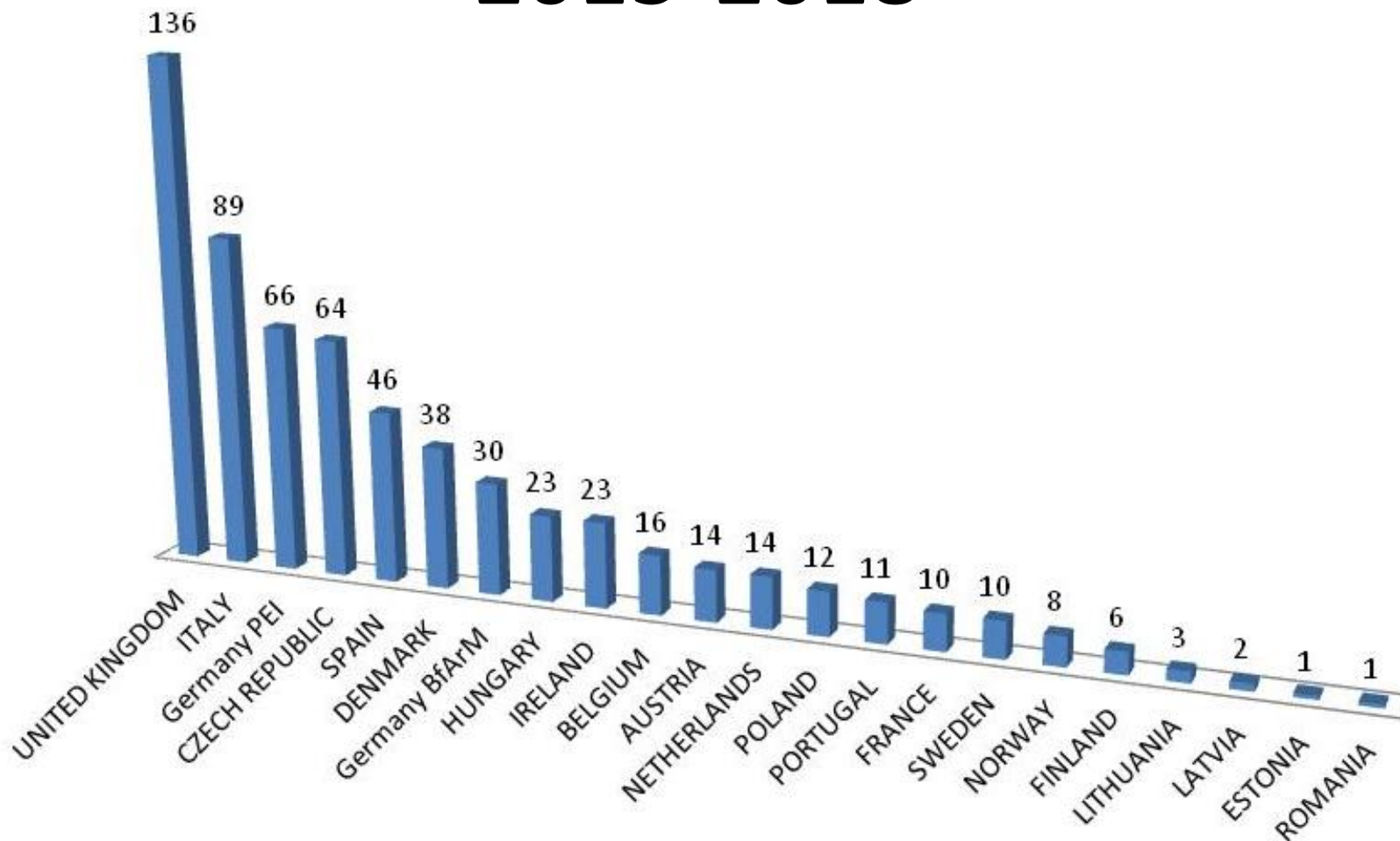


# Percentages of VHP SA decisions from 3/2009 to 01.02.2019



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

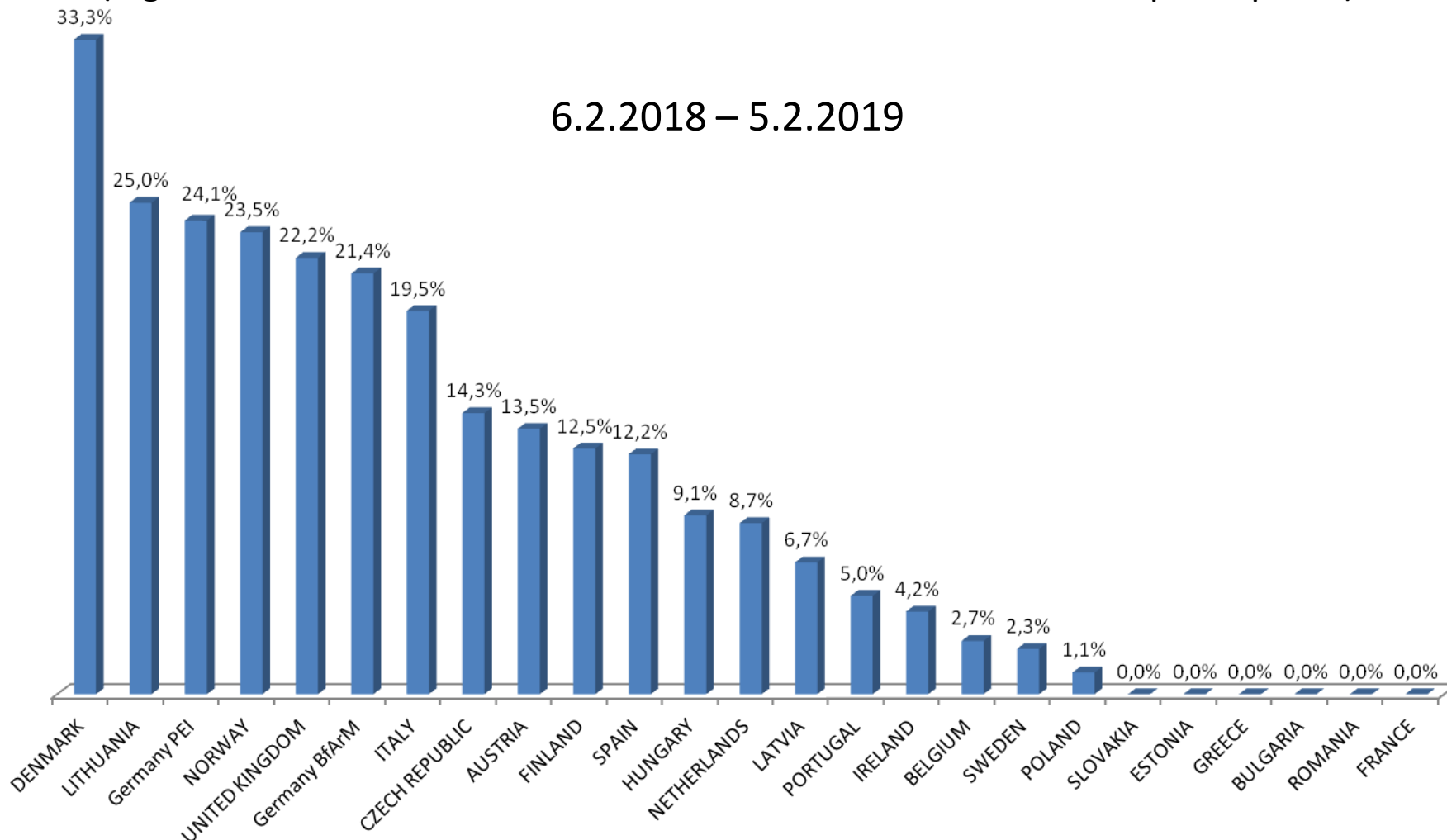
# Number of VHP as REF-NCA per NCA 2015-2018



# Priority i.e. Number of VHPs divided by REF-NCA- ships of the last 365 days

(e.g. Denmark was the REF-NCA in 33,3% of the VHPs, in which it participated)

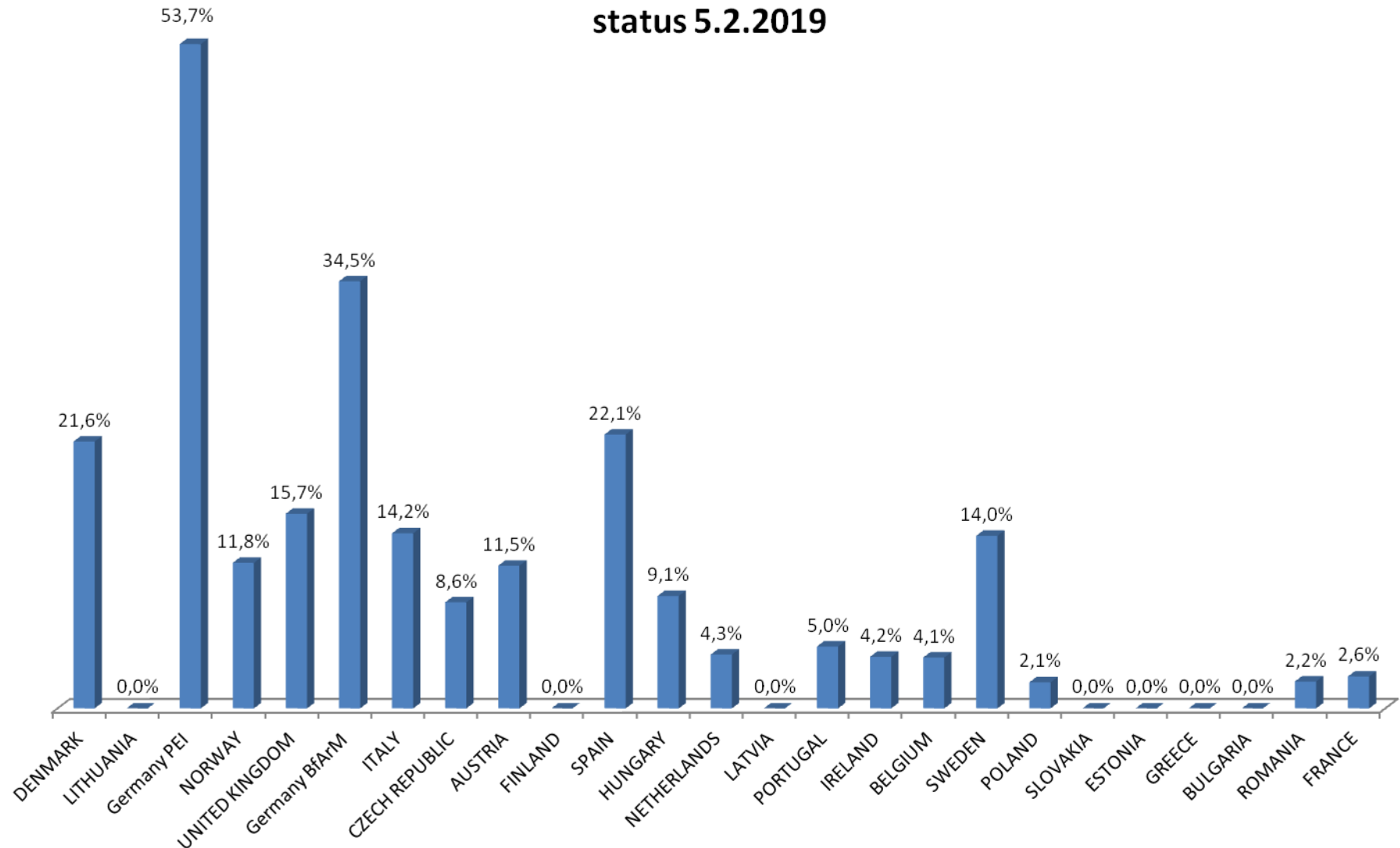
6.2.2018 – 5.2.2019



# % sponsor proposal in **nominated** VHPs of the last 365 days

e.g. Denmark was proposed by sponsors in 21,6% of VHPs in which it participated

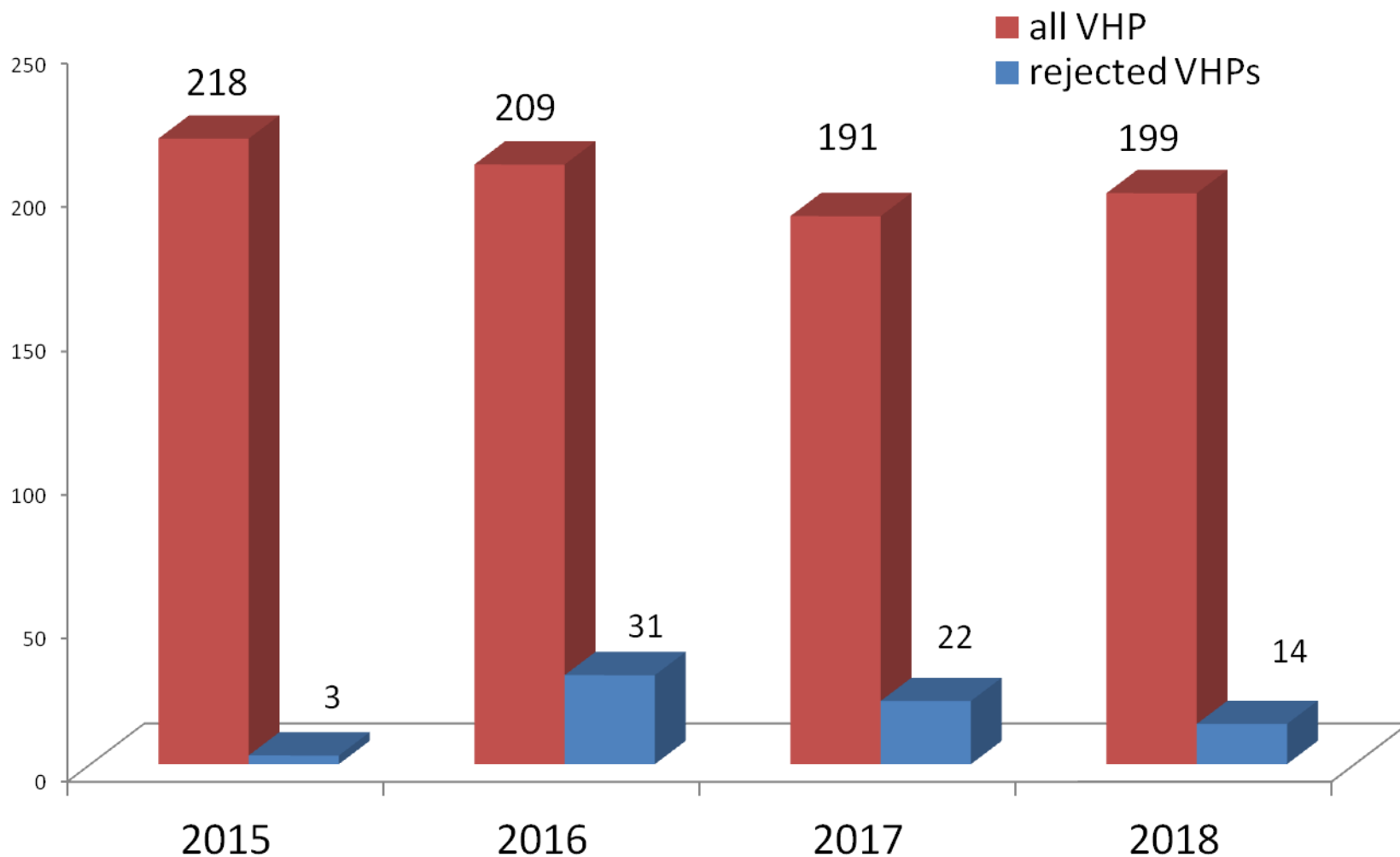
status 5.2.2019



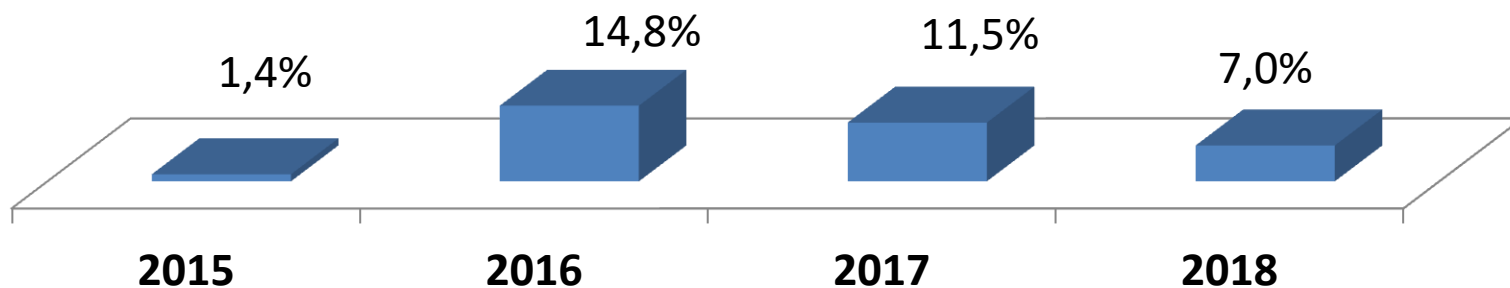
# **Rejections due to lack of REF-NCA**

**DETERMINED BY CTFG-ALGORITHM PRIORITY AND NOT BY  
SPONSOR PRIORITY**

# rejections due to lack of REF-NCA



# % rejections due to lack of REF-NCA



N.B. A proactive measure to avoid rejections was introduced late 2017 and works

questions / comments can be sent via  
mail to

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