

Amendment 2

Karl-Heinz Florenz, Françoise Grossetête, Peter Liese, Angélique Delahaye, Cristian-Silviu Buşoi, Norbert Lins, Michel Dantin, Francesc Gambús, Nuno Melo, Alberto Cirio, Christofer Fjellner, Aldo Patriciello, Alojz Peterle, Elisabetta Gardini, Giovanni La Via, Annie Schreijer-Pierik, Adina-Ioana Vălean, Pilar Ayuso, Miroslav Mikolášik, Birgit Collin-Langen, Ivica Tolić, Siegfried Mureşan, Cristian Dan Preda, Marian-Jean Marinescu, Mairead McGuinness, Luis de Grandes Pascual, Alain Lamassoure, Tom Vandenkendelaere, Iuliu Winkler, José Manuel Fernandes, Ramona Nicole Mănescu, Ivana Maletić, Seán Kelly, Constance Le Grip, Jérôme Lavrilleux, Fernando Ruas, Angelika Niebler, Herbert Reul, Paulo Rangel, Markus Pieper, Maurice Ponga, Christian Ehler, Monika Hohlmeier, Werner Langen, Elmar Brok, Sabine Verheyen, Joachim Zeller, Andrey Kovatchev, Esther de Lange, Sirpa Pietikäinen, Massimiliano Salini, Roberta Metsola, Burkhard Balz, Lambert van Nistelrooij, Róza Gräfin von Thun und Hohenstein, Danuta Maria Hübner, Jacek Saryusz-Wolski, Tadeusz Zwiefka, Mariya Gabriel, Esteban González Pons, Jan Olbrycht, Francisco José Millán Mon, Jerzy Buzek, Danuta Jazłowiecka, Csaba Sógor, Andrzej Grzyb, Peter Jahr, Salvatore Cicu, Jens Gieseke, Wim van de Camp, Michał Boni, Franck Proust, Herbert Dorfmann, Stanislav Polčák, Cláudia Monteiro de Aguiar, Arnaud Danjean, Traian Ungureanu, Andreas Schwab, Ingeborg Gräßle, Werner Kuhn, Sven Schulze, Daniel Caspary, Hermann Winkler, Reimer Böge, Elisabeth Köstinger, José Inácio Faria, Gabriel Mato, Paul Rübig, Thomas Mann, Daniel Buda, Bendt Bendtsen, Teresa Jiménez-Becerril Barrio, Renate Sommer, David Casa, David McAllister, Gesine Meissner, Lieve Wierinck, Frédérique Ries, Alexander Graf Lambsdorff, Jan Huitema, Ulrike Müller, Nils Torvalds, Cora van Nieuwenhuizen, Johannes Cornelis van Baalen, Gerben-Jan Gerbrandy, Sophia in 't Veld, Julie Girling

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A8-0040/2017

Soledad Cabezón Ruiz

Options for improving access to medicines
2016/2057(INI)**Motion for a resolution****Paragraph 50***Motion for a resolution**Amendment*

50. **Welcomes** the report of the United Nations Secretary-General's High-Level Panel on Access to Medicines, **and calls on the Commission and on Member States to take steps to implement the recommendations made therein;**

50. **Notes** the report of the United Nations Secretary-General's High-Level Panel on Access to Medicines;

Or. en

Amendment 3

Karl-Heinz Florenz, Françoise Grossetête, Peter Liese, Angélique Delahaye, Cristian-Silviu Buşoi, Norbert Lins, Michel Dantin, Francesc Gambús, Nuno Melo, Alberto Cirio, Christofer Fjellner, Aldo Patriciello, Alojz Peterle, Elisabetta Gardini, Giovanni La Via, Annie Schreijer-Pierik, Adina-Ioana Vălean, Pilar Ayuso, Miroslav Mikolášik, Birgit Collin-Langen, Ivica Tolić, Siegfried Mureşan, Cristian Dan Preda, Marian-Jean Marinescu, Mairead McGuinness, Luis de Grandes Pascual, Alain Lamassoure, Tom Vandenkendelaere, Iuliu Winkler, José Manuel Fernandes, Ramona Nicole Mănescu, Ivana Maletić, Seán Kelly, Constance Le Grip, Jérôme Lavrilleux, Fernando Ruas, Angelika Niebler, Herbert Reul, Paulo Rangel, Markus Pieper, Maurice Ponga, Christian Ehler, Monika Hohlmeier, Werner Langen, Elmar Brok, Sabine Verheyen, Joachim Zeller, Andrey Kovatchev, Esther de Lange, Sirpa Pietikäinen, Massimiliano Salini, Roberta Metsola, Burkhard Balz, Lambert van Nistelrooij, Róza Gräfin von Thun und Hohenstein, Danuta Maria Hübner, Jacek Saryusz-Wolski, Tadeusz Zwiefka, Mariya Gabriel, Esteban González Pons, Jan Olbrycht, Francisco José Millán Mon, Jerzy Buzek, Danuta Jazłowiecka, Csaba Sógor, Andrzej Grzyb, Peter Jahr, Salvatore Cicu, Jens Gieseke, Wim van de Camp, Michał Boni, Franck Proust, Herbert Dorfmann, Stanislav Polčák, Cláudia Monteiro de Aguiar, Arnaud Danjean, Traian Ungureanu, Andreas Schwab, Ingeborg Gräßle, Werner Kuhn, Sven Schulze, Daniel Caspary, Hermann Winkler, Reimer Böge, Elisabeth Köstinger, José Inácio Faria, Gabriel Mato, Paul Rübig, Thomas Mann, Daniel Buda, Bendt Bendtsen, Teresa Jiménez-Becerril Barrio, Renate Sommer, David Casa, David McAllister, Gesine Meissner, Lieve Wierinck, Frédérique Ries, Alexander Graf Lambsdorff, Jan Huitema, Ulrike Müller, Nils Torvalds, Cora van Nieuwenhuizen, Johannes Cornelis van Baalen, Gerben-Jan Gerbrandy, Sophia in 't Veld

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Soledad Cabezón RuizOptions for improving access to medicines
2016/2057(INI)**Motion for a resolution****Paragraph 52***Motion for a resolution**Amendment*

52. Calls on the *Member States* to develop *closer collaboration in order to fight such market fragmentation, in particular by developing shared HTA processes and results, and to work on shared criteria to instruct* price and reimbursement decisions at national level;

52. Calls on the *Commission* to develop *a European Health Technology Assessment process with common tools and shared criteria that can produce reports to inform* price and reimbursement decisions at national level;

Or. en

Amendment 4

Karl-Heinz Florenz, Françoise Grossetête, Peter Liese, Angélique Delahaye, Cristian-Silviu Buşoi, Norbert Lins, Michel Dantin, Francesc Gambús, Nuno Melo, Alberto Cirio, Christofer Fjellner, Aldo Patriciello, Alojz Peterle, Elisabetta Gardini, Giovanni La Via, Annie Schreijer-Pierik, Adina-Ioana Vălean, Pilar Ayuso, Miroslav Mikolášik, Birgit Collin-Langen, Ivica Tolić, Siegfried Mureşan, Cristian Dan Preda, Marian-Jean Marinescu, Mairead McGuinness, Luis de Grandes Pascual, Alain Lamassoure, Tom Vandenkendelaere, Iuliu Winkler, José Manuel Fernandes, Ramona Nicole Mănescu, Ivana Maletić, Seán Kelly, Constance Le Grip, Jérôme Lavrilleux, Fernando Ruas, Angelika Niebler, Herbert Reul, Paulo Rangel, Markus Pieper, Maurice Ponga, Christian Ehler, Monika Hohlmeier, Werner Langen, Elmar Brok, Sabine Verheyen, Joachim Zeller, Andrey Kovatchev, Esther de Lange, Sirpa Pietikäinen, Massimiliano Salini, Roberta Metsola, Burkhard Balz, Lambert van Nistelrooij, Róza Gräfin von Thun und Hohenstein, Danuta Maria Hübner, Jacek Saryusz-Wolski, Tadeusz Zwiefka, Mariya Gabriel, Esteban González Pons, Jan Olbrycht, Francisco José Millán Mon, Jerzy Buzek, Danuta Jazłowiecka, Csaba Sógor, Andrzej Grzyb, Peter Jahr, Salvatore Cicu, Jens Gieseke, Wim van de Camp, Michał Boni, Franck Proust, Herbert Dorfmann, Stanislav Polčák, Cláudia Monteiro de Aguiar, Arnaud Danjean, Traian Ungureanu, Andreas Schwab, Ingeborg Gräßle, Werner Kuhn, Sven Schulze, Daniel Caspary, Hermann Winkler, Reimer Böge, Elisabeth Köstinger, José Inácio Faria, Gabriel Mato, Paul Rübig, Thomas Mann, Daniel Buda, Bendt Bendtsen, Teresa Jiménez-Becerril Barrio, Renate Sommer, David Casa, David McAllister, Gesine Meissner, Lieve Wierinck, Frédérique Ries, Alexander Graf Lambsdorff, Jan Huitema, Ulrike Müller, Nils Torvalds, Cora van Nieuwenhuizen, Johannes Cornelis van Baalen, Gerben-Jan Gerbrandy, Sophia in 't Veld, Soledad Cabezón Ruiz, Clara Eugenia Aguilera García, José Blanco López, Juan Fernando López Aguilar, Enrique Guerrero Salom, Simona Bonafè, Richard Corbett, Andrea Cozzolino, Jonás Fernández, Eider Gardiazabal Rubial, Jo Leinen, Javi López, Sergio Gutiérrez Prieto, Marlene Mizzi, Renata Briano, Biljana Borzan, Inmaculada Rodríguez-Piñero Fernández, Iratxe García Pérez, Susanne Melior, Ulrike Rodust, Lucy Anderson, Nikos Androulakis, Elena Valenciano, Miriam Dalli, Dan Nica, Inés Ayala Sender, Karin Kadenbach, Nicola Caputo, Liliana Rodrigues, Maria Arena

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Soledad Cabezón Ruiz

Options for improving access to medicines
2016/2057(INI)

Motion for a resolution**Paragraph 81***Motion for a resolution*

81. Calls on the Commission to propose legislation on a European system for health technology assessment as soon

Amendment

81. Calls on the Commission to propose legislation on a European system for health technology assessment as soon

as possible, to harmonise transparent HTA criteria in order to assess the added therapeutic value of medicines compared with the best available alternative taking into account the level of innovation and value for the patients among others, to introduce compulsory relative effectiveness assessments at EU level as a first step for new medicines, and to put in place a European classification system to chart their therapeutic added value level, using an independent and transparent procedure that avoids conflicts of interests;

as possible, to harmonise transparent HTA criteria in order to assess the added therapeutic value of medicines compared with the best available alternative taking into account the level of innovation and value for the patients among others, to introduce compulsory relative effectiveness assessments at EU level as a first step for new medicines, and to put in place a European classification system to chart their therapeutic added value level, using an independent and transparent procedure that avoids conflicts of interests; ***considers that such legislation shall ensure that HTA output jointly produced at EU level is used at national level; calls, furthermore, on the Commission to strengthen early dialogues and to consider a coordination mechanism based on an independent body, which could foster cooperation between national HTA bodies while at the same time ensuring that expertise on HTA remains within national (and regional) HTA;***

Or. en

Amendment 5

Karl-Heinz Florenz, Françoise Grossetête, Peter Liese, Angélique Delahaye, Cristian-Silviu Buşoi, Norbert Lins, Michel Dantin, Francesc Gambús, Nuno Melo, Alberto Cirio, Christofer Fjellner, Aldo Patriciello, Alojz Peterle, Elisabetta Gardini, Giovanni La Via, Annie Schreijer-Pierik, Adina-Ioana Vălean, Pilar Ayuso, Miroslav Mikolášik, Birgit Collin-Langen, Ivica Tolić, Siegfried Mureşan, Cristian Dan Preda, Marian-Jean Marinescu, Mairead McGuinness, Luis de Grandes Pascual, Alain Lamassoure, Tom Vandenkendelaere, Iuliu Winkler, José Manuel Fernandes, Ramona Nicole Mănescu, Ivana Maletić, Seán Kelly, Constance Le Grip, Jérôme Lavrilleux, Fernando Ruas, Angelika Niebler, Herbert Reul, Paulo Rangel, Markus Pieper, Maurice Ponga, Christian Ehler, Monika Hohlmeier, Werner Langen, Elmar Brok, Sabine Verheyen, Joachim Zeller, Andrey Kovatchev, Esther de Lange, Sirpa Pietikäinen, Massimiliano Salini, Roberta Metsola, Burkhard Balz, Lambert van Nistelrooij, Róza Gräfin von Thun und Hohenstein, Danuta Maria Hübner, Jacek Saryusz-Wolski, Tadeusz Zwiefka, Mariya Gabriel, Esteban González Pons, Jan Olbrycht, Francisco José Millán Mon, Jerzy Buzek, Danuta Jazłowiecka, Csaba Sógor, Andrzej Grzyb, Peter Jahr, Salvatore Cicu, Jens Gieseke, Wim van de Camp, Michał Boni, Franck Proust, Herbert Dorfmann, Stanislav Polčák, Cláudia Monteiro de Aguiar, Arnaud Danjean, Traian Ungureanu, Andreas Schwab, Ingeborg Gräßle, Werner Kuhn, Sven Schulze, Daniel Caspary, Hermann Winkler, Reimer Böge, Elisabeth Köstinger, José Inácio Faria, Gabriel Mato, Paul Rübig, Thomas Mann, Daniel Buda, Bendt Bendtsen, Teresa Jiménez-Becerril Barrio, Renate Sommer, David Casa, David McAllister, Gesine Meissner, Lieve Wierinck, Frédérique Ries, Alexander Graf Lambsdorff, Jan Huitema, Ulrike Müller, Nils Torvalds, Cora van Nieuwenhuizen, Johannes Cornelis van Baalen, Gerben-Jan Gerbrandy, Sophia in 't Veld, Julie Girling

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Soledad Cabezón RuizOptions for improving access to medicines
2016/2057(INI)**Motion for a resolution****Paragraph 109***Motion for a resolution**Amendment*

109. Emphasises that, while some new medicines are examples of breakthrough innovations, other new medicines demonstrate insufficient therapeutic added value to be deemed genuine innovations; ***emphasises*** that the repurposing and reformulation of known molecules, ***and the development of new medicines for the same indication ('me-too' substances), should be assessed carefully, especially as***

109. Emphasises that, while some new medicines are examples of breakthrough innovations, other new medicines demonstrate insufficient therapeutic added value to be deemed genuine innovations (***'me-too' substances***); ***recalls that incremental innovation may also be beneficial for patients and*** that the repurposing and reformulation of known molecules ***may deliver*** added therapeutic

regards their added therapeutic value;
measurable benefits should be
demonstrated and the patentability
requirements of novelty, inventive step
and industrial applicability should be
strictly fulfilled; warns against the
potential misuse of IP protection rules
allowing the ‘evergreening’ of patent rights
and avoidance of competition;

value, ***which should be carefully assessed***;
warns against the potential misuse of IP
protection rules allowing the
‘evergreening’ of patent rights and
avoidance of competition;

Or. en