



EUROPEAN MEDICINES AGENCY  
SCIENCE MEDICINES HEALTH

# Orphan Medicines Figures

2000-2015

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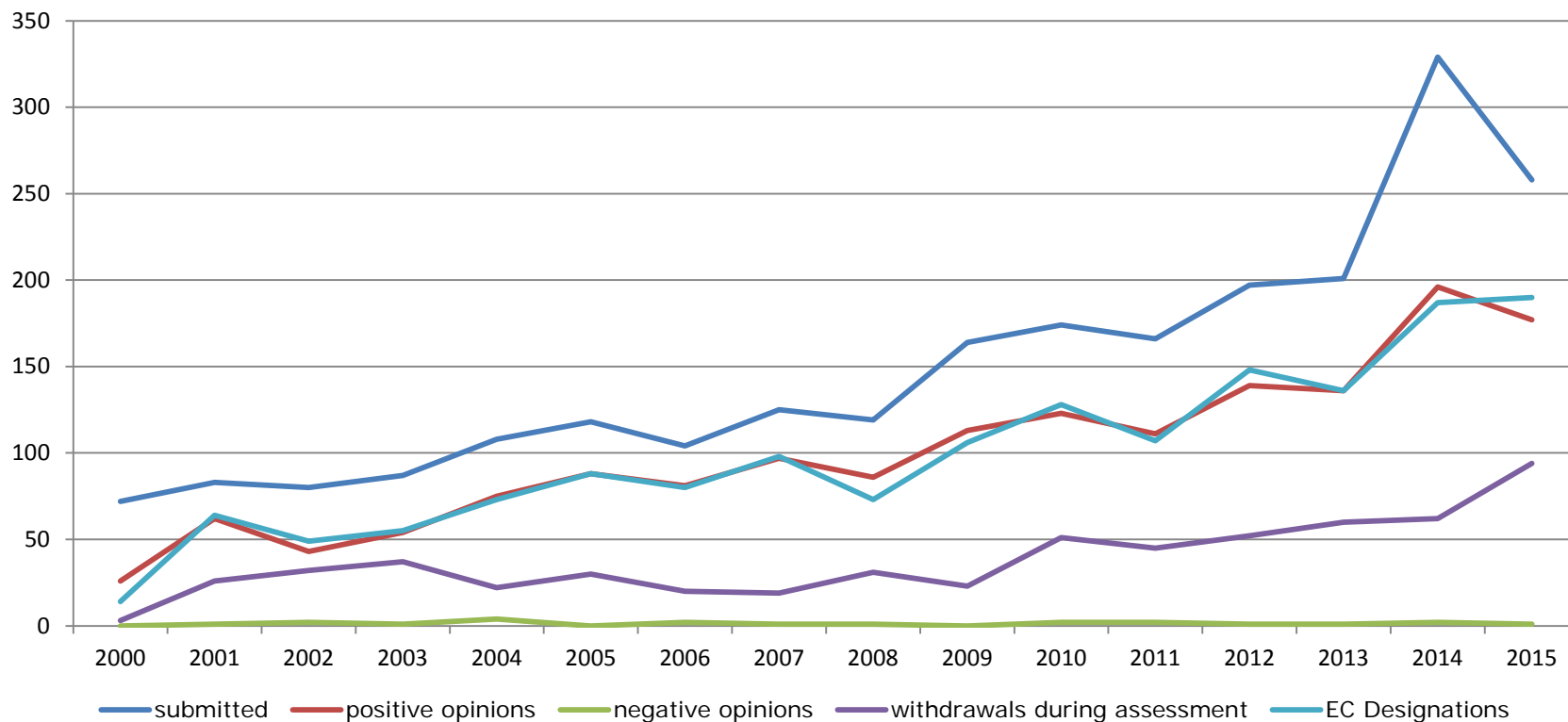


# Status of Orphan Applications

	2000 2005	2006 2010	2011	2012	2013	2014	2015	Total
Applications submitted	548	686	166	197	201	329	258	2385
Positive COMP Opinions	348	500	111	139	136	196	177	1607
Negative COMP Opinions	8	6	2	1	1	2	1	21
EC Designations	343	485	107	148	136	187	190	1596
Withdrawals during assessment	150	144	45	52	60	62	94	607



# Status of Orphan Applications

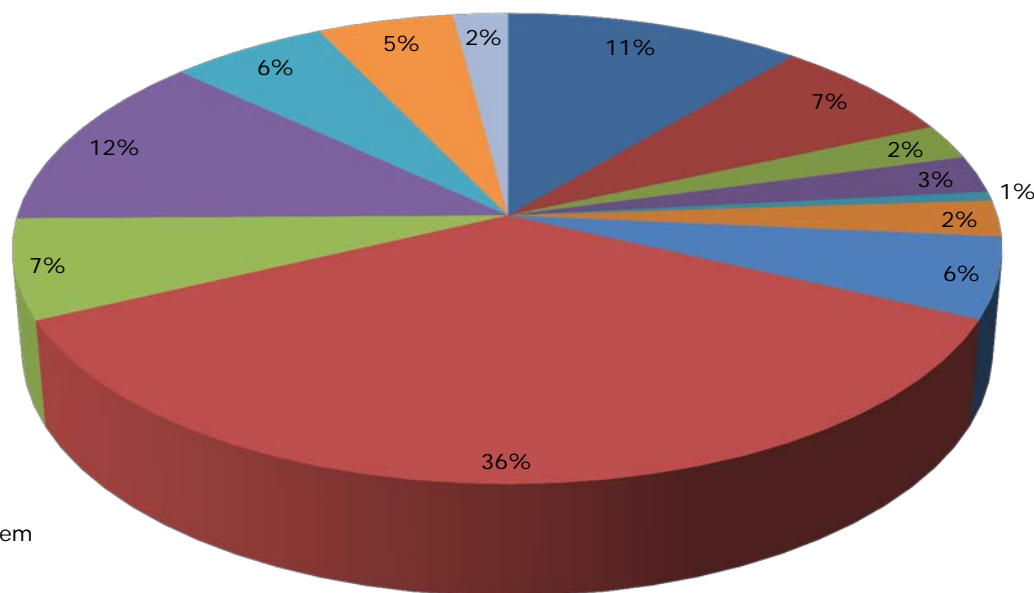




# Distribution of Opinions by therapeutic area from year 2000 – 2015 Total opinions 1607

## ATC codes

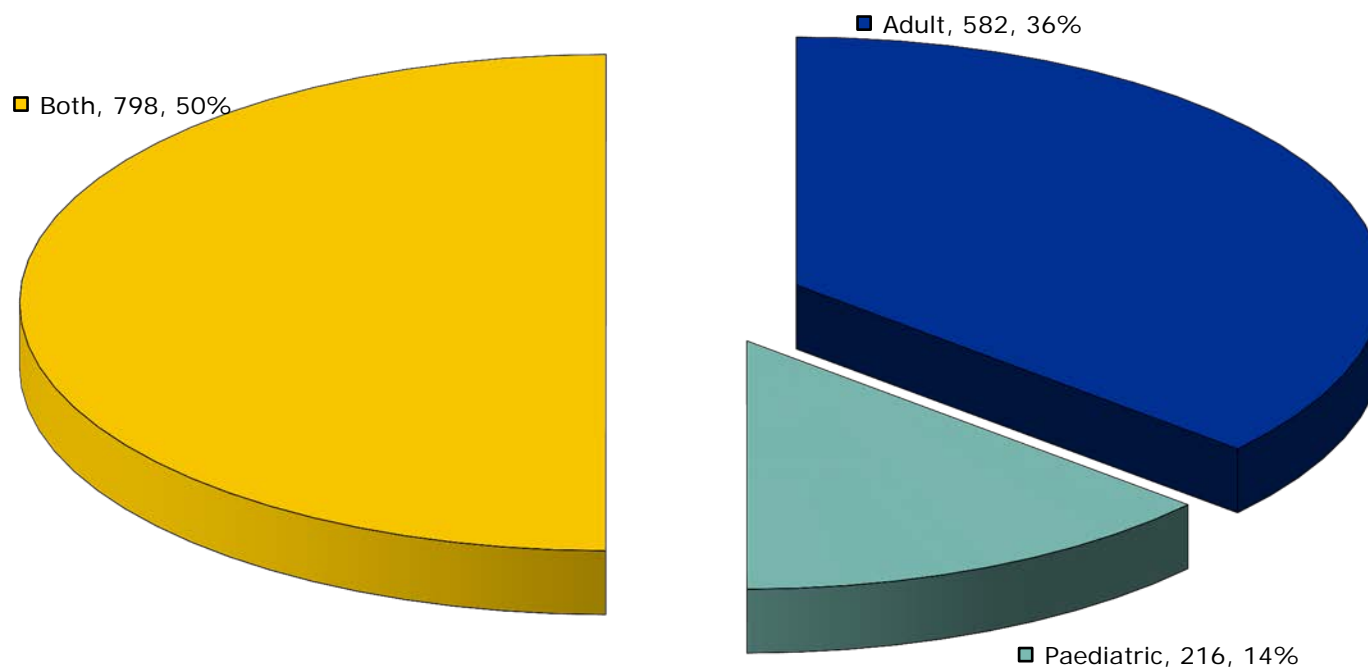
- A- alimentary tract & metabolism
- B - blood & blood forming organs
- C - cardiovascular system
- D - dermatology
- G - genito urinary tract
- H - systemic hormonal preparations
- J & P - antiinfectives & antiparasitic
- L - antineoplastic agents
- L - immunomodulating agents
- M & N - musculoskeletal & nervous system
- R - respiratory system
- S - sensory organs
- V - various





# Adult/Paediatric Use

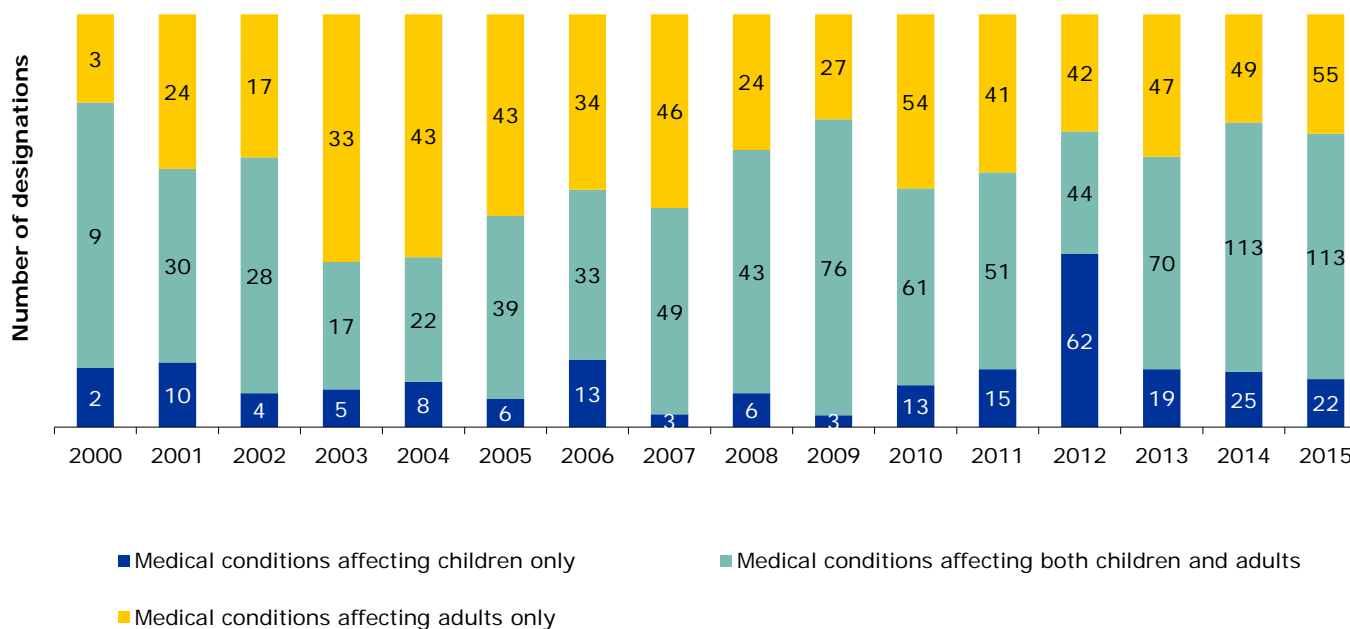
1596 designations from 2000 - 2015





# Adult/Paediatric Use

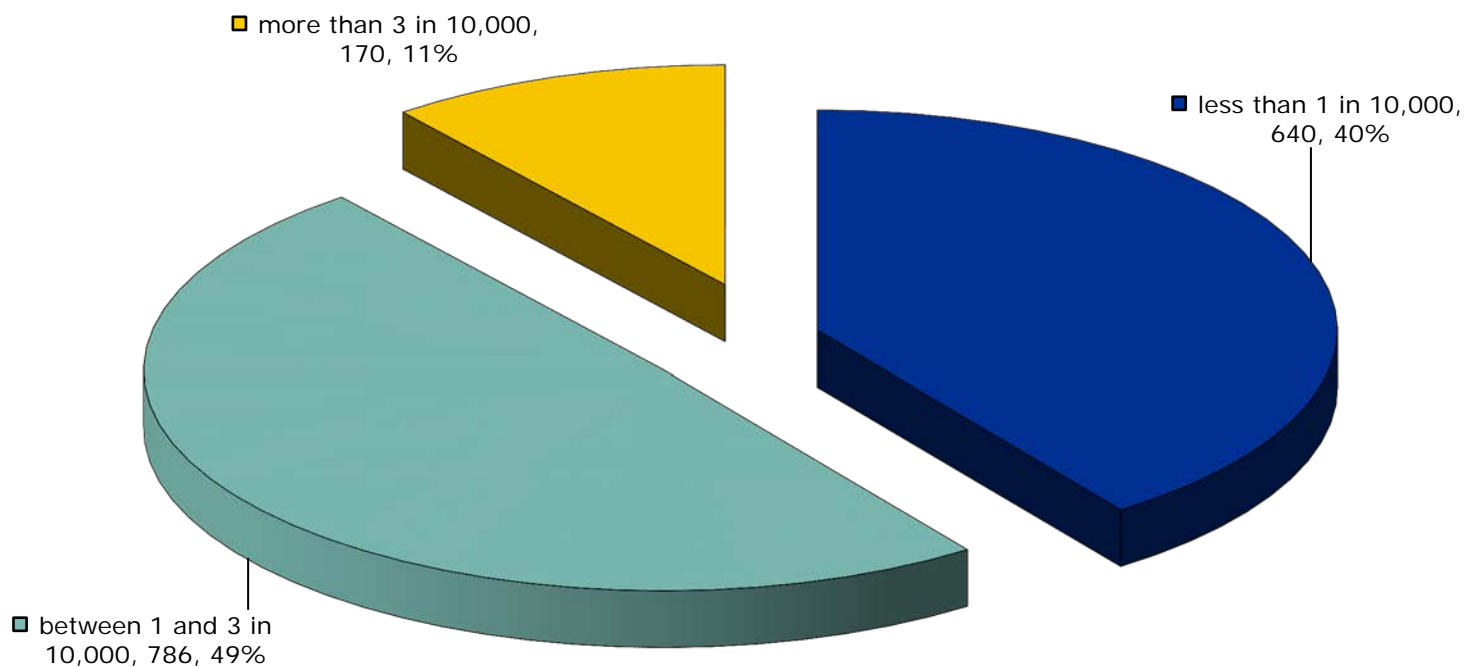
## 1596 designations from 2000 - 2015





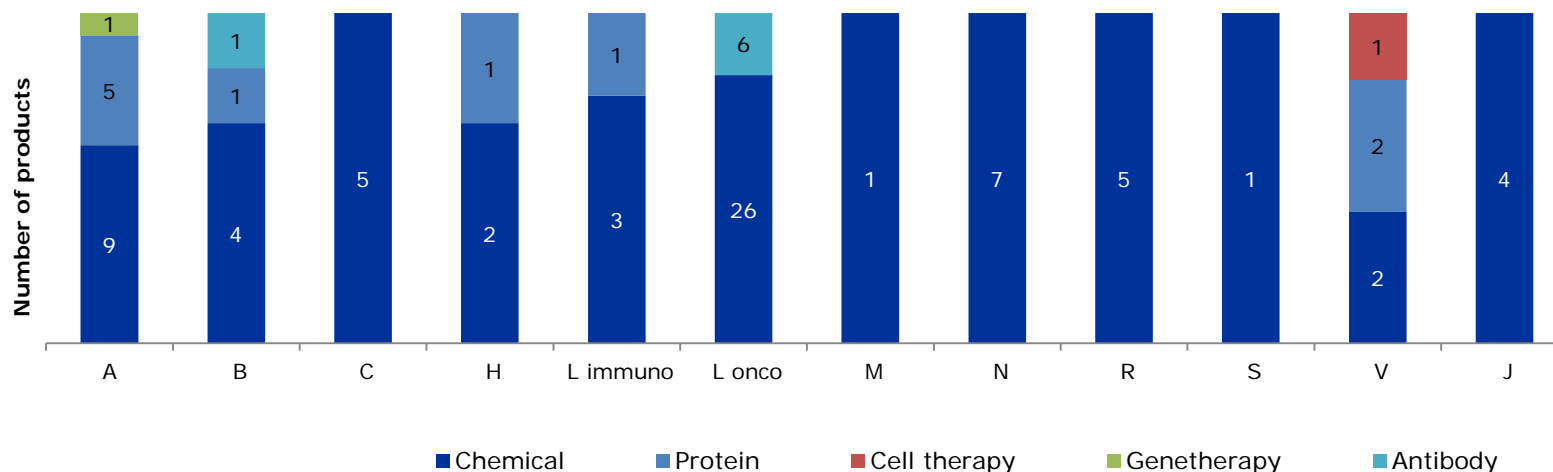
# Prevalence Designated Conditions

1596 designations from 2000 - 2015





# Indications and type of product excluding extension of indications/ variations Period 2000- July 2015



### Therapeutic area

A - alimentary tract & metabolism

H - systemic hormonal preparations

M & N - musculoskeletal & nervous system

V - various

B - blood & blood forming organs

L - antineoplastic agents

R - respiratory system

J & P - anti-infectives & antiparasitic

C - cardiovascular system

L - immunomodulating agents

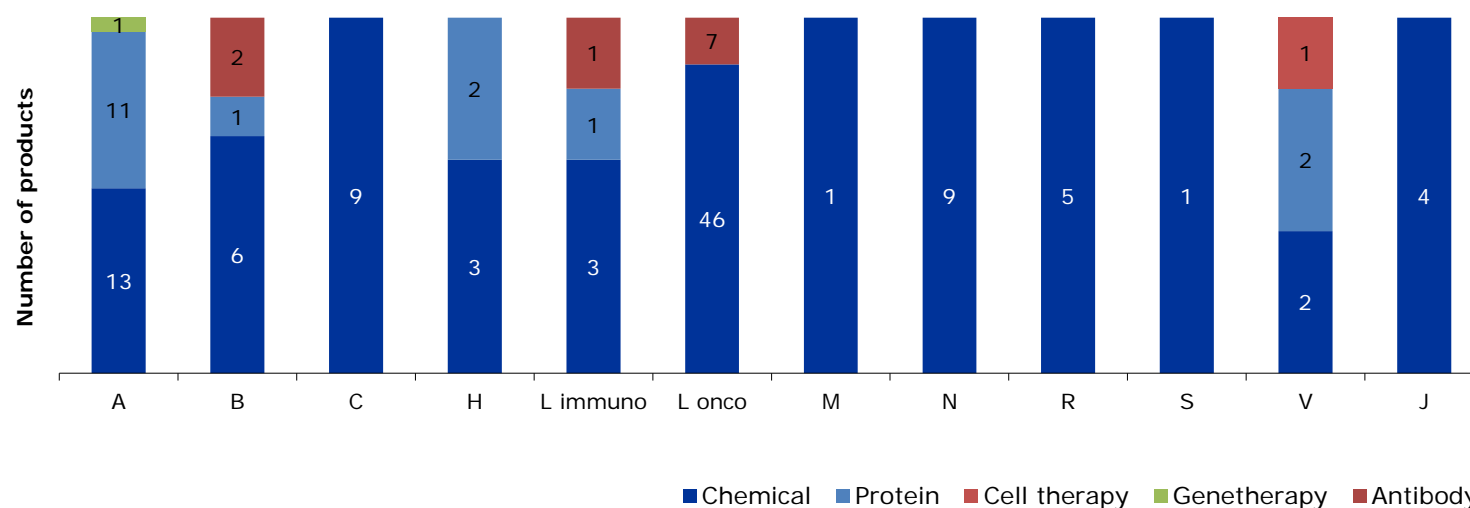
S - Sensory Organs

88 authorisations including 4 withdrawals from the register of medicinal products human use





# Indications and type of product including extension of indications Period 2000- July 2015



### Therapeutic area

A - alimentary tract & metabolism

H - systemic hormonal preparations

M & N - musculoskeletal & nervous system

V - various

B - blood & blood forming organs

L - antineoplastic agents

R - respiratory system

J & P - antiinfectives & antiparasitic

C - cardiovascular system

L - immunomodulating agents

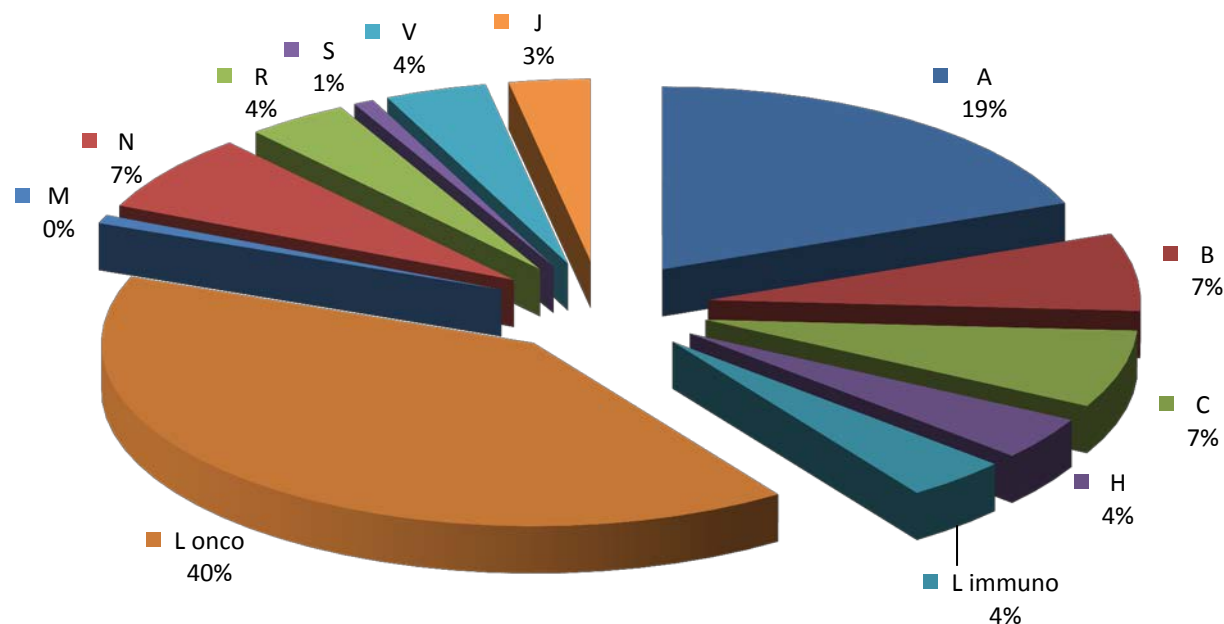
S - Sensory Organs

131 products including the withdrawals from register of orphan medicinal products, register medicinal products human use and expired orphan status



# Distribution of Orphan MAA 114 granted to date\* Period 2000-2015

- A** Alimentary tract and metabolism
- B** Haematology
- C** Cardiovascular system
- H** Systemic hormonal
- J** Antiinfectives for systemic use
- L** Immunology
- L** Antineoplastic
- M** Musculo-skeletal system
- N** Nervous system
- R** Respiratory system
- S** Sensory organs
- V** Various



Number of conditions: 94

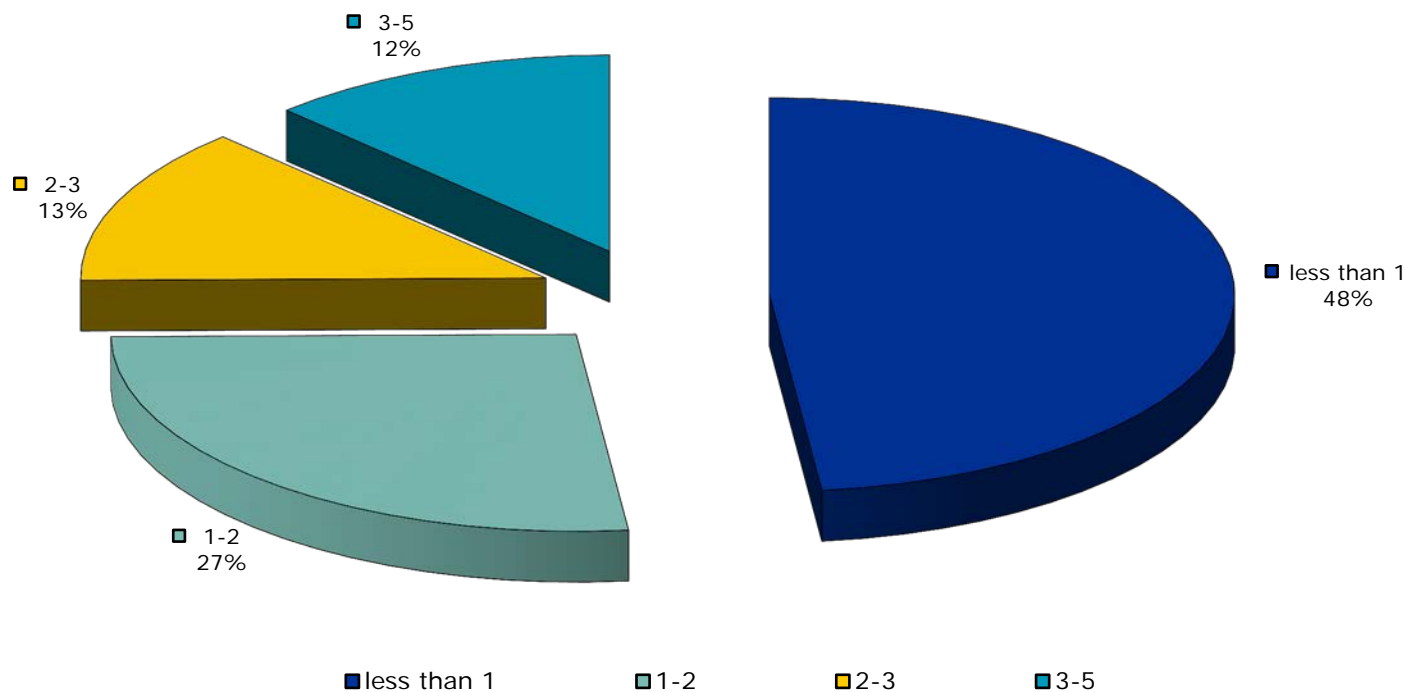
\* Including:  
 10 authorised extensions of indication  
 14 withdrawals from the register of orphan medicinal products (including 7 ext. of indication)  
 4 withdrawals from register medicinal products human use  
 19 removals from register after expire of the market exclusivity period



# Prevalence Period 2000-2015

## Prevalence per 10,000 All orphan products

Including products later withdrawn and extension of indication





# Thank you for your attention

## Further information

orphandrugs@ema.europa.eu

### **European Medicines Agency**

30 Churchill Place • Canary Wharf • London E14 5EU • United Kingdom

**Telephone** +44 (0)20 3660 6000 **Facsimile** +44 (0)20 3660 5555

**Send a question via our website** [www.ema.europa.eu/contact](http://www.ema.europa.eu/contact)

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