



TEDDY Network activities and plan of action

TEDDY EPMD 2016 Report

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Paediatric medicines in Europe: data from European Paediatric Medicines Database

A database containing information on paediatric drugs authorised by the European Medicine Agency (EMA) under the centralised procedure. It is aimed to create a harmonised, integrated and reliable European source of information on paediatric medicines in Europe



European Paediatric Medicines Database (EPMD)

Search an active substance by ATC code

Insert the exact or partial ATC code or build it by above dropdown menu, then use the search button to get the results.

ATC Code:

Anatomical main group:

Therapeutic subgroup:

Active substances found: 15

Active substance
C1 inhibitor (human)
Catridecacog
coagulation factor IX
darbepoetin alfa
Defibrotide
Epoetin alfa

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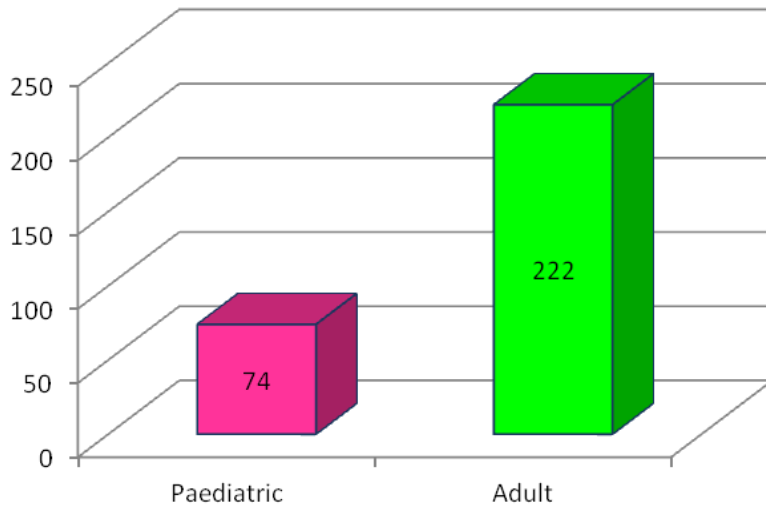
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In EU only ~ 30% of marketed drugs includes in their documentation (SmPC or PL) information on paediatric use.

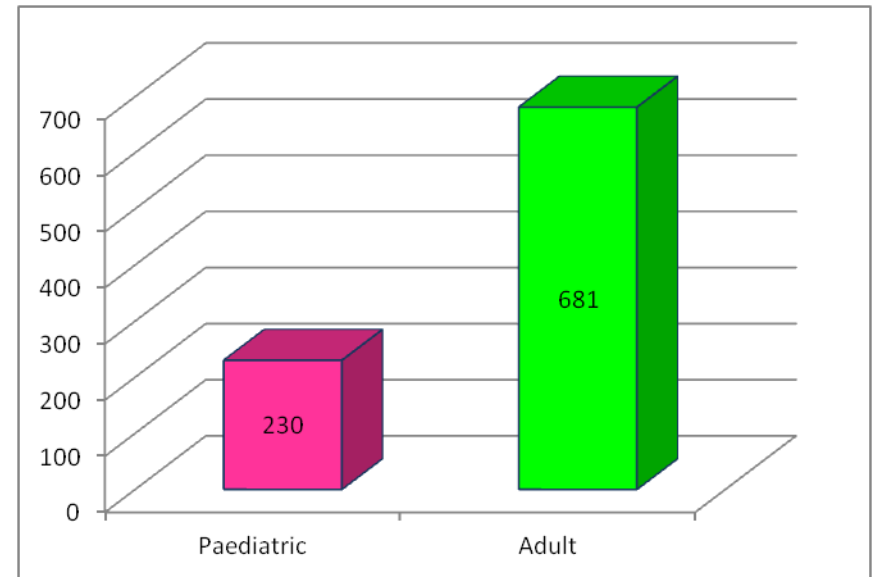
After 10 years from the entry into force of the Paediatric Regulation, the number of paediatric medicines has tripled, but they remain ~ 1/3 of all the centrally authorised medicines

Centrally-approved medicines up to 2003



Ceci A. and al, on behalf of TEDDY NoE, EJCP, 2006

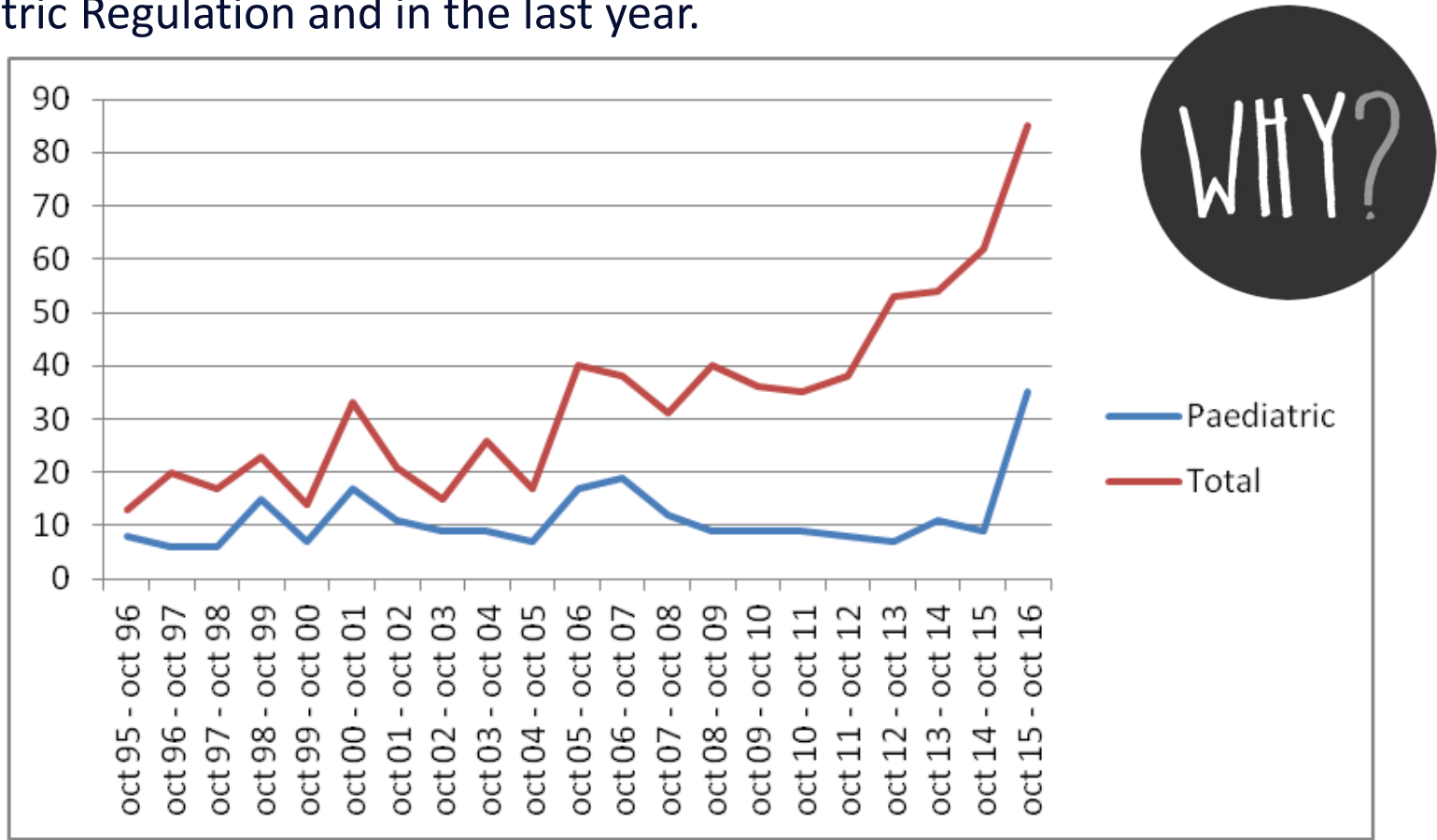
Medicines approved up to 2016



European Paediatric Medicines Database, update October 2016

Paediatric medicines in EU – trends by year

No clear trend: increase observed for 2 years after the entry into force of the Paediatric Regulation and in the last year.

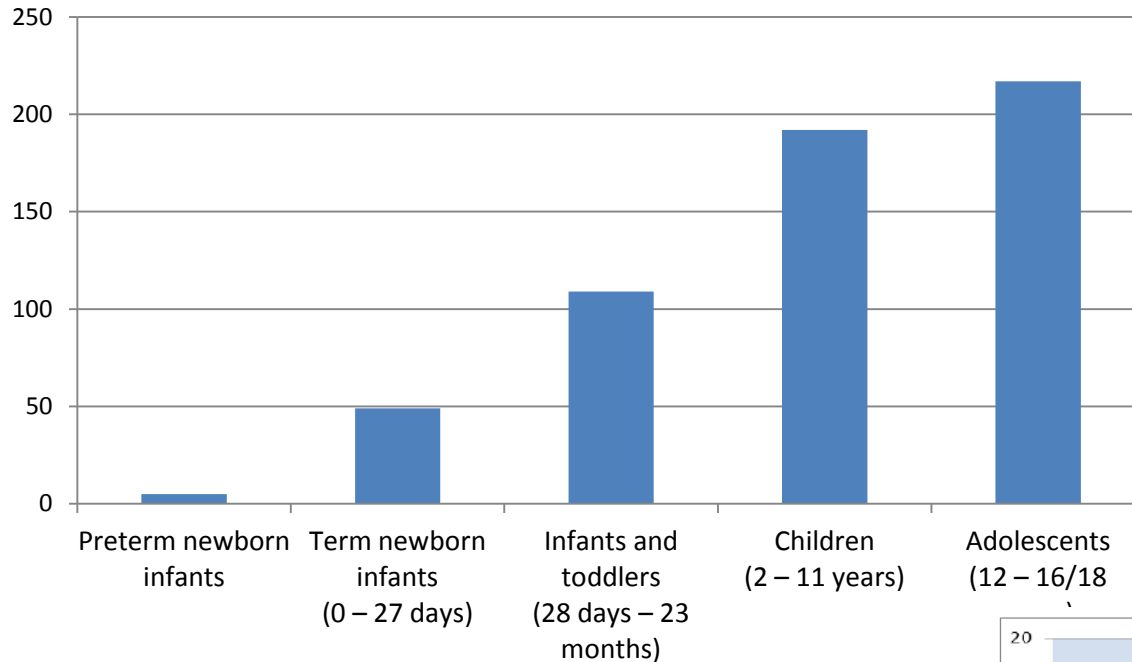


Paediatric medicines – distribution by ATC

- Anti-infectives for systemic use drugs have the highest ratio on the total of authorised medicines
- The drugs of the genitourinary system and sex hormones, and drugs for musculoskeletal system have the lowest ones

	Paediatric/Total	
	N	%
A -Alimentary tract and metabolism	33/81	41
B - Blood and blood forming organs	20/56	36
C - Cardiovascular system	5/38	13
D - Dermatologicals	3/9	33
G - Genito-urinary system and sex hormones	1/27	4
H - Systemic hormonal preparations, excluding sex hormones and insulins	3/12	25
J - Anti-infectives for systemic use	91/134	68
L - Antineoplastic and immunomodulating agents	34/155	22
M - Musculo-skeletal system	1/19	5
N - Nervous system	14/57	25
P -Antiparasitic products, insecticides and repellents	1/1	100
R - Respiratory system	9/24	38
S - Sensory organs	3/21	14
V -Various	9/41	22
Not assigned yet	3/6	50
TOTAL	230/681	34%

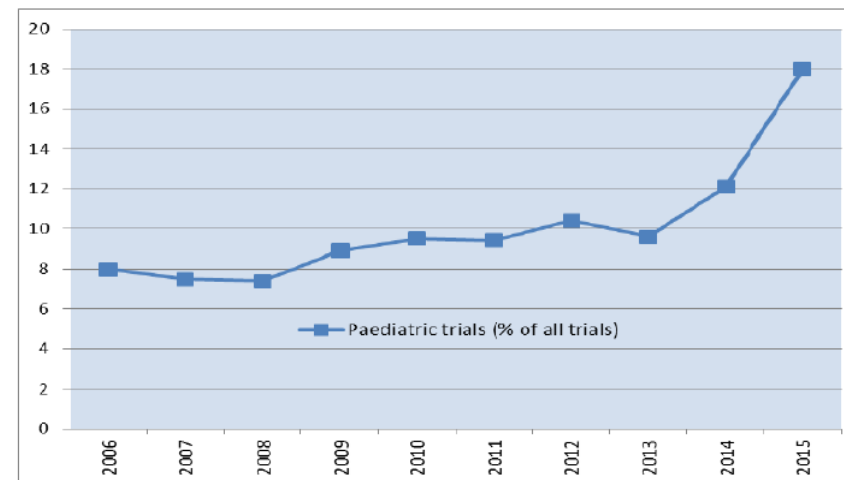
Paediatric medicines – distribution by age



It still persists a paucity of medicines approved for preterm and term newborns

Despite this, the number of trials conducted in the paediatric population has increased.

Neonates are more and more considered in paediatric clinical research

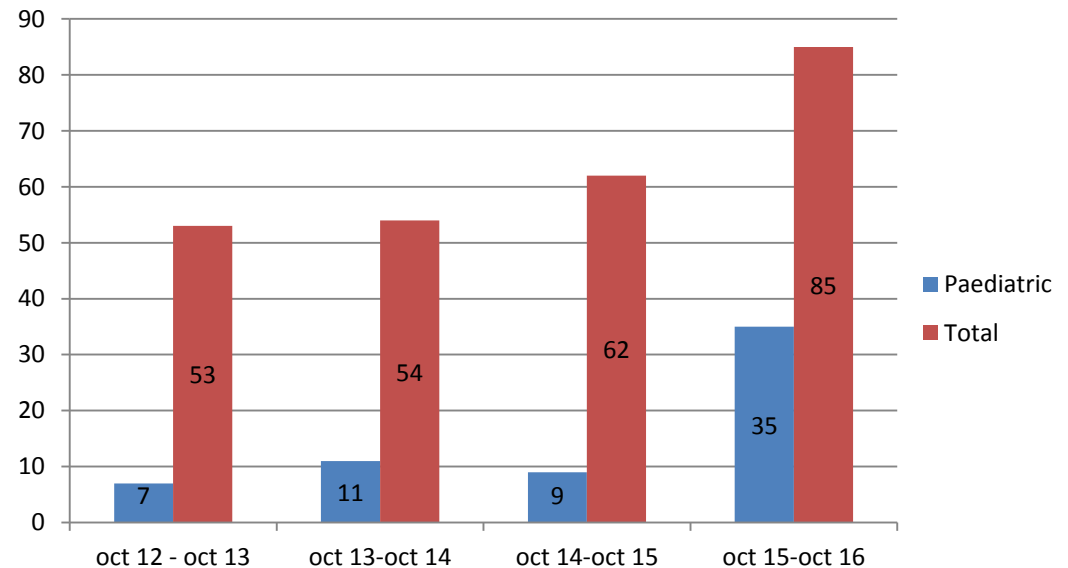


An insight on the last year...

In the last year, a higher number of centrally-approved paediatric medicines. More in details:

35/85 medicines having a paediatric indication (41%)

- 5 generics, 1 biosimilar: 29 new active substances
- 6 orphan medicinal products
- 9 medicines have been approved for use in all ages, including newborns



An insight on the last year...

Distribution by ATC: almost the same trend of the global period, with some exceptions

	Oct 2015- Oct 2016	
	Paediatric/Total	
	N	%
A -Alimentary tract and metabolism	7/10	70
B - Blood and blood forming organs	7/12	58
C - Cardiovascular system	1/3	33
D - Dermatologicals	0/1	0
G - Genito-urinary system and sex hormones	1/1	100
H - Systemic hormonal preparations, excluding sex hormones and insulins	0/2	0
J - Anti-infectives for systemic use	10/11	90
L - Antineoplastic and immunomodulating agents	4/29	14
M - Musculo-skeletal system	0/1	0
N - Nervous system	3/8	37
P -Antiparasitic products, insecticides and repellents	0/0	0
R - Respiratory system	1/5	20
S - Sensory organs	0/0	0
V -Various	0/2	0
Not assigned yet	1/1	0
TOTAL	35/85	41%

Delay in Marketing Paediatric Medicines

Year from the first MA	1	2	3	4	6	7	8	9	10
EDURANT rilpivirine									
CUBICIN daptomycin									
EMEND aprepitant									
REVOLADE eltrombopag									
HYQVIA H normal Ig									

Lights and Shadows.....

Expected Delay in Marketing Paediatric Medicines

ACTIVE SUBSTANCE	CONDITION(S)	THERAPEUTIC AREA	PIP	DEFERRED MEASURES
Adeno-associated vector expressing the (human) lipoprotein lipase	Familial lipoprotein lipase deficiency	Inborn errors of metabolism	Yes (patients aged 2-18 yrs)	Date of completion: December 2021
Afamelanotide	Erythropoietic protoporphyria	Inborn errors of metabolism	Yes (patients aged 2-18 yrs)	Date of completion: June 2022
Brentuximab vedotin	Anaplastic large cell lymphoma	Oncology	Yes (patients aged 2-18 yrs)	Date of completion: December 2020
	Hodgkin lymphoma (Hodgkin's disease)	Oncology	Yes (patients aged 5-18 yrs)	Date of completion: December 2020
Ex vivo expanded autologous human corneal epithelium containing stem cells	Limbal stem cell deficiency	Ophthalmology	Yes (patients aged 2-18 yrs)	Date of completion: May 2020
Recombinant megakaryopoiesis-stimulating protein	Immune thrombocytopenic purpura	Haematology	Yes (patients aged 1-18 years)	Date of completion: January 2019
Rituximab	Non-Hodgkin's lymphoma	Oncology	Yes (patients aged 2-18 yrs)	Date of completion: May 2018
Teduglutide	Short bowel syndrome	Gastrointestinal and hepatobiliary diseases	Yes (patients 4 months-18 years)	Date of completion: June 2018



Conclusions

- After 10 years, the principal aim of the Paediatric Regulation is partially achieved
- Inequality between adults and children is still relevant
- Advantages should be better distributed among all the therapeutic categories and the paediatric ages
- There is the need to increase the efforts to not reduce the Paediatric Regulation's effects.