AMENDMENTS
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Draft motion for a resolution
Giovanni La Via, Françoise Grossetête, Elena Gentile, Boleslaw G. Piecha, Frédérique Ries, Stefan Eck, Joëlle Mélin
(PE589.147v01-00)

on the Regulation on Paediatric Medicines
Amendment 1
Ivan Jakovčić

Draft motion for a resolution
Citation 1 a (new)

Draft motion for a resolution

Amendment

— having regard to Regulation (EC) No 1901/2006 (‘Paediatric Regulation’), which entered into force on 1 January 2007 with the objective of improving children’s health through clinical studies, facilitating their development and improving the availability of safe and effective medicines intended for children,

Or. hr

Amendment 2
Michèle Rivasi
on behalf of the Verts/ALE Group

Draft motion for a resolution
Citation 3 a (new)

Draft motion for a resolution

Amendment

— having regard to the Report of the United Nations Secretary-General’s High Level Panel on access to medicines - Promoting innovation and access to health technologies - published in September 2016;

Or. en

Amendment 3
Notis Marias

Draft motion for a resolution
Citation 5 a (new)
Draft motion for a resolution

Amendment

— having regard to the Protocol (No 1) of the Treaty on the Functioning of the European Union (TFEU) on the role of National Parliaments in the European Union,

Or. el

Amendment 4
Notis Marias

Draft motion for a resolution
Citation 5 b (new)

Draft motion for a resolution

Amendment

— having regard to Protocol (No 2) of the Treaty on the Functioning of the European Union (TFEU) on the application of the principles of subsidiarity and proportionality,

Or. el

Amendment 5
Notis Marias

Draft motion for a resolution
Recital A

Draft motion for a resolution

Amendment

A. whereas the Paediatric Medicines Regulation had a substantial impact on paediatric medicines development as most pharmaceutical companies consider paediatric development to be an integral part of the overall development of a product; whereas the number of paediatric research projects has increased considerably and there is more high quality information available on approved

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medicines; whereas the relative number of paediatric clinical trials has also increased;

Amendment 6
Elena Gentile, Damiano Zoffoli

Draft motion for a resolution
Recital A

A. whereas the Paediatric Medicines Regulation had a substantial impact on paediatric medicines development as most pharmaceutical companies consider paediatric development to be an integral part of the overall development of a product; whereas the number of paediatric research projects has increased considerably and there is more high quality information available on approved medicines; whereas the relative number of paediatric clinical trials has also increased;

Amendment

A. whereas the Paediatric Medicines Regulation had a substantial impact on paediatric medicines development as most pharmaceutical companies consider paediatric development to be an integral part of the overall development of a product; whereas the number of paediatric research projects has increased considerably and there is more high quality information available regarding the paediatric use of approved medicines; whereas the relative number of paediatric clinical trials has also increased;

Or. en

Amendment 7
Frédérique Ries, Jasenko Selimovic, Françoise Grossetête

Draft motion for a resolution
Recital A

A. whereas the Paediatric Medicines Regulation had a substantial impact on paediatric medicines development as most pharmaceutical companies consider paediatric development to be an integral part of the overall development of a product; whereas the number of paediatric

Amendment

A. whereas the Paediatric Medicines Regulation had a substantial impact on paediatric medicines development as most pharmaceutical companies consider paediatric development to be an integral part of the overall development of a product; whereas the number of paediatric
research projects has increased considerably and there is more high quality information available on approved medicines; whereas the relative number of paediatric clinical trials has also increased; research projects has increased considerably and there is more high quality information available on the paediatric use of approved medicines; whereas the relative number of paediatric clinical trials has also increased;
no new treatments in 25 years, a fact which is indicative of the serious shortcomings seen repeatedly in the ways of carrying out research and clinical trials, in spite of the generous subsidies from the EU and some Member States;

Or. fr

Amendment 10
Frédérique Ries, Jasenko Selimovic, Françoise Grossetête

Draft motion for a resolution
Recital B

Draft motion for a resolution

B. whereas the Paediatric Medicines Regulation contributed to improve the overall situation and led to tangible benefits for a series of childhood diseases but not enough progresses were made in a number of fields, in particular in paediatric oncology and neonatology;

Amendment

B. whereas the Paediatric Medicines Regulation has contributed to improve the overall situation and has led to tangible benefits for a series of childhood diseases, but not enough progresses were made in a number of fields, in particular in paediatric oncology and neonatology;

Or. en

Amendment 11
Ivan Jakovčić

Draft motion for a resolution
Recital B a (new)

Draft motion for a resolution

Ba. whereas five years after the implementation of PIP (‘Paediatric Regulation’), the availability of medicines for the paediatric population has increased, while studies on newborns accounted for 30% of some 600 paediatric investigation plans;

Amendment

Ba. whereas five years after the implementation of PIP (‘Paediatric Regulation’), the availability of medicines for the paediatric population has increased, while studies on newborns accounted for 30% of some 600 paediatric investigation plans;

Or. hr
Amendment 12
Elena Gentile, Glenis Willmott, Damiano Zoffoli

Draft motion for a resolution
Recital C

C. whereas childhood cancer remains the first cause of death by disease in children aged one year and over and 6,000 young people die of cancer each year in Europe; whereas two thirds of those who survive suffer from treatment-related side effects (severe for up to 50% of survivors) due to the effects of existing chemotherapy drugs prescribed in highly toxic doses;

Amendment

C. whereas childhood cancer remains the first cause of death by disease in children aged one year and over and 6,000 young people die of cancer each year in Europe; whereas two thirds of those who survive suffer from treatment-related side effects due to existing treatments (severe for up to 50% of survivors) and there is the need to continuously improve the quality of life of childhood cancer survivors;

Or. en

Amendment 13
Joëlle Mélin, Jean-François Jalkh, Sylvie Goddyn

Draft motion for a resolution
Recital C

C. whereas childhood cancer remains the first cause of death by disease in children aged one year and over and 6,000 young people die of cancer each year in Europe; whereas two thirds of those who survive suffer from treatment-related side effects (severe for up to 50% of survivors) due to the effects of existing chemotherapy drugs prescribed in highly toxic doses;

Amendment

C. whereas childhood cancer remains the first cause of death by disease in children aged one year and over and 6,000 young people die of cancer each year in Europe; whereas two thirds of those who survive suffer from treatment-related side effects (severe for up to 50% of survivors) due to the effects of existing chemotherapy drugs, especially when treatments are not properly supervised and/or are used in doses known to be dangerous, sequelae being most likely to develop when treatment includes radiotherapy;

Or. fr
Amendment 14
Nicola Caputo, Doru-Claudian Frunzulică

Draft motion for a resolution
Recital C a (new)

Draft motion for a resolution Amendment

Ca. whereas data collected on the use of a specific medicinal product in the paediatric population should be appropriately communicated to paediatricians so that they can use that information in their daily work to the benefit of their patients;

Or. it

Amendment 15
Joëlle Mélin, Sylvie Goddyn, Jean-François Jalkh

Draft motion for a resolution
Recital D

Draft motion for a resolution Amendment

D. whereas the Paediatric Medicines Regulation fostered increased multi-stakeholder dialogue and cooperation on paediatric medicines development;

D. whereas the Paediatric Medicines Regulation has by no means fostered increased multi-stakeholder dialogue and cooperation on paediatric medicines development;

Or. fr

Amendment 16
Michèle Rivasi
on behalf of the Verts/ALE Group

Draft motion for a resolution
Recital D a (new)
Da. whereas the articles 36 and 37 of the Paediatric Regulation don't impose any patient access conditionality to the incentives;

Or. en

Amendment 17
Notis Marias

Draft motion for a resolution
Recital E

Draft motion for a resolution
Amendment

E. whereas less than 10% of children with a non-curable life-threatening relapse have access to new, experimental drugs in clinical trials from which they could benefit;

Or. el

Amendment 18
Joëlle Mélin, Sylvie Goddyn, Jean-François Jalkh

Draft motion for a resolution
Recital E

Draft motion for a resolution
Amendment

E. whereas less than 10% of children with a non-curable life-threatening relapse have access to new, experimental drugs in clinical trials from which they could benefit; whereas in the Member States, however, every child with cancer undergoes, on average, more than one and a half trials, the sole object, in some cases, being to obtain a marketing authorisation, thus – paradoxically – creating a risk that children’s chances of
survival might be reduced;

Amendment 19
Joëlle Mélin, Sylvie Goddyn, Jean-François Jalkh

Draft motion for a resolution
Recital E a (new)

Draft motion for a resolution Amendment

Ea. whereas it is totally unacceptable that trial reports should be difficult to obtain;

Amendment

Amendment 20
Frédérique Ries, Jasenko Selimovic, Françoise Grossetête

Draft motion for a resolution
Recital F

Draft motion for a resolution Amendment

F. whereas significantly increased access to innovative therapies can save the lives of children and adolescents with life-threatening diseases;

Amendment

F. whereas significantly increased access to innovative therapies can save the lives of children and adolescents with life-threatening diseases, and thus these therapies need to be investigated without undue delay via appropriate studies in children;

Amendment 21
Elena Gentile, Damiano Zoffoli

Draft motion for a resolution
Recital F
Draft motion for a resolution

F. whereas significantly increased access to innovative therapies can save the lives of children and adolescents with life-threatening diseases;

Amendment

F. whereas significantly increased access to innovative therapies can save the lives of children and adolescents with life-threatening diseases such as cancer;

Amendment 22
Piernicola Pedicini, Marco Affronte, Eleonora Evi

Draft motion for a resolution
Recital F a (new)

Draft motion for a resolution

Fa. whereas off-label use of medicine in children is still widespread in the EU in several therapeutic areas; whereas, although studies on the extent of off-label use in the paediatric population differ in scope and patient population, there has not been a decrease in off-label prescribing after the introduction of the Paediatric Regulation; whereas EMA has already been called upon to develop guidelines on the off-label/unlicensed use of medicines based on medical need, as well as to compile a list of off-label medicines in use despite licensed alternatives;

Amendment

Or. en

Amendment 23
Frédérique Ries, Jasenko Selimovic, Françoise Grossetête

Draft motion for a resolution
Recital H

Draft motion for a resolution

H. whereas only two innovative

Amendment

H. whereas only four innovative
targeted anti-cancer drugs were authorised for a paediatric malignancy since the Paediatric Medicines Regulation came into force;

targeted anti-cancer drugs were authorised for a paediatric malignancy based on an agreed Paediatric Investigation Plan (PIP) since the Paediatric Medicines Regulation came into force;

Amendment 24
Elena Gentile, Damiano Zoffoli

Draft motion for a resolution
Recital II

Draft motion for a resolution

Amendment

H. whereas only two innovative targeted anti-cancer drugs were authorised for a paediatric malignancy since the Paediatric Medicines Regulation came into force;

H. whereas only two innovative targeted anti-cancer drugs were authorised for a paediatric malignancy based on an agreed PIP since the Paediatric Medicines Regulation came into force;

Amendment 25
Elena Gentile, Damiano Zoffoli

Draft motion for a resolution
Recital I

Draft motion for a resolution

Amendment

I. whereas under the current regulatory framework, the legal requirement to pursue paediatric drug development is often waived because drugs are developed in typical pathologic conditions for adults that do not occur in children;

I. whereas under the current regulatory framework, the legal requirement to pursue paediatric drug development is waived when drugs are developed for adult conditions that do not occur in children;
Amendment 26
Piernicola Pedicini, Marco Affronte, Eleonora Evi

Draft motion for a resolution
Recital I

Draft motion for a resolution

I. whereas under the current regulatory framework, the legal requirement to pursue paediatric drug development is often waived because drugs are developed in typical pathologic conditions for adults that do not occur in children;

Amendment

I. whereas under the current regulatory framework, the legal requirement to pursue paediatric drug development is often waived because drugs are developed in typical pathologic conditions for adults that do not occur in children; where, furthermore, the number of Annual Reports on deferred measures submitted to EMA under Article 34(4) of the Paediatric Regulation is increasing every year;

Or. en

Amendment 27
Elena Gentile, Glenis Willmott, Damiano Zoffoli

Draft motion for a resolution
Recital J

Draft motion for a resolution

J. whereas many childhood cancer types do not occur in adults, but the mechanism of action of drugs works in an adult type of cancer may be relevant to a cancer type that occurs in children;

Amendment

J. whereas many childhood cancer types do not occur in adults, but the mechanism of action of a drug that is effective in treating an adult type of cancer may be relevant to a cancer type that occurs in children;

Or. en

Amendment 28
Notis Marias

Draft motion for a resolution
Recital K
Draft motion for a resolution

K. whereas for those cancers (or rare diseases) that only occur in children, the industry has no financial incentive for the development of specific paediatric drugs;

Amendment

K. whereas for those cancers (or rare diseases) that only occur in children, the *private sector* has no financial incentive for the development of specific paediatric drugs *and therefore, at least for that particular category of drug, private initiative is ill-equipped and unable to bring about the desired results*;

Or. el

Amendment 29
Michèle Rivasi
on behalf of the Verts/ALE Group

Draft motion for a resolution
Recital K

Draft motion for a resolution

K. whereas for those *cancers (or rare diseases)* that only occur in children, the industry *has no financial incentive for* the development of specific paediatric drugs;

Amendment

K. whereas for those diseases that only occur in children, the *current widely recognised market failure leads* industry *to refrain from investing in* the development of *non-competitive markets such as* specific paediatric drugs;

Or. en

Amendment 30
Françoise Grossetête

Draft motion for a resolution
Recital K

Draft motion for a resolution

K. whereas for those *cancers (or rare diseases)* that only occur in children, the industry *has no financial incentive for* the development of specific paediatric drugs;

Amendment

K. whereas for those diseases that only occur in children, *such as paediatric cancers*, the industry has no incentive for the development of specific paediatric drugs;
Amendment 31  
Elena Gentile, Damiano Zoffoli

Draft motion for a resolution  
Recital K

Draft motion for a resolution

K. whereas for those cancers (or rare diseases) that only occur in children, the industry has no financial incentive for the development of specific paediatric drugs;

Amendment

K. whereas for those diseases that only occur in children, such as paediatric cancers the industry has limited financial incentive for the development of specific paediatric drugs;

Or. en

Amendment 32  
Frédérique Ries, Jasenko Selimovic

Draft motion for a resolution  
Recital K

Draft motion for a resolution

K. whereas for those cancers (or rare diseases) that only occur in children, the industry has no financial incentive for the development of specific paediatric drugs;

Amendment

K. whereas for those cancers (or rare diseases) that only occur in children, the market provides insufficient financial incentive for the development of specific paediatric drugs;

Or. en

Amendment 33  
Michèle Rivasi  
on behalf of the Verts/ALE Group

Draft motion for a resolution  
Recital K a (new)
Ka. whereas delinkage mechanisms, where the end prices of a medicine is not linked anymore to the costs of R&D, are presented by the UN high level panel on promotion of innovation and access to health technologies as a credible and effective alternative to IP related incentives for financing medical R&D;
Amendment 36
Daciana Octavia Sârbu

Draft motion for a resolution
Recital K a (new)

Draft motion for a resolution

Amendment

Ka. whereas the third EU Health Programme (2014–2020) commits to improving resources and expertise for patients affected by rare diseases;

Or. en

Amendment 37
Elena Gentile, Glenis Willmott, Damiano Zoffoli

Draft motion for a resolution
Recital L

Draft motion for a resolution

Amendment

L. whereas there are major delays in starting clinical trials of oncology drugs for children as it is expected that the drug shows promise in adult cancer patients;

L. whereas there are major delays in starting paediatric clinical trials for oncology drugs as developers wait for the drug to show promise in adult cancer patients first;

Or. en

Amendment 38
Joëlle Mélin, Sylvie Goddyn, Jean-François Jalkh

Draft motion for a resolution
Recital L

Draft motion for a resolution

Amendment

L. whereas there are major delays in starting clinical trials of oncology drugs for children as it is expected that the drug shows promise in adult cancer patients;

L. whereas there are major delays in starting clinical trials of oncology drugs for children as it is expected that the drug shows promise in adult cancer patients, and whereas only very few new molecules are in prospect;
Amendment 39
Glenis Willmott, Elena Gentile

Draft motion for a resolution
Recital L a (new)

Draft motion for a resolution

Amendment

L a. whereas there is nothing to stop an investigator terminating a promising paediatric trial early if a drug fails to deliver positive results in the target adult population;

Amendment 40
Piernicola Pedicini, Marco Affronte, Eleonora Evi

Draft motion for a resolution
Recital M

Draft motion for a resolution

Amendment

M. whereas financial rewards for developing drugs in the paediatric population come late; whereas the existing system of rewards must be assessed to determine how it could be improved to better stimulate research and development of paediatric medicines, especially in paediatric oncology, by pharmaceutical companies;

M. whereas the existing system of rewards must be assessed to determine how it could be improved to better stimulate research and development of paediatric medicines, and how to ensure that it is not misused or abused by pharmaceutical companies asking for paediatric indications that are not likely to be effective, that are unsafe or not useful for children, just to obtain a six-month extension on the patent or supplementary protection certificate of their product for adults;
Amendment 41
Michèle Rivasi
on behalf of the Verts/ALE Group

Draft motion for a resolution
Recital M

M. whereas financial rewards for developing drugs in the paediatric population come late; whereas the existing system of rewards must be assessed to determine how it could be improved to better stimulate research and development of paediatric medicines, especially in paediatric oncology, by pharmaceutical companies;

Or. en

Amendment 42
Notis Marias

Draft motion for a resolution
Recital M

M. whereas financial rewards for developing drugs in the paediatric population come late; whereas the existing system of rewards must be assessed to determine how it could be improved to better stimulate research and development of paediatric medicines, especially in paediatric oncology, by pharmaceutical companies;

Or. el

Amendment 43
Joëlle Mélin, Jean-François Jalkh

Draft motion for a resolution
Recital M

M. whereas financial rewards for developing drugs in the paediatric population come late; whereas research into and the development of paediatric medicines should be possible and profitable without a system of rewards;

Or. el
Draft motion for a resolution
Recital M a (new)

Draft motion for a resolution
Ma. whereas the pharmaceutical industry's research and development costs amount to 20% and whereas 20% of its trading profits should, whenever possible, be channelled towards personalised innovative research, instead of the present situation, in which 95% is passed on to shareholders;

Or. fr

Amendment 44
Nicola Caputo, Doru-Claudian Frunzulică

Draft motion for a resolution
Recital M a (new)

Draft motion for a resolution
Ma. whereas manufacturers are effectively requesting to take advantage of the rewards provided for in the regulation to counterbalance the additional burdens placed on them, in particular the six-month extension of the supplementary protection certificate;

Or. it

Amendment 45
Nicola Caputo, Doru-Claudian Frunzulică

Draft motion for a resolution
Recital M b (new)

Draft motion for a resolution
Mb. whereas the regulation grants waivers where the disease or condition for which the specific medicinal product is
intended occurs only in adults; whereas this regulatory approach is unsatisfactory in the case of specific diseases that are found only in children;

Or. it

Amendment 46
Nicola Caputo, Doru-Claudian Frunzulică

Draft motion for a resolution
Recital Mc (new)

Draft motion for a resolution Amendment
Mc. whereas the incentive consisting of the exclusivity of data and marketing rights (PUMA) is having no effect on these medicinal products because the sector considers the current market opportunities to be insufficient to counterbalance the economic risks inherent in the development of a drug;

Or. it

Amendment 47
Nicola Caputo, Doru-Claudian Frunzulică

Draft motion for a resolution
Recital Md (new)

Draft motion for a resolution Amendment
Md. whereas marketing authorisation holders are required to update product information taking account of the latest scientific knowledge;

Or. it

Amendment 48
Joëlle Mélin, Sylvie Goddyn, Jean-François Jalkh
Draft motion for a resolution
Recital N

N. whereas Paediatric Investigation Plans (PIPs) are approved following lengthy negotiations with regulatory authorities and too often prove unfeasible or are conducted too late because of their focus on the rare occurrence of an adult cancer in a child, rather than the potentially wider use of the new drug in other relevant children’s cancers;

Amendment 49
Elena Gentile, Glenis Willmott, Damiano Zoffoli

Draft motion for a resolution
Recital N

N. whereas Paediatric Investigation Plans (PIPs) are approved following complex negotiations between regulatory authorities and pharmaceutical companies and too often prove unfeasible and/or are started too late because of their focus on the rare occurrence of an adult cancer in a child, rather than the potentially wider use of the new drug in other relevant children’s cancers;

Amendment 50
Nicola Caputo, Doru-Claudian Frunzulică
Draft motion for a resolution

N. whereas Paediatric Investigation Plans (PIPs) are approved following lengthy negotiations with regulatory authorities and too often prove unfeasible or are conducted too late because of their focus on the rare occurrence of an adult cancer in a child, rather than the potentially wider use of the new drug in other relevant children’s cancers;

Amendment

N. whereas Paediatric Investigation Plans (PIPs) are approved following lengthy negotiations with regulatory authorities and too often prove unfeasible or are conducted too late because of their focus on the rare occurrence of an adult cancer in a child, rather than the potentially wider use of the new drug in other relevant children’s cancers; whereas not all approved PIPs are completed, given that research into an active substance is often abandoned at a later stage, if initial hopes regarding the safety and efficacy of the medicinal product are not confirmed;

Or. it

Amendment 51
Piernicola Pedicini, Marco Affronte, Eleonora Evi

Draft motion for a resolution
Recital N

Draft motion for a resolution

N. whereas Paediatric Investigation Plans (PIPs) are approved following lengthy negotiations with regulatory authorities and too often prove unfeasible or are conducted too late because of their focus on the rare occurrence of an adult cancer in a child, rather than the potentially wider use of the new drug in other relevant children’s cancers;

Amendment

N. whereas Paediatric Investigation Plans (PIPs) are approved following lengthy negotiations with regulatory authorities and too often prove unfeasible or are conducted too late because of their focus on the rare occurrence of an adult cancer in a child, rather than the potentially wider use of the new drug in other relevant children’s cancers; whereas to date only 10% of the agreed PIPs have been completed;

Or. en

Amendment 52
Michèle Rivasi
on behalf of the Verts/ALE Group
Draft motion for a resolution

Recital N

N. whereas Paediatric Investigation Plans (PIPs) are approved following lengthy negotiations with regulatory authorities and too often prove unfeasible or are conducted too late because of their focus on the rare occurrence of an adult cancer in a child, rather than the potentially wider use of the new drug in other relevant children’s cancers;

Amendment

N. whereas Paediatric Investigation Plans (PIPs) are approved following lengthy negotiations with regulatory authorities and too often prove unfeasible or are conducted too late because of their misuse through a focus on the rare occurrence of an adult cancer in a child, rather than the potentially wider use of the new drug in other relevant children’s cancers;

Or. en

Amendment 53
Glenis Willmott, Elena Gentile

Draft motion for a resolution
Recital N a (new)

Draft motion for a resolution

Amendment

Na. whereas Regulation (EU) No 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use provides for the establishment of a single application portal allowing sponsors to submit a single application for trials conducted in more than one Member State; whereas such cross border trials are particularly important for rare diseases, such as paediatric cancer, as there may not be enough patients in one country to make a trial viable;

Or. en

Amendment 54
Nicola Caputo, Doru-Claudian Frunzulică
Draft motion for a resolution
Recital Na (new)

Draft motion for a resolution

Amendment

Na. whereas a large number of modifications are made to PIPs; whereas if, on the one hand, extensive modifications to a PIP are discussed with the Paediatric Committee, where the modifications have a lesser impact the issue is less clearly defined;

Or. it

Amendment 55
Piernicola Pedicini, Marco Affronte, Eleonora Evi

Draft motion for a resolution
Recital Na (new)

Draft motion for a resolution

Amendment

Na. whereas, according to Article 39(2) of the Regulation, the Member States have to provide to the Commission detailed proof on concrete commitment to support research into, development and availability of medicinal products for paediatric use;

Or. en

Amendment 56
Nicola Caputo, Doru-Claudian Frunzulică

Draft motion for a resolution
Recital Nb (new)

Draft motion for a resolution

Amendment

Nb. whereas the Paediatric Committee is able to waive paediatric trial requirements where the specific medicinal
product does not represent a significant therapeutic benefit over an existing treatment for paediatric patients; whereas this option is of no particular benefit at the early stages of product development, where the Committee has to ensure equal treatment and non-discriminatory approaches;

Or. it

Amendment 57
Piernicola Pedicini, Marco Affronte, Eleonora Evi

Draft motion for a resolution
Recital N b (new)

Draft motion for a resolution

Amendment

Nb. whereas, according to Article 40(1) of the Paediatric Regulation, funds for research into medicinal products for the paediatric population shall be provided for in the Community budget in order to support studies relating to medicinal products or active substances not covered by a patent or a supplementary protection certificate;

Or. en

Amendment 58
Piernicola Pedicini, Marco Affronte, Eleonora Evi

Draft motion for a resolution
Recital N c (new)

Draft motion for a resolution

Amendment

Nc. whereas, as foreseen by Article 45(1) of the Paediatric Regulation, a large number of paediatric studies has been submitted by the marketing authorisation holders for assessment to the competent authority with a view to possibly updating
the summary of product characteristics and package leaflet; however, only 37 out of 992 outcomes of assessment are currently available;

Or. en

Amendment 59
Nicola Caputo, Doru-Claudian Frunzulică

Draft motion for a resolution
Recital O a (new)

Draft motion for a resolution Amendment

Oa. whereas it is in the EU’s interest that paediatric trials stemming from paediatric investigation plans are conducted within the EU to provide European patients with early access to innovative medicines; whereas at present insufficient data are available on the ratio between paediatric trials conducted within the EU and those conducted outside the EU;

Or. it

Amendment 60
José Inácio Faria

Draft motion for a resolution
Paragraph 1

Draft motion for a resolution Amendment

1. Calls on the Commission to deliver the report foreseen in Article 50 of the Paediatric Regulation in a timely fashion; stresses the need for such report to provide a comprehensive identification and an in-depth analysis of the obstacles currently hampering innovation in medicinal products targeting the paediatric area; highlights the importance
Amendment 61
Michèle Rivasi
on behalf of the Verts/ALE Group

Draft motion for a resolution
Paragraph 2

2. Urges the Commission, on the basis of those findings, to consider changes, including through a legislative revision of the Paediatric Medicines Regulation that give due consideration to (a) mechanism-of-action-based, and not only cancer-type-based, paediatric development plans, (b) drug prioritisation models, (c) earlier and more feasible PIPs and (d) incentives that better stimulate research and more effectively serve the need of the paediatric population such as the numerous tools based on delinkage mechanisms mentioned in the report of the United Nations Secretary General's high level Panel on access to medicines - Promoting innovation and access to health technologies, while ensuring full transparency of the research and development costs and results;
Draft motion for a resolution

2. Urges the Commission, on the basis of those findings, to consider changes, including through a legislative revision of the Paediatric Medicines Regulation that give due consideration to (a) mechanism-of-action-based, and not only cancer-type-based, paediatric development plans, (b) drug prioritisation models, (c) earlier and more feasible PIPs and (d) incentives that better stimulate research and more effectively serve the need of the paediatric population, while ensuring transparency of the research and development process;

Amendment

2. Urges the Commission, on the basis of those findings, to consider changes, including through a legislative revision of the Paediatric Medicines Regulation that give due consideration to (a) mechanism-of-action-based, and not only disease-type-based, paediatric development plans, (b) disease prioritisation models taking into account paediatric unmet medical needs and feasibility, (c) earlier and more feasible PIPs and (d) incentives that better stimulate research and more effectively serve the need of the paediatric population, while ensuring transparency of the research and development process;

Or. en

Amendment 63
Elena Gentile, Damiano Zoffoli

Draft motion for a resolution
Paragraph 2

Draft motion for a resolution

2. Urges the Commission, on the basis of those findings, to consider changes, including through a legislative revision of the Paediatric Medicines Regulation that give due consideration to (a) mechanism-of-action-based, and not only cancer-type-based, paediatric development plans, (b) drug prioritisation models, (c) earlier and more feasible PIPs and (d) incentives that better stimulate research and more effectively serve the need of the paediatric population, while ensuring transparency of the research and development process;

Amendment

2. Urges the Commission, on the basis of those findings, to consider changes, including through a legislative revision of the Paediatric Medicines Regulation that give due consideration to (a) mechanism-of-action-based, and not only adult indication-based, paediatric development plans, (b) drug prioritisation models, (c) earlier and more feasible PIPs and (d) incentives that better stimulate research and more effectively serve the need of the paediatric population, while ensuring transparency of the research and development process;

Or. en
Amendment 64
Piernicola Pedicini

Draft motion for a resolution
Paragraph 2

2. Urges the Commission, on the basis of those findings, to consider changes, including through a legislative revision of the Paediatric Medicines Regulation that give due consideration to (a) mechanism-of-action-based, and not only cancer-type-based, paediatric development plans, (b) drug prioritisation models, (c) earlier and more feasible PIPs and (d) incentives that better stimulate research and more effectively serve the need of the paediatric population, while ensuring transparency of the research and development process;

Amendment

2. Urges the Commission, on the basis of those findings, to consider changes, including through a legislative revision of the Paediatric Medicines Regulation that give due consideration to (a) mechanism-of-action-based, and not only cancer-type-based, paediatric development plans, (b) drug prioritisation models, (c) earlier and more feasible PIPs and (d) incentives that better stimulate research and more effectively serve the need of the paediatric population, while ensuring transparency of the research and development process, (e) strategies to overcome paediatric off-label use;

Or. en

Amendment 65
Joëlle Mélin, Jean-François Jalkh

Draft motion for a resolution
Paragraph 2 a (new)

2a. Considers that the regulation could be amended with a view to supporting teams working on projects whose results are partially or wholly proven, while affording the widest possible measure of freedom in terms of aims and action;

Amendment

Or. fr
Amendment 66
Joëlle Mélin, Sylvie Goddyn, Jean-François Jalkh

Draft motion for a resolution
Paragraph 3

Draft motion for a resolution
Amendment

3. Stresses the life-saving benefits, in paediatric oncology, of mandatory paediatric development based on a drug’s mechanism of action matched to a tumour’s biology rather than on indication limiting the drug’s use to a specific type of cancer;

Or. fr

Amendment 67
Elena Gentile, Damiano Zoffoli

Draft motion for a resolution
Paragraph 3

Draft motion for a resolution
Amendment

3. Stresses the life-saving benefits, in paediatric oncology, of mandatory paediatric development based on a drug’s mechanism of action matched to a tumour’s biology rather than on indication limiting the drug’s use to a specific type of cancer;

3. Stresses the life-saving benefits, in paediatric oncology, of mandatory paediatric development based on a drug’s mechanism of action matched to a tumour’s biology rather than on an indication in adults;

Or. en

Amendment 68
Joëlle Mélin, Jean-François Jalkh

Draft motion for a resolution
Paragraph 4

Draft motion for a resolution
Amendment

4. Stresses that prioritisation of drugs

4. Stresses that there must be no

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from different companies, based on scientific data, should be done to match the best available therapies to the therapeutic needs of children affected by cancers and would enable to optimise the resources used for research;

prioritisation of drugs from different companies, based on scientific data, for the purpose of matching the best available therapies to the therapeutic needs of children affected by cancers and hence optimising the resources used for research;

Or. fr

Amendment 69
Françoise Grossetête

Draft motion for a resolution
Paragraph 4

Draft motion for a resolution

4. Stresses that prioritisation of drugs from different companies, based on scientific data, should be done to match the best available therapies to the therapeutic needs of children affected by cancers and would enable to optimise the resources used for research;

Amendment

4. Stresses that prioritisation of paediatric needs, based on scientific data, should be done to match the best available therapies to the therapeutic needs of children, especially those affected by cancers, and would enable to optimise the resources used for research;

Or. en

Amendment 70
Glenis Willmott, Elena Gentile

Draft motion for a resolution
Paragraph 4 a (new)

Draft motion for a resolution

4a. Stresses the importance of cross-border trials for research into many paediatric and rare illnesses, therefore welcomes Regulation (EU) No 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use, which will make it easier to carry out these sorts of trials, and calls on the European Medicines Agency to ensure that the infrastructure
necessary for its implementation is in place as soon as possible;

Amendment 71
Frédérique Ries, Jasenko Selimovic, Françoise Grossetête

Draft motion for a resolution
Paragraph 5

5. Stresses that conducting timely PIPs enables early regulatory dialogue and joint development with the European Medicines Agency, allowing companies to develop more feasible PIPs;

Amendment

5. Stresses that conducting early PIPs, and early scientific and regulatory dialogue and joint development with the European Medicines Agency allows companies to optimise global paediatric development, and in particular develop more feasible PIPs;

Amendment 72
Elena Gentile, Damiano Zoffoli

Draft motion for a resolution
Paragraph 5

5. Stresses that conducting timely PIPs enables early regulatory dialogue and joint development with the European Medicines Agency, allowing companies to develop more feasible PIPs;

Amendment

5. Stresses the importance of early interaction and continuous regulatory dialogue with the European Medicines Agency, allowing companies to develop more feasible PIPs, and to optimise global paediatric development;

Amendment 73
Glenis Willmott, Elena Gentile
5a. Calls on the Commission to consider amending the Paediatric Regulation so that promising trials in the paediatric population cannot be terminated early due to disappointing results in the target adult population;

Or. en

Amendment 74
Joëlle Mélin, Jean-François Jalkh

6. Stresses the urgent need to assess how different types of rewards can be best utilised to drive and accelerate clinical development of drugs for childhood cancers and specifically for those cancers which only occur in children. The rewards should drive paediatric development of any oncology-targeted drug to start as soon as sufficient scientific rationale for use in a paediatric population and adult safety data are available, and should not be dependent on proven therapeutic value in an adult cancer indication;

Or. fr

Amendment 75
Notis Marias
Draft motion for a resolution

6. Stresses the urgent need to assess how different types of rewards can be best utilised to drive and accelerate clinical development of drugs for childhood cancers and specifically for those cancers which only occur in children. The rewards should drive paediatric development of any oncology-targeted drug to start as soon as sufficient scientific rationale for use in a paediatric population and adult safety data are available, and should not be dependent on proven therapeutic value in an adult cancer indication;

Amendment

6. Stresses the urgent need to accelerate clinical development of drugs for childhood cancers and specifically for those cancers which only occur in children.

Or. el

Amendment 76
José Inácio Faria

Draft motion for a resolution
Paragraph 6

Draft motion for a resolution

6. Stresses the urgent need to assess how different types of rewards can be best utilised to drive and accelerate clinical development of drugs for childhood cancers and specifically for those cancers which only occur in children. The rewards should drive paediatric development of any oncology-targeted drug to start as soon as sufficient scientific rationale for use in a paediatric population and adult safety data are available, and should not be dependent on proven therapeutic value in an adult cancer indication;

Amendment

6. Stresses the urgent need to define an effective framework that is tailored to best address existing obstacles, driving and accelerating clinical development of drugs for paediatrics, including for childhood cancers and specifically for those cancers which only occur in children; believes that rewards should drive paediatric development of any oncology-targeted drug to start as soon as sufficient scientific rationale for use in a paediatric population and adult safety data are available, and should not be entirely dependent on proven therapeutic value in an adult cancer indication;

Or. en
Amendment 77
Frédérique Ries, Jasenko Selimovic, Françoise Grossetête

Draft motion for a resolution
Paragraph 6

6. Stresses the urgent need to assess how different types of rewards can be best utilised to drive and accelerate clinical development of drugs for childhood cancers and specifically for those cancers which only occur in children. The rewards should drive paediatric development of any oncology-targeted drug to start as soon as sufficient scientific rationale for use in a paediatric population and adult safety data are available, and should not be dependent on proven therapeutic value in an adult cancer indication;

Amendment

6. Stresses the urgent need to assess how different types of rewards can be best utilised to drive and accelerate paediatric drugs development in areas of need, in particular drugs for neonatology and childhood cancers, especially those cancers which only occur in children. The rewards should drive paediatric development of these drugs to start as soon as sufficient scientific rationale for use in a paediatric population and adult safety data are available, and should not be dependent on proven therapeutic value in an adult indication;

Or. en

Amendment 78
Daciana Octavia Sârbu

Draft motion for a resolution
Paragraph 6

6. Stresses the urgent need to assess how different types of rewards can be best utilised to drive and accelerate clinical development of drugs for childhood cancers and specifically for those cancers which only occur in children. The rewards should drive paediatric development of any oncology-targeted drug to start as soon as sufficient scientific rationale for use in a paediatric population and adult safety data are available, and should not be dependent on proven therapeutic value in an adult cancer indication;

Amendment

6. Stresses the urgent need to assess how different types of funding and rewards can be best utilised to drive and accelerate clinical development of drugs for childhood cancers and specifically for those cancers which only occur in children. The rewards should drive paediatric development of any oncology-targeted drug to start as soon as sufficient scientific rationale for use in a paediatric population and adult safety data are available, and should not be dependent on proven therapeutic value in an adult cancer indication;
Amendment 79
Nicola Caputo, Doru-Claudian Frunzulică

Draft motion for a resolution
Paragraph 6 a (new)

Draft motion for a resolution

6a. Calls on the Member States to develop tools to communicate with health professionals efficiently and effectively, for example by holding regular conferences, setting up internet-based information systems or introducing national forms;

Or. it

Amendment 80
Nicola Caputo, Doru-Claudian Frunzulică

Draft motion for a resolution
Paragraph 6 b (new)

Draft motion for a resolution

6b. Calls on the Commission to review its communication on the format and content of applications for approval or modification of a PIP to take into account the experience gained, including the considerable number of modification requests;

Or. it

Amendment 81
Nicola Caputo, Doru-Claudian Frunzulică

Draft motion for a resolution
Paragraph 6 c (new)
6c. Calls on the Commission to include in its 2017 report an in-depth assessment of the economic impact of the regulation, in order to offset the burdens against the rewards and the advantages for the national health service;

Or. it

Amendment 82
Nicola Caputo, Doru-Claudian Frunzulică

6d. Calls on the Commission to start collecting data on the ratio between paediatric trials conducted within the EU and those conducted outside the EU;

Or. it

Amendment 83
Nicola Caputo

6e. Calls on the Commission to look into new forms of incentives to replace or supplement PUMA, which has turned out to be ineffective;

Or. it
Amendment 84
Nicola Caputo

Draft motion for a resolution
Paragraph 6 f (new)

6f. **Calls on the authorities responsible to make greater use of the coercive measures permitted by the regulation in order to overcome manufacturers’ reservations by independently updating summaries of product characteristics and subsequently amending marketing authorisations;**

Or. it

Amendment 85
Nicola Caputo

Draft motion for a resolution
Paragraph 7 a (new)

7a. **Calls on the Commission to change the current approach of the regulation with regard to the system of waivers granted for the development of medicinal products to treat diseases affecting only adults, which has turned out to be unsatisfactory for the treatment of diseases that are specific and exclusive to children;**

Or. it

Amendment 86
Piernicola Pedicini, Marco Affronte, Eleonora Evi

Draft motion for a resolution
Paragraph 7 a (new)
7a. Calls on the Commission to renew in Horizon 2020 the funding provisions developed to support high-quality paediatric clinical research, following a critical review of the projects currently funded;

Or. en

Amendment 87
Piernicola Pedicini, Marco Affronte, Eleonora Evi

Paragraph 7 b (new)

7b. Calls on the Commission to strengthen the role of European networking for paediatric clinical research; and to ensure that Member States enact measures to support research, development and availability of medicinal products for paediatric use;

Or. en