



2015/2103(INL)

21.9.2016

AMENDMENTS

1 - 121

Draft opinion
Cristian-Silviu Buşoi
(PE587.414v01-00)

on Civil Law Rules on Robotics
(2015/2103(INL))

Amendment 1
Notis Marias

Draft opinion
Recital A

Draft opinion

A. whereas ageing is the result of an increased life expectancy due to progress in modern medicine, and is one of the greatest ***social and economic challenges*** of the 21st century for European societies; whereas by 2025 more than 20% of Europeans will be 65 or over, with a particularly rapid increase in numbers of over 80s;

Amendment

A. whereas ageing is the result of an increased life expectancy due to ***major*** progress in modern medicine, and is one of the greatest ***achievements*** of the 21st century for European societies; whereas by 2025 more than 20% of Europeans will be 65 or over, with a particularly rapid increase in numbers of over 80s;

Or. el

Amendment 2
Nikolay Barekov

Draft opinion
Recital A

Draft opinion

A. whereas ageing is the result of an increased life expectancy due to progress in modern medicine, and is one of the greatest social and economic challenges of the 21st century for European societies; whereas by 2025 more than 20% of Europeans will be 65 or over, with a particularly rapid increase in numbers of over-80s;

Amendment

A. whereas ageing is the result of an ***unprecedented shortfall in births and*** increased life expectancy due to progress in ***living conditions and in*** modern medicine, and is one of the greatest ***political***, social, and economic challenges of the 21st century for European societies; whereas by 2025 more than 20% of Europeans will be 65 or over, with a particularly rapid increase in numbers of over-80s;

Or. fr

Amendment 3
Mireille D'Ornano, Jean-François Jalkh, Sylvie Goddyn

Draft opinion
Recital A

Draft opinion

A. whereas ageing is the result of an increased life expectancy due to progress in modern medicine, and is one of the greatest social and economic challenges of the 21st century for European societies; whereas by 2025 more than 20% of Europeans will be 65 or over, with a particularly rapid increase in numbers of over-80s;

Amendment

A. whereas ageing is the result of an increased life expectancy due to progress in modern medicine, and, ***like the aspiration of growing old in good health***, is one of the greatest social and economic challenges of the 21st century for European societies; whereas by 2025 more than 20% of Europeans will be 65 or over, with a particularly rapid increase in numbers of over-80s;

Or. fr

Amendment 4
Jasenko Selimovic

Draft opinion
Recital A

Draft opinion

A. whereas ageing is the result of an increased life expectancy due to progress in modern medicine, and is one of the greatest social and economic challenges of the 21st century for European societies; whereas by 2025 more than 20% of Europeans will be 65 or over, with a particularly rapid increase in numbers of over 80s;

Amendment

A. whereas ageing is the result of an increased life expectancy due to progress in modern medicine, and is one of the greatest social and economic challenges of the 21st century for European societies; whereas by 2025 more than 20% of Europeans will be 65 or over, with a particularly rapid increase in numbers of over 80s, ***which will lead to a fundamentally different balance between generations within our societies***;

Or. en

Amendment 5
Ádám Kósa

Draft opinion
Recital A

Draft opinion

A. whereas ageing is the result of an increased life expectancy due to progress in modern medicine, and is one of the greatest social and economic challenges of the 21st century for European societies; whereas by 2025 more than 20% of Europeans will be 65 or over, with a particularly rapid increase in numbers of over 80s;

Amendment

A. whereas ageing is the result of an increased life expectancy due to progress in modern medicine, and is one of the greatest social and economic challenges of the 21st century for European societies; whereas by 2025 more than 20% of Europeans will be 65 or over, with a particularly rapid increase in numbers of over 80s, ***and whereas it is in the interest of society and families that older people should remain healthy and active for as long as possible;***

Or. hu

Amendment 6
Enrico Gasbarra

Draft opinion
Recital A a (new)

Draft opinion

Amendment

Aa. whereas the sale and production of robots rose significantly between 2010 and 2014, with an increase of almost 30% in 2014 alone, particularly in the health and care sector;

Or. it

Amendment 7
Cristian-Silviu Buşoi

Draft opinion
Recital A a (new)

Draft opinion

Amendment

Aa. whereas in an ageing society the

prevalence and incident rate of disabilities, chronic diseases, the risk of stroke, brain injuries and diminished abilities is increasing;

Or. en

Amendment 8
Notis Marias

Draft opinion
Recital B

Draft opinion

B. whereas societies and health systems will need to *adapt to* the ageing process and elderly healthcare requirements, so they can provide adequate care and *remain financially sustainable*;

Amendment

B. whereas societies and health systems will need to *keep pace with* the ageing process and elderly healthcare requirements, so they can provide adequate care and *retain the necessary degree of financial stability*;

Or. el

Amendment 9
Enrico Gasbarra

Draft opinion
Recital B a (new)

Draft opinion

Ba. whereas the development of robotics could result in greater efficiency and savings for the internal market, particularly in the health and care sectors, while reducing human exposure to harmful and hazardous conditions;

Amendment

Or. it

Amendment 10
Ádám Kósa

Draft opinion
Recital C

Draft opinion

C. whereas cyber-physical systems (CPS) are technical systems of network computers, robots and artificial intelligence that interact with *the physical world* and have numerous applications in the healthcare sector;

Amendment

C. whereas cyber-physical systems (CPS) are technical systems of network computers, robots and artificial intelligence that interact with *an integrated artificial environment* and have numerous applications in the healthcare sector, *and whereas it may be possible for some elements even to be implanted in the human body*;

Or. hu

Amendment 11
Mireille D'Ornano, Jean-François Jalkh, Sylvie Goddyn

Draft opinion
Recital C

Draft opinion

C. whereas cyber-physical systems (CPS) are technical systems of network computers, robots and artificial intelligence that interact with the physical world and have numerous applications in the healthcare sector;

Amendment

C. whereas cyber-physical systems (CPS) are technical systems of network computers, robots and artificial intelligence that interact with the physical world and *already* have numerous applications in the healthcare sector;

Or. fr

Amendment 12
Elena Gentile

Draft opinion
Recital C a (new)

Draft opinion

Amendment

Ca. having regard to the nature of CPS and the need to achieve specific,

more detailed standards that are the same throughout the European Union;

Or. it

Amendment 13
Piernicola Pedicini, Eleonora Evi, Marco Affronte

Draft opinion
Recital C a (new)

Draft opinion

Amendment

Ca. whereas the quantity of medical data that can be collected by 2020 is doubling every 73 days; whereas this means that the automatic learning techniques of cybernetic machines with artificial intelligence point to a trend which is moving decisively towards the exclusion of human beings from certain activities, which will be carried out increasingly often and increasingly better by machines and will involve ever fewer mistakes and adverse events;

Or. it

Amendment 14
Piernicola Pedicini, Eleonora Evi, Marco Affronte

Draft opinion
Recital C b (new)

Draft opinion

Amendment

Cb. whereas, in spite of this trend, which appears to be inevitable, the principle of the autonomy of cybernetic machines supervised by human beings must be determined as a basic precautionary rule;

Or. it

Amendment 15

Mireille D'Ornano, Jean-François Jalkh, Sylvie Goddyn

Draft opinion

Recital D

Draft opinion

D. whereas such systems **will provide** the foundation and the basis of emerging and future smart services, and will bring advances in personalised health care, emergency response and telemedicine;

Amendment

D. whereas such systems **are providing** the foundation and the basis of emerging and future smart services, and will bring advances in personalised health care, emergency response and telemedicine;

Or. fr

Amendment 16

Notis Marias

Draft opinion

Recital D

Draft opinion

D. whereas such systems will provide the foundation and the basis of emerging and future smart services, and **will** bring advances in personalised health care, emergency response and telemedicine;

Amendment

D. whereas such systems will provide the foundation and the basis of emerging and future smart services, and **should** bring advances in personalised health care, emergency response and telemedicine;

Or. el

Amendment 17

Ádám Kósa

Draft opinion

Recital D

Draft opinion

D. whereas such systems will provide the foundation and the basis of emerging

Amendment

D. whereas such systems will provide the foundation and the basis of emerging

and future smart services, and will bring advances in personalised health care, emergency response and telemedicine;

and future smart services, and will bring advances in personalised health care, emergency response and telemedicine, *and whereas their application raises far-reaching issues of ethics, human rights and social philosophy, particularly with regard to self-determination and integrity of the person;*

Or. hu

Amendment 18
Nikolay Barekov

Draft opinion
Recital D a (new)

Draft opinion

Amendment

Da. whereas personal freedom is a cardinal value of European civilisation, whereas the promise to be had from robotisation might lead to a new form of alienation if humankind, having chosen to regard technology as sacred, failed to control its development, whereas the Nietzschean overman ('Übermensch'), a transhumanist project, is the last surviving utopia, whereas Europeans, however, must make it clear that everything which is technically possible is not always morally acceptable;

Or. fr

Amendment 19
Elena Gentile

Draft opinion
Recital D a (new)

Draft opinion

Amendment

Da. whereas under no circumstances should the use of robotic or high-

technology diagnostic or treatment instruments result in increased liability for the doctors or healthcare personnel who are required to use them; whereas it is therefore considered advisable to increase the liability of the healthcare facilities or manufacturers involved;

Or. it

Amendment 20
Piernicola Pedicini, Eleonora Evi, Marco Affronte

Draft opinion
Recital D a (new)

Draft opinion

Amendment

Da. whereas, moreover, the use of tools such as self-diagnosis does not take account of human ethical, moral and professional responsibilities, in addition to civil and criminal liability, in the medical sector;

Or. it

Amendment 21
Cristian-Silviu Buşoi

Draft opinion
Recital D a (new)

Draft opinion

Amendment

Da. whereas the economic and societal potential of such systems is vastly greater than what has been realized, and major investments are being made worldwide to develop the technology;

Or. en

Amendment 22
Notis Marias

Draft opinion
Recital D a (new)

Draft opinion

Amendment

Da. whereas the widespread and increasingly frequent use of robotics and AI has unmistakably provoked a variety of reactions and objections;

Or. el

Amendment 23
Elena Gentile

Draft opinion
Recital D b (new)

Draft opinion

Amendment

Db. whereas the use of such technology should not diminish or harm the doctor-patient relationship, but should provide doctors with assistance in diagnosing and/or treating patients;

Or. it

Amendment 24
Nikolay Barekov

Draft opinion
Recital D b (new)

Draft opinion

Amendment

Db. whereas it does not invariably follow that everything which is technically feasible is morally acceptable;

Or. fr

Amendment 25
Cristian-Silviu Buşoi

Draft opinion
Recital D b (new)

Draft opinion

Amendment

Db. whereas these systems raise many high expectations and have much potential, the effects of newly introduced technologies will never be completely predicted and can only be successfully integrated if society can adjust to a new way of interacting with technology;

Or. en

Amendment 26
Mireille D'Ornano, Jean-François Jalkh, Sylvie Goddyn

Draft opinion
Paragraph 1

Draft opinion

Amendment

1. acknowledges that the adoption of new technologies in the field of healthcare is likely to bring major benefits in terms of patient care and effectiveness of treatment, leading to increased ***quality of life and*** life expectancy;

1. acknowledges that the adoption of new technologies in the field of healthcare is likely to bring major benefits in terms of ***the quality of*** patient care and effectiveness of treatment, leading to increased ***healthy*** life expectancy;

Or. fr

Amendment 27
Notis Marias

Draft opinion
Paragraph 1

Draft opinion

1. acknowledges that the adoption of new technologies in the field of healthcare is **likely** to bring major benefits in terms of patient care and effectiveness of treatment, leading to increased quality of life and life expectancy;

Amendment

1. acknowledges that the adoption of new technologies in the field of healthcare is **expected** to bring major benefits in terms of patient care and effectiveness of treatment, leading to increased quality of life and life expectancy;

Or. el

Amendment 28
Nikolay Barekov

Draft opinion
Paragraph 1

Draft opinion

1. acknowledges that the adoption of new technologies in the field of healthcare is likely to bring major benefits in terms of patient care and effectiveness of treatment, leading to increased quality of life and life expectancy;

Amendment

1. acknowledges that the adoption of new technologies in the field of healthcare, ***assuming that the emphasis is laid at all times on the doctor-patient relationship and free will***, is likely to bring major benefits in terms of patient care and effectiveness of treatment, leading to increased quality of life and life expectancy;

Or. fr

Amendment 29
Merja Kyllönen

Draft opinion
Paragraph 1

Draft opinion

1. acknowledges that the adoption of new technologies in the field of healthcare is likely to bring major benefits in terms of patient care and effectiveness of treatment, leading to increased quality of life and life

Amendment

1. acknowledges that the adoption of new technologies in the field of healthcare is likely to bring major benefits in terms of patient care and effectiveness of treatment ***i.e. by minimizing the risks of medication***

expectancy;

errors, such as miscalculation of drug dosage, leading to increased quality of life and life expectancy;

Or. en

Amendment 30
Ádám Kósa

Draft opinion
Paragraph 1

Draft opinion

1. acknowledges that the adoption of new technologies in the field of healthcare is likely to bring major benefits in terms of patient care and effectiveness of treatment, leading to increased quality of life and life expectancy;

Amendment

1. acknowledges that the adoption of new technologies in the field of healthcare is likely to bring major benefits in terms of patient care and effectiveness **and precision** of treatment, leading to increased quality of life and life expectancy, **which, however, may yet further accentuate the challenges presented to societies by aging, while at the same time they may moderate the degree of dependence;**

Or. hu

Amendment 31
Margrete Auken
on behalf of the Verts/ALE Group

Draft opinion
Paragraph 1 a (new)

Draft opinion

Amendment

1a. considers that although robotics can bring societal benefits, they can at the same time dramatically change the ways people interact with each other and therefore have a real impact on current societal structures; therefore, underlines the urgent need for extensive and informed public debate around this new technological revolution;

Amendment 32
Enrico Gasbarra

Draft opinion
Paragraph 1 a (new)

Draft opinion

Amendment

1a. considers that the internal market and European industry would benefit from the rapid introduction of a uniform legal and regulatory framework for robotics, so as to endow Member States with modern and effective common standards ahead of further technological and social developments;

Or. it

Amendment 33
Enrico Gasbarra

Draft opinion
Paragraph 1 b (new)

Draft opinion

Amendment

1b. considers it essential for the European Union to indicate a regulatory framework based on ethical principles in line with the complexity of robotics and its many social, medical and bioethical implications;

Or. it

Amendment 34
Notis Marias

Draft opinion
Paragraph 2

Draft opinion

2. underlines that innovation providing better diagnoses and better insights into treatment, care and rehabilitation options leads to more accurate medical decisions, quicker recovery times, ***and could therefore alleviate shortages of healthcare professionals in care and rehabilitation processes;***

Amendment

2. underlines that innovation providing better diagnoses and better insights into treatment, care and rehabilitation options leads to more accurate medical decisions, quicker recovery times;

Or. el

Amendment 35
Ádám Kósa

Draft opinion
Paragraph 2

Draft opinion

2. underlines that innovation providing better diagnoses and better insights into treatment, care and rehabilitation options ***leads*** to more accurate medical decisions, quicker recovery times, and could therefore alleviate shortages of healthcare professionals in care and rehabilitation processes;

Amendment

2. underlines that innovation providing better diagnoses and better insights into treatment, care and rehabilitation options ***may lead*** to more accurate ***and rapid*** medical decisions, quicker recovery times, and could therefore alleviate shortages of healthcare ***and rehabilitation*** professionals in care and rehabilitation processes;

Or. hu

Amendment 36
Nikolay Barekov

Draft opinion
Paragraph 2

Draft opinion

2. underlines that innovation providing better diagnoses and better

Amendment

2. underlines that innovation providing better diagnoses and better

insights into treatment, care and rehabilitation options leads to more accurate medical decisions, quicker recovery times, and could therefore alleviate shortages of healthcare professionals in care and rehabilitation processes;

insights into treatment, care and rehabilitation options leads to more accurate medical decisions, quicker recovery times, and, ***provided that human presence and contact were not reduced***, could therefore alleviate shortages of healthcare professionals in care and rehabilitation processes; ***urges that steps be taken to forestall the effects of robotisation in terms of staff cuts and reduction in the fund of experience embodied in medical and paramedical personnel***;

Or. fr

Amendment 37
Jasenko Selimovic, Fredrick Federley

Draft opinion
Paragraph 2 a (new)

Draft opinion

Amendment

2a. stresses that the increase in demand in CPS units has the potential to create a large number of high-skilled jobs in Europe;

Or. en

Amendment 38
Piernicola Pedicini, Eleonora Evi, Marco Affronte

Draft opinion
Paragraph 2 a (new)

Draft opinion

Amendment

2a. considers it useful for robots to be present to support the work of doctors or healthcare assistants, in order to improve the human experience of diagnosis and treatment, without, however, disregarding

the need to ensure that medical practice and patient care practices are not dehumanised;

Or. it

Amendment 39
Ádám Kósa

Draft opinion
Paragraph 3

Draft opinion

3. notes that CPS are able to change the life of people suffering from a disability, as smart technologies can be used for prevention, assistance, monitoring and *companionship*;

Amendment

3. notes that CPS – *whether without contact with the human body or else worn on the human body or implanted in it* – are able to change the life of people suffering from a disability, as smart technologies can be used for prevention, assistance, monitoring and *to provide a social, interactive (natural or artificial) environment*;

Or. hu

Amendment 40
Notis Marias

Draft opinion
Paragraph 3

Draft opinion

3. notes that CPS are able to change the life of people suffering from a disability, as smart technologies can be used for prevention, assistance, *monitoring and companionship*;

Amendment

3. notes that CPS are able to change the life of people suffering from a disability, as smart technologies can be used for prevention, assistance, *etc.*;

Or. el

Amendment 41
Nikolay Barekov

Draft opinion
Paragraph 3

Draft opinion

3. notes that CPS are able to change the life of people suffering from a disability, as smart technologies can be used for prevention, assistance, monitoring and companionship;

Amendment

3. notes that CPS are able to change the life of people suffering from a disability, as smart technologies can be used, ***without altering the indispensable need for human contact***, for prevention, assistance, ***including independent living aids***, monitoring and companionship;

Or. fr

Amendment 42
Elena Gentile

Draft opinion
Paragraph 3

Draft opinion

3. notes that CPS are able to change the life of people suffering from a disability, as smart technologies can be used for prevention, assistance, monitoring and companionship;

Amendment

3. notes that CPS are able to change the life of people suffering from a disability ***for the better***, as smart technologies can be used for prevention, assistance, monitoring and companionship;

Or. it

Amendment 43
Jasenko Selimovic, Fredrick Federley

Draft opinion
Paragraph 3 a (new)

Draft opinion

Amendment

3a. notes that CPS are likely to have a profound impact on the healthcare sector, with the potential to lower the overall

costs of healthcare by enabling medical professionals to shift their focus from treatment to prevention;

Or. en

Amendment 44

Notis Marias

Draft opinion

Paragraph 4

Draft opinion

4. underlines that elder care robot research and development has grown more mainstream and cheaper, producing products with greater functionality and broader consumer acceptance; notes the wide range of applications of such technologies providing prevention, assistance, *monitoring and companionship* to elderly people *and* people suffering from dementia;

Amendment

4. underlines that elder care robot research and development has grown more mainstream and cheaper, producing products with greater functionality and broader consumer acceptance; notes the wide range of applications of such technologies providing prevention, assistance *and other services* to elderly people, *as well as* people suffering from dementia;

Or. el

Amendment 45

Elena Gentile

Draft opinion

Paragraph 4

Draft opinion

4. underlines that elder care robot research and development has grown more mainstream and cheaper, producing products with greater functionality and broader consumer acceptance; notes the wide range of applications of such technologies providing prevention, assistance, monitoring and companionship to elderly people and people suffering from dementia;

Amendment

4. underlines that elder care robot research and development has, *in time*, grown more mainstream and cheaper, producing products with greater functionality and broader consumer acceptance; notes the wide range of applications of such technologies providing prevention, assistance, monitoring and companionship to elderly people and people suffering from dementia;

Amendment 46
Nikolay Barekov

Draft opinion
Paragraph 4

Draft opinion

4. underlines that elder care robot research and development has grown more mainstream and cheaper, producing products with greater functionality and broader consumer acceptance; notes the wide range of applications of such technologies providing prevention, assistance, monitoring and companionship to elderly people and people suffering from dementia;

Amendment

4. underlines that elder care robot research and development has grown more mainstream and cheaper, producing products with greater functionality and broader consumer acceptance; notes the wide range of applications of such technologies providing prevention, assistance, monitoring, *stimulation*, and companionship to elderly people and people suffering from dementia, *cognitive disorders, or memory loss; maintains that ‘companion’ robots are purely therapeutic by nature and should not be used for any other purpose;*

Amendment 47
Jasenko Selimovic, Fredrick Federley

Draft opinion
Paragraph 5

Draft opinion

5. stresses that although CPS has the potential to enhance the mobility and sociability of people with disabilities and elderly people, human caregivers will still be needed and provide an important source of social interaction for them; *notes that CPS technologies or robots can only augment human care and make the rehabilitation process more targeted, so that medical staff and caregivers can*

Amendment

5. stresses that although CPS has the potential to enhance the mobility and sociability of people with disabilities and elderly people, human caregivers will still be needed and provide an important source of social interaction for them;

allocate more time for diagnosis and better treatment options;

Or. en

Amendment 48
Ádám Kósa

Draft opinion
Paragraph 5

Draft opinion

5. stresses that although CPS has the potential to enhance the mobility and sociability of people with disabilities and elderly people, human caregivers will still be needed and provide an important source of social interaction for them; *notes* that CPS technologies *or* robots *can only* augment human care and make the rehabilitation process more targeted, so that medical staff and caregivers can allocate more time for diagnosis and better treatment options;

Amendment

5. stresses that although CPS has the potential to enhance the mobility and sociability of people with disabilities and elderly people, human caregivers will still be needed and provide an important source of social interaction for them, *as well as monitoring the artificial infrastructure; is convinced* that *it is essential for the use of* CPS technologies *and* robots *to be unambiguously regulated so that those technologies genuinely* augment human care and make the rehabilitation process more targeted, so that medical staff and caregivers can allocate more time for diagnosis and better treatment options;

Or. hu

Amendment 49
Nikolay Barekov

Draft opinion
Paragraph 5

Draft opinion

5. stresses that although CPS has the potential to enhance the mobility and sociability of people with disabilities and elderly people, human caregivers will still be needed and provide an *important* source of social interaction for them; *notes* that

Amendment

5. stresses that although CPS has the potential to enhance the mobility and sociability of people with disabilities and elderly people, human caregivers will still be needed and provide an *irreplaceable* source of social interaction for them; *notes*

CPS technologies or robots can only augment human care and make the rehabilitation process more targeted, so that medical staff and caregivers can allocate more time for diagnosis and better treatment options;

that CPS technologies or robots can only augment human care and make the rehabilitation process more targeted, so that medical staff and caregivers can allocate more time for diagnosis and better treatment options; ***calls for any debate or change to the law to be placed clearly within the World Health Organisation (WHO) framework;***

Or. fr

Amendment 50

Mireille D'Ornano, Jean-François Jalkh, Sylvie Goddyn

Draft opinion

Paragraph 5

Draft opinion

5. stresses that although CPS has the potential to enhance the mobility and sociability of people with disabilities and elderly people, human caregivers will still be needed and provide an important source of social interaction for them; notes that CPS technologies or robots can only ***augment*** human care and make the rehabilitation process more targeted, so that medical staff and caregivers can allocate more time for diagnosis and better treatment options;

Amendment

5. stresses that although CPS has the potential to enhance the mobility and sociability of people with disabilities and elderly people, human caregivers will still be needed and provide an important source of social interaction for them; notes that CPS technologies or robots can only ***complement*** human care and make the rehabilitation process more targeted, so that medical staff and caregivers can allocate more time for diagnosis and better treatment options;

Or. fr

Amendment 51

Elena Gentile

Draft opinion

Paragraph 5

Draft opinion

5. stresses that although CPS has the potential to enhance the mobility and

Amendment

5. stresses that although CPS has the potential to enhance the mobility and

sociability of people with disabilities and elderly people, human caregivers will still be needed and provide an important source of social interaction for them; notes that CPS technologies or robots can only augment human care and make the rehabilitation process more targeted, so that medical staff and caregivers can allocate more time for diagnosis and better treatment options;

sociability of people with disabilities and elderly people, human caregivers will still be needed and provide an important source of social interaction for them ***that is not totally replaceable***; notes that CPS technologies or robots can only ***considerably*** augment human care and make the rehabilitation process more targeted, so that medical staff and caregivers can allocate more time for diagnosis and better treatment options;

Or. it

Amendment 52

Margrete Auken

on behalf of the Verts/ALE Group

Draft opinion

Paragraph 5

Draft opinion

5. stresses that although CPS has the potential to enhance the mobility and sociability of people with disabilities and elderly people, human caregivers will still be needed and provide an important source of social interaction for them; notes that CPS technologies or robots can only augment human care and make the rehabilitation process more targeted, so that medical staff and caregivers can allocate more time for diagnosis and better treatment options;

Amendment

5. stresses that although CPS has the potential to enhance the mobility and sociability of people with disabilities and elderly people, human caregivers will still be needed and provide an important source of social interaction for them; notes that CPS technologies or robots can only augment human care and make the rehabilitation process more targeted, so that medical staff and caregivers can allocate more ***quality*** time for diagnosis and better treatment options;

Or. en

Amendment 53

Ádám Kósa

Draft opinion

Paragraph 6

Draft opinion

6. notes that early forms of robots and smart CPS devices are already used in healthcare, such as e-Health devices and surgical robots and that in the near future this technology will continue to develop, having the potential to also reduce healthcare costs;

Amendment

6. notes that early forms of robots and smart CPS devices are already used in healthcare, such as e-Health devices and surgical robots and that in the near future this technology will continue to develop, having the potential ***on the one hand*** to also reduce healthcare costs ***in the field concerned, while on the other hand, as CPS systems are capable of storing in their memories every instruction and observation they register during an operation or other medical intervention, these data may serve as evidence in the event of an error by the CPS and/or the doctor and may constitute a basis for compensation cases;***

Or. hu

Amendment 54

Margrete Auken

on behalf of the Verts/ALE Group

Draft opinion

Paragraph 6

Draft opinion

6. notes that early forms of robots and smart CPS devices are already used in healthcare, such as e-Health devices and surgical robots and that in the near future this technology will continue to develop, having the potential to also reduce healthcare costs;

Amendment

6. notes that early forms of robots and smart CPS devices are already used in healthcare, such as e-Health devices and surgical robots and that in the near future this technology will continue to develop, having the potential to also reduce healthcare costs, ***making more budget available for better adjustment to the diversity of patients' needs, continuous training of the healthcare professionals and research;***

Or. en

Amendment 55
Jasenko Selimovic

Draft opinion
Paragraph 6 a (new)

Draft opinion

Amendment

6a. *underlines that the increased use of CPS could result in a healthier society as procedures become less invasive, leading to quicker recovery times, and reducing health-care absenteeism;*

Or. en

Amendment 56
Cristian-Silviu Buşoi

Draft opinion
Paragraph 6 a (new)

Draft opinion

Amendment

6a. *notes that medical robotic devices continue to evolve and will likely become more frequently utilized in surgical procedures, moving forward the boundaries of medicine;*

Or. en

Amendment 57
Notis Marias

Draft opinion
Paragraph 7

Draft opinion

Amendment

7. *acknowledges that surgical robots have been envisaged to extend the capabilities of human surgeons beyond the limits of conventional laparoscopy, and that the development of surgical*

deleted

robots is rooted in the desire to overcome such limitations and to expand the benefits of minimally invasive surgery, fine movements and accuracy;

Or. el

Amendment 58
Ádám Kósa

Draft opinion
Paragraph 7

Draft opinion

7. acknowledges that surgical robots have been envisaged to extend the capabilities of human surgeons beyond the limits of conventional laparoscopy, and that the development of surgical robots is rooted in the desire to overcome such limitations and to expand the benefits of minimally invasive surgery, fine movements and accuracy;

Amendment

7. acknowledges that surgical robots have been envisaged to extend the capabilities of human surgeons beyond the limits of conventional laparoscopy, and that the development of surgical robots is rooted in the desire to overcome such limitations and to expand the benefits of minimally invasive surgery, fine movements and accuracy, ***but also considers it conceivable that in future, in some cases, surgical robots may even perform routine interventions without medical supervision;***

Or. hu

Amendment 59
Sylvie Goddyn, Mireille D'Ornano, Jean-François Jalkh

Draft opinion
Paragraph 7 a (new)

Draft opinion

7a. maintains that Member States have to retain full sovereignty for the purposes of authorising or prohibiting the use of medical robots, especially in the field of reproductive health;

Amendment

warns, given the need to protect humankind, against the likely temptation to use robots for ex utero pregnancies or ectogenesis;

Or. fr

Amendment 60
Ádám Kósa

Draft opinion
Paragraph 8

Draft opinion

8. underlines that CPS allow for telesurgery, with numerous advantages such as increased precision of hand motion, removing tremor from hand motion, magnified view, improved dexterity and remote surgery;

Amendment

8. underlines that CPS allow for telesurgery, with numerous advantages such as increased precision of hand motion, removing tremor from hand motion, magnified view, ***which they can analyse and assess immediately***, improved dexterity and remote surgery, ***while it must be a fundamental requirement for doctors to acquire skills and accreditation for the performance of interventions with individual CPS devices;***

Or. hu

Amendment 61
Margrete Auken
on behalf of the Verts/ALE Group

Draft opinion
Paragraph 9

Draft opinion

9. notes that recent years have seen significant changes in the medical education and training sector; further notes that, as medical care has become increasingly complex, the climate in academic health centres provides an opportunity to rethink the way medical

Amendment

9. notes that recent years have seen significant changes in the medical education and training sector; further notes that, as medical care has become increasingly complex, the climate in academic health centres provides an opportunity to ***enhance a holistic***

education and lifelong learning is delivered, while preserving the core competence of doctors to retain their expertise and authority over robots;

approach to health, rethink the way medical education and lifelong learning is delivered, while preserving the core competence of doctors to retain their expertise and authority over robots;

Or. en

Amendment 62
Elena Gentile

Draft opinion
Paragraph 9

Draft opinion

9. notes that recent years have seen significant changes in the medical education and training sector; further notes that, as medical care has become increasingly complex, the climate in academic health centres provides an opportunity to rethink the way medical education and lifelong learning is delivered, while preserving the core competence of doctors to retain their expertise and authority over robots;

Amendment

9. notes that recent years have seen significant changes in the medical education and training sector; further notes that, as medical care has become increasingly complex, the climate in academic health centres provides an opportunity to rethink the way medical education and lifelong learning is delivered, while preserving the core competence of doctors to retain their expertise and authority over robots; *calls on the Member States to promote training and specialisation courses to encourage the free movement of surgeons who intend to use robots to carry out their operations; calls on the Commission, therefore, to promote high training standards at EU level for surgeons who are planning to use robotic technologies;*

Or. it

Amendment 63
Mireille D'Ornano, Jean-François Jalkh, Sylvie Goddyn

Draft opinion
Paragraph 9

Draft opinion

9. notes that recent years have seen significant changes in the medical education and training sector; further notes that, as medical care has become increasingly complex, the climate in academic health centres provides an opportunity to rethink the way medical education and lifelong learning *is* delivered, while preserving the core competence of doctors to retain their expertise and authority over robots;

Amendment

9. notes that recent years have seen significant changes in the medical education and training sector; further notes that, as medical care has become increasingly complex, the climate in academic health centres provides an opportunity to rethink the way medical education and lifelong learning *are* delivered, while preserving the core competence of doctors to retain their expertise and authority over robots; ***draws attention to the considerable risk that medical and paramedical professionals who use robots might to some extent be deprived of experience of conventional procedures;***

Or. fr

Amendment 64

Piernicola Pedicini, Eleonora Evi, Marco Affronte

Draft opinion

Paragraph 9 a (new)

Draft opinion

Amendment

9a. calls on the Commission and the Member States to strengthen the financial instruments for research projects in robotics for the social and health emergency;

Or. it

Amendment 65

Piernicola Pedicini, Eleonora Evi, Marco Affronte

Draft opinion

Paragraph 9 b (new)

Draft opinion

Amendment

9b. *considers it vital to respect the principle of the supervised autonomy of robots, whereby the initial planning of treatment and the final decision regarding its execution will always remain the decision of the human surgeon;*

Or. it

Amendment 66
Jasenko Selimovic

Draft opinion
Subheading 3

Draft opinion

Amendment

Clinical *trials*

Clinical *evaluation and clinical investigations*

Or. en

Amendment 67
Notis Marias

Draft opinion
Paragraph 10

Draft opinion

Amendment

10. *stresses that medical CPS should meet the high standards set for medical equipment, through effective verification and certification procedures which allow assessment of the safety and effectiveness of the proposed technology, even at the design stage;*

deleted

Or. el

Amendment 68
Margrete Auken
on behalf of the Verts/ALE Group

Draft opinion
Paragraph 10

Draft opinion

10. stresses that medical CPS should meet the high standards set for medical equipment, through effective verification and certification procedures which allow assessment of the safety and effectiveness of the proposed technology, even at the design stage;

Amendment

10. stresses that medical CPS should meet the high standards set for medical equipment, through effective verification and certification procedures which allow assessment ***by adequately trained staff*** of the safety and effectiveness of the proposed technology, even at the design stage;

Or. en

Amendment 69
Elena Gentile

Draft opinion
Paragraph 10 a (new)

Draft opinion

Amendment

10a. stresses the importance of distinguishing surgical robots from prostheses and exoskeletons from robot companions whose function is to assist persons with disabilities or those who are temporarily incapacitated; stresses the importance of subjecting both species to checks to be carried out in accordance with standards that are as precise and detailed as possible and are monitored by a specific European authority;

Or. it

Amendment 70
Elena Gentile

**Draft opinion
Paragraph 11**

Draft opinion

Amendment

11. calls on the Commission to consider adapting the existing trial procedures designed for testing medicines to the purpose of testing new medical robotic devices;

deleted

Or. it

**Amendment 71
Jasenko Selimovic**

**Draft opinion
Paragraph 11**

Draft opinion

Amendment

11. calls on the Commission to consider adapting the existing trial procedures designed for testing medicines to the purpose of testing new medical robotic devices;

deleted

Or. en

**Amendment 72
Nikolay Barekov**

**Draft opinion
Paragraph 11**

Draft opinion

Amendment

11. calls on the Commission to consider adapting the existing trial procedures designed for testing medicines to the purpose of testing new medical robotic devices;

11. calls on the Commission to consider adapting the existing trial procedures designed for testing medicines to the purpose of testing new medical robotic devices ***while ensuring that those procedures are safe;***

Or. fr

Amendment 73
Margrete Auken
on behalf of the Verts/ALE Group

Draft opinion
Paragraph 11

Draft opinion

11. calls on the Commission to consider adapting the existing trial procedures designed for testing medicines to the purpose of testing new medical robotic devices;

Amendment

11. calls on the Commission to consider adapting the existing trial procedures designed for testing medicines to the purpose of testing new medical robotic devices *in order to safeguard the overarching interests of the patients, notably through enhancing prior informed consent and insurances schemes as there must be full transparency for patients to their own data and full transparency to the public on failed and successful trials; further notes that the responsibility of failed trials and CPS must be clear to patients and the public;*

Or. en

Amendment 74
Ádám Kósa

Draft opinion
Paragraph 11

Draft opinion

11. calls on the Commission to consider adapting the existing trial procedures designed for testing medicines to the purpose of testing new medical robotic devices;

Amendment

11. calls on the Commission to consider adapting the existing trial procedures designed for testing medicines to the purpose of testing new medical robotic devices, *particularly in the case of devices that are implanted in the human body;*

Or. hu

Amendment 75
Elena Gentile

Draft opinion
Subheading 3 a (new) and paragraph 11 a (new)

Draft opinion

Amendment

European Robotics Authority: adaptation of legislation, control, safety, standardisation

11a. recommends the establishment of an independent European authority with expertise in robotics, which will be responsible for oversight in the sector, with the aim of adapting EU legislation to progressive rapid technological developments, by preventing structural delays and governing, also from a social point of view (in terms of Responsible Research and Innovation), the development of a market and a European robotics industry in accordance with uniform criteria throughout the Union;

Or. it

Amendment 76
Jasenko Selimovic

Draft opinion
Paragraph 11 a (new)

Draft opinion

Amendment

11a. welcomes the political agreement on the new medical devices regulation which will improve the safety and quality of medical devices, including robots and CPS, by strengthening the scrutiny of products before they are placed on the market and tightening the surveillance once they are available;

Or. en

Amendment 77

Notis Marias

Draft opinion

Paragraph 12

Draft opinion

12. *points out* that while the development of technology is increasing exponentially, our social systems cannot respond as quickly, and healthcare systems have an even slower response; stresses that these discoveries have a significant impact on civilisation as we know it, and that it is therefore imperative to assess the moral and ethical implications of new technologies in *the early phase of* their development;

Amendment

12. *emphasises* that while the development of technology is increasing exponentially, our social systems cannot respond as quickly, and healthcare systems have an even slower response; stresses that these discoveries have a significant impact on civilisation as we know it, and that it is therefore imperative to assess the moral and ethical implications of new technologies *before and throughout* their development;

Or. el

Amendment 78

Margrete Auken

on behalf of the Verts/ALE Group

Draft opinion

Paragraph 12

Draft opinion

12. points out that while the development of technology is increasing exponentially, our social systems cannot respond as quickly, and healthcare systems have an even slower response; stresses that these discoveries have a significant impact on civilisation as we know it, and that it is therefore imperative to assess the *moral and* ethical implications of new technologies in the early phase of their development;

Amendment

12. points out that while the development of technology is increasing exponentially, our social systems cannot respond as quickly, and healthcare systems have an even slower response; stresses that these discoveries have a significant impact on civilisation as we know it , and that it is therefore imperative to *apply the precautionary principle and* assess the *long term* ethical implications of new technologies in the early phase of their development;

Or. en

Amendment 79
Nikolay Barekov

Draft opinion
Paragraph 12

Draft opinion

12. points out that while the development of technology is increasing exponentially, our social systems cannot respond as quickly, and healthcare systems have an even slower response; stresses that these discoveries have a significant impact on civilisation as we know it, and that it is therefore imperative to *assess* the moral and ethical implications of new technologies in the early phase of their development;

Amendment

12. points out that while the development of technology is increasing exponentially, our social systems cannot respond as quickly, and healthcare systems have an even slower response; stresses that these discoveries have a significant impact on civilisation as we know it, and that it is therefore imperative ***for technological advances to go hand in hand with assessments of*** the moral and ethical implications of new technologies in the early phase of their development;

Or. fr

Amendment 80
Ádám Kósa

Draft opinion
Paragraph 12 a (new)

Draft opinion

Amendment

12a. observes that CPS systems (supplemented by gene surgery) will be usable not only to cure sick people but also to improve the capacities of people who, according to our current conceptions, are healthy and will thus bring into existence special people with capacities that are not yet known, and that CPS systems may even become an integral part of the human body, transforming our conceptions of the human body and health, which may have a major impact on human society as a whole, for which reason care must be taken to ensure that

those people who do not have access to such advanced technologies or do not wish to use them do not suffer discrimination in comparison with people who are integrated with CPS systems, avoiding any reduction in their social mobility and the possibility that (for example in education or on the labour market) they may be placed at a competitive disadvantage in comparison with people whose capacities have been enhanced;

Or. hu

Amendment 81
Elena Gentile

Draft opinion
Paragraph 12 a (new)

Draft opinion

Amendment

12a. stresses the importance, as regards ethical standards, of ensuring that robotic products respect the fundamental rights of individuals and society, which should be protected at EU level, by providing for any necessary technical measures which ensure such respect as from the design stage, in accordance with the so-called privacy by design approach;

Or. it

Amendment 82
Ádám Kósa

Draft opinion
Paragraph 12 b (new)

Draft opinion

Amendment

12b. draws attention to the risks associated with the possibility that CPS

systems integrated into the human body may be hacked or switched off or have their memories wiped, because this could endanger human health, and in extreme cases even human life, and stresses therefore the priority that must be attached to protecting such systems;

Or. hu

Amendment 83

Ádám Kósa

Draft opinion

Paragraph 12 c (new)

Draft opinion

Amendment

12c. considers that it should be adopted as a principle that nobody may be discriminated against because a CPS system or other auxiliary technology constitutes an integral part of their body or because smart technology has been implanted in the human body for purposes of medical treatment, to compensate for some disability or to improve the capacities of the human body; considers that in this context it is necessary to establish, for example, for how long a person remains a human being and at what point they become a robot, which may result in robots being assigned human rights;

Or. hu

Amendment 84

Jasenko Selimovic

Draft opinion

Paragraph 13

Draft opinion

13. acknowledges the vulnerability of patients with special needs, including children, elderly and people suffering from disabilities, *who may develop an emotional connection with CPS and robots, and underlines the ethical considerations posed by their possible attachment;*

Amendment

13. acknowledges the vulnerability of patients with special needs, including children, elderly and people suffering from disabilities; *encourages the Commission to start a reflection on how to ensure that CPS will not negatively impact the autonomy and independence of vulnerable persons;*

Or. en

Amendment 85

Ádám Kósa

Draft opinion

Paragraph 13

Draft opinion

13. acknowledges the vulnerability of patients with special needs, including children, elderly and people suffering from disabilities, *who* may develop an emotional connection with CPS and robots, and underlines the ethical considerations posed by their possible attachment;

Amendment

13. acknowledges the vulnerability of patients with special needs, including children, elderly and people suffering from disabilities, *and stresses that any user* may develop an emotional connection with CPS and robots, *particularly if the latter are capable of learning independently from their environment and expressing appropriate emotional reactions to human emotions*, and underlines the ethical considerations posed by their possible attachment, *for example the emotional or physical impact on people of the switching-off of a robot or the wiping of its memory;*

Or. hu

Amendment 86

Nikolay Barekov

Draft opinion

Paragraph 13

Draft opinion

13. acknowledges the vulnerability of patients with special needs, including children, elderly and people suffering from disabilities, who may develop an emotional connection with CPS and robots, and underlines the ethical considerations posed by their possible attachment;

Amendment

13. acknowledges the vulnerability of patients with special needs, including children, *the* elderly and people suffering from disabilities, who may develop an emotional connection with CPS and robots, *in particular humanoid or animal-like robots*, and underlines the ethical considerations posed by their possible attachment *to such figments of the imagination*;

Or. fr

Amendment 87

Mireille D'Ornano, Jean-François Jalkh, Sylvie Goddyn

**Draft opinion
Paragraph 13**

Draft opinion

13. acknowledges the vulnerability of patients with special needs, including children, elderly and people suffering from disabilities, who may develop an emotional connection with CPS and robots, and underlines the ethical considerations posed by their possible attachment;

Amendment

13. acknowledges the vulnerability of patients with special needs, including children, *the* elderly and people suffering from disabilities, who may develop an emotional connection with CPS and robots, and underlines the ethical considerations posed by their possible attachment, *which imply an imperative need to maintain sufficient human contact at all times*;

Or. fr

Amendment 88

Elena Gentile

**Draft opinion
Paragraph 13**

Draft opinion

13. acknowledges the vulnerability of

Amendment

13. acknowledges the vulnerability of

patients with special needs, including children, elderly and people suffering from disabilities, who may develop an emotional connection with CPS and robots, and underlines the ethical considerations posed by their possible attachment;

patients with special needs, including children, elderly and people suffering from disabilities, who may develop an emotional connection with CPS and robots, and underlines the ethical considerations posed by their possible attachment; ***suggests that the Commission supplement existing legislation with a legislative proposal that makes it compulsory for manufacturers, at the design stage, to adapt to criteria that prevent the feelings of patients or users, especially if they are sick, children, or persons with disabilities, from being manipulated, so that inappropriate emotional bonds are not created, or to prevent humans from being deceived into thinking that the machine is sentient and has feelings that it does not actually possess;***

Or. it

Amendment 89
Elena Gentile

Draft opinion
Paragraph 13 a (new)

Draft opinion

Amendment

13a. calls on the Commission and on the Member States to promote the development of assistive technologies, also through liability schemes that are different from those currently applicable, in order to facilitate the development and adoption of these technologies by those who need them, in accordance with Article 4 of the UN Convention on the Rights of Persons with Disabilities, to which the Union is party;

Or. it

Amendment 90

Ádám Kósa

Draft opinion

Paragraph 14

Draft opinion

14. highlights the importance of preserving the patient-doctor care relationship, in particular as regards communication of the *medical diagnosis and treatment*;

Amendment

14. highlights the importance of preserving the patient-doctor care relationship, in particular as regards *medical diagnosis using data gathered by means of diagnostic CPS systems worn on or implanted in the body and communication of the treatment thus revealed to be necessary, avoiding the adverse consequences of faulty self-diagnosis*;

Or. hu

Amendment 91

Elena Gentile

Draft opinion

Subheading 4 a (new) and paragraph 14 a (new)

Draft opinion

Amendment

Human enhancement: ethical profiles and regulations

14a. *Notes that the adoption of CPS raises the issue of human enhancement, which is defined as the enhancement of existing natural human skills or the conferral of new skills, allowing individuals to overcome disability; in this regard, considers it necessary to address the issues raised by this phenomenon in order to ensure equal access to this new technology;*

Or. en

Amendment 92
Margrete Auken
on behalf of the Verts/ALE Group

Draft opinion
Paragraph 15

Draft opinion

15. acknowledges the need to minimise the ***possible environmental or*** ecological footprint of robotics, as the use of CPS and robots is expected to increase overall energy consumption; emphasises the need to increase energy efficiency by promoting the use of renewable technologies for robotics and to reduce waste;

Amendment

15. acknowledges the need to minimise the ecological footprint of robotics, as the use of CPS and robots is expected to increase overall energy consumption ***and amount of electric and electronic waste***; emphasises the need to ***apply the principles of regenerative design***, increase energy efficiency by promoting the use of renewable technologies for robotics, ***use and reuse of secondary raw materials***, and to reduce waste;

Or. en

Amendment 93
Elena Gentile

Draft opinion
Paragraph 15

Draft opinion

15. acknowledges the need to minimise the possible environmental or ecological footprint of robotics, ***as the use of CPS and robots is expected to increase overall energy consumption***; emphasises the need to increase energy efficiency by promoting the use of renewable technologies for robotics and to reduce waste;

Amendment

15. acknowledges the need to minimise the possible environmental or ecological footprint of robotics; emphasises the need to increase energy efficiency by promoting the use of renewable technologies for robotics and to reduce waste; ***stresses the importance of a European framework for remotely piloted systems that are used in the sea and below the sea's surface to protect the safety of EU citizens and of the environment, and calls on the Commission to supplement and update EU regulations concerning such matters***;

Or. it

Amendment 94
Daciana Octavia Sârbu

Draft opinion
Paragraph 15

Draft opinion

15. acknowledges the need to minimise the possible environmental or ecological footprint of robotics, as the use of CPS and robots is expected to increase overall energy consumption; emphasises the need to increase energy efficiency by promoting the use of renewable technologies for robotics and to reduce waste;

Amendment

15. acknowledges the need to minimise the possible environmental or ecological footprint of robotics, as the use of CPS and robots is expected to increase overall energy consumption; emphasises the need to increase energy efficiency by promoting the use of renewable technologies for robotics and to reduce waste, ***and to maximise the potential for robotics to make processes more resource efficient;***

Or. en

Amendment 95
Sylvie Goddyn, Jean-François Jalkh, Mireille D'Ornano

Draft opinion
Paragraph 15

Draft opinion

15. acknowledges the need to minimise the possible environmental or ecological footprint of robotics, as the use of CPS and robots is expected to increase overall energy consumption; emphasises the need to increase energy efficiency by promoting the use of renewable technologies for robotics and to reduce waste;

Amendment

15. acknowledges the need to minimise the possible environmental or ecological footprint of robotics, as the use of CPS and robots is expected to increase overall energy consumption; emphasises the need to increase energy efficiency by promoting the use of renewable technologies for robotics and to reduce waste; ***considers that Asimov's First Law should be broadened to encompass the environment so as to ensure that no robot could injure a human being or damage the environment or, by inaction, allow a human being or the environment to come to harm;***

Amendment 96
Merja Kyllönen

Draft opinion
Paragraph 15 a (new)

Draft opinion

Amendment

15a. emphasises that the full lifecycle approach from production and consumption to waste management and the market for secondary raw materials should be included in the designing process of new CPS and robots and therefore calls on the Commission to incorporate the principles of circular economy in to any Union policy on robotics to ensure that all materials, some of which are among most critical, are used in the most efficient and sustainable way;

(To be inserted before the subheading 'Safety')

Or. en

Amendment 97
Jasenko Selimovic, Fredrick Federley, Ulrike Müller

Draft opinion
Paragraph 15 a (new)

Draft opinion

Amendment

15a. notes also that the use of CPS will have a positive impact on the environment, especially in the fields of agriculture and food supply, notably through the reduced size of machinery and the reduced use of fertilizers, energy and water, as well as through precision farming;

*(To be inserted before the subheading
'Safety')*

Or. en

Amendment 98
Margrete Auken
on behalf of the Verts/ALE Group

Draft opinion
Paragraph 15 a (new)

Draft opinion

Amendment

15a. emphasises that all negative externalities should be taken into account in the price setting;

*(To be inserted before the subheading
'Safety')*

Or. en

Amendment 99
Jasenko Selimovic, Fredrick Federley, Ulrike Müller

Draft opinion
Paragraph 15 b (new)

Draft opinion

Amendment

15b. stresses that CPS will lead to the creation of energy and infrastructure systems that are able to control the flow of electricity from producer to consumer, as well as will result in the creation of energy 'prosumers', who both produce and consume energy; thus allowing for major environmental benefits;

*(To be inserted before the subheading
'Safety')*

Or. en

Amendment 100

Elena Gentile

Draft opinion

Paragraph 16

Draft opinion

16. Safety of medical robotic devices is a precondition for their introduction in the healthcare sector. The effectiveness and safety of care and medical robots should be assessed against special safety safeguards and certification procedures, with special attention given to their use by impaired users or in emergency situations;

Amendment

16. Safety of medical robotic devices is a precondition for their introduction in the healthcare sector. The effectiveness and safety of care and medical robots should be assessed against special, ***very detailed***, safety safeguards and ***standard*** certification procedures, with special attention given to their use by impaired users or in emergency situations; ***calls on the Commission to promote the adoption of very specific and detailed EU-wide standards***;

Or. it

Amendment 101

Mireille D'Ornano, Jean-François Jalkh, Sylvie Goddyn

Draft opinion

Paragraph 16

Draft opinion

16. Safety of medical robotic devices is a precondition for their introduction in the healthcare sector. The effectiveness and safety of care and medical robots should be assessed against special safety safeguards and certification procedures, with special attention given to their use by impaired users or in emergency situations;

Amendment

16. Safety of medical robotic devices is a precondition for their introduction in the healthcare sector. The effectiveness and safety of care and medical robots should be assessed against special safety safeguards and certification procedures, with special attention given to their use by impaired ***or elderly*** users or ***users*** in emergency situations;

Or. fr

Amendment 102

Notis Marias

Draft opinion
Paragraph 16

Draft opinion

16. Safety of medical robotic devices is a precondition for their introduction in the healthcare sector. The effectiveness and safety of care and medical robots should be assessed against special safety safeguards and certification procedures, with special attention given to their use by impaired users or in emergency situations;

Amendment

16. Safety of medical robotic devices is a precondition for their introduction in the healthcare sector. The effectiveness and safety of care and medical robots should be assessed against special safety safeguards and certification procedures, with special attention given to their use by impaired users or in emergency situations;
particular attention should be paid to the security of CPS networks so as to remove any possibility of hacking into and stealing sensitive personal data;

Or. el

Amendment 103
Ádám Kósa

Draft opinion
Paragraph 16 a (new)

Draft opinion

Amendment

16a. underlines that the safety of CPS systems implanted in the human body is a fundamental requirement, because any fault in them may be fatal, and in this context stresses the importance of providing information and of unambiguous regulation of issues of liability, including that of whose property these implanted CPS systems are, who has rights over them and who may change their implantation, strictly prohibiting any experimentation on people without their consent;

Or. hu

Amendment 104
Margrete Auken
on behalf of the Verts/ALE Group

Draft opinion
Paragraph 16 a (new)

Draft opinion

Amendment

16a. calls on the Commission to put in place without delay systems for centralised premarket approval, traceability and post-market surveillance, that include correspondent publicly accessible databases; the criteria for approval should include the following: safe, effective and necessary technology, positive risks/ benefits balance for the patients, societal readiness to take the risks via sufficient available insurance coverage, clear identification of liability, non-discriminatory sharing of the benefits and the risks among society. "Pioneer" patients should not be used as representatives of all patients. Instead, estimation of users' actual wishes must be given priority before the implementation of CPS;

Or. en

Amendment 105
Piernicola Pedicini, Eleonora Evi, Marco Affronte

Draft opinion
Paragraph 16 a (new)

Draft opinion

Amendment

16a. stresses the need to equip each cybernetic machine used in medicine directly on human beings with an audio-video recording system (similar to black boxes in aircraft or ships), which may

also be used to determine objective liability;

Or. it

Amendment 106
Nicola Caputo

Draft opinion
Paragraph 16 a (new)

Draft opinion

Amendment

16a. stresses the importance, for safety purposes, of adequate training for medical or paramedical personnel who use, or advise on the use of, new robotic medical devices;

Or. it

Amendment 107
Nikolay Barekov

Draft opinion
Subheading 6 a (new) and paragraph 16 a (new)

Draft opinion

Amendment

Ethics

16a. The use of care, assistance, and companionship robotics should proceed within a context emphasising human relationships. It should manifestly improve the patient's quality of life and bring objective comfort. It must respect the dignity of the human person and the patient's consent, however given. The patient should, in addition, be encouraged at all times to make use of and, if possible, develop his or her own cognitive faculties. The use of robotics should not exempt

persons from assuming their professional, social, family, or moral responsibilities for those who are most vulnerable – children, elderly or dependent persons, or the sick;

Or. fr

Amendment 108

Ádám Kósa

Draft opinion

Paragraph 16 b (new)

Draft opinion

Amendment

16b. considers that CPS systems implanted in the human body must be regarded as an integral part of the human body, in the same way as human organs, and that the rules that apply to human organs must also be applied to them, bearing in mind also that switching off an implanted CPS system requires similarly strict regulation to euthanasia;

Or. hu

Amendment 109

Mireille D'Ornano, Jean-François Jalkh, Sylvie Goddyn

Draft opinion

Paragraph 17

Draft opinion

Amendment

17. Medical CPS and the use of a robot as an “electronic health record” raise questions concerning laws on patient privacy, medical professional secrecy, and data protection in the area of public health. *Union* data protection rules should be adapted to take into account the increasing

17. Medical CPS and the use of a robot as an “electronic health record” raise questions concerning laws on patient privacy, medical professional secrecy, and data protection in the area of public health. *National and international* data protection rules should be adapted to take into

complexity and interconnectivity of care and medical robots handling highly sensitive personal information and health data. The codes of conduct on medical professional secrecy should be reviewed concerning the health data stored on CPS systems that can be accessed by third parties;

account the increasing complexity and interconnectivity of care and medical robots handling highly sensitive personal information and health data. The codes of conduct on medical professional secrecy should be reviewed concerning the health data stored on CPS systems that can be accessed by third parties; *The necessary discussions should take place within the World Health Organisation, given the international nature of the issues at stake;*

Or. fr

Amendment 110

Margrete Auken

on behalf of the Verts/ALE Group

Draft opinion

Paragraph 17

Draft opinion

17. Medical CPS and the use of a robot as an “electronic health record” raise questions concerning laws on patient privacy, medical professional secrecy, and data protection in the area of public health. Union data protection rules should be adapted to take into account the increasing complexity and interconnectivity of care and medical robots handling highly sensitive personal information and health data. The codes of conduct on medical professional secrecy should be *reviewed* concerning the health data stored on CPS systems that can be accessed by third parties;

Amendment

17. Medical CPS and the use of a robot as an “electronic health record” raise questions concerning laws on patient privacy, medical professional secrecy, and data protection in the area of public health. Union data protection rules should be adapted to take into account the increasing complexity and interconnectivity of care and medical robots handling highly sensitive personal information and health data. The codes of conduct on medical professional secrecy should be *enhanced* concerning the health data stored on CPS systems that can be accessed by third parties;

Or. en

Amendment 111

Notis Marias

Draft opinion
Paragraph 17

Draft opinion

17. Medical CPS and the use of a robot as an “electronic health record” raise questions concerning laws on patient privacy, medical professional secrecy, and data protection in the area of public health. Union data protection rules should be adapted to take into account the increasing complexity and interconnectivity of care and medical robots handling highly sensitive personal information and health data. The codes of conduct on medical professional secrecy should be reviewed concerning the health data stored on CPS systems that can be accessed by third parties;

Amendment

17. Medical CPS and the use of a robot as an “electronic health record” raise questions concerning laws on patient privacy, medical professional secrecy, and data protection in the area of public health. Union data protection rules should be adapted to take into account the increasing complexity and interconnectivity of care and medical robots **possibly** handling highly sensitive personal information and health data. The codes of conduct on medical professional secrecy should be reviewed concerning the health data stored on CPS systems that can be accessed by third parties;

Or. el

Amendment 112
Elena Gentile

Draft opinion
Paragraph 17

Draft opinion

17. Medical CPS and the use of a robot as an “electronic health record” raise questions concerning laws on patient privacy, medical professional secrecy, and data protection in the area of public health. Union data protection rules should be adapted to take into account the increasing complexity and interconnectivity of care and medical robots handling highly sensitive personal information and health data. The codes of conduct on medical professional secrecy should be reviewed concerning the health data stored on CPS systems that can be accessed by third parties;

Amendment

17. Medical CPS and the use of a robot as an “electronic health record” raise questions concerning laws on patient privacy, medical professional secrecy, and data protection in the area of public health. Union data protection rules should be adapted to take into account the increasing complexity and interconnectivity of care and medical robots handling highly sensitive personal information and health data; **they should comply with the concept of privacy by design, as laid down in Regulation (EU) 2016/679 concerning privacy**. The codes of conduct on medical professional secrecy should be reviewed concerning the health data stored on CPS systems that can be accessed by third

parties;

Or. it

Amendment 113

Ádám Kósa

Draft opinion

Paragraph 17 a (new)

Draft opinion

Amendment

17a. stresses the need for clear regulation of the right to use data on health and life style obtained using CPS systems implanted in the human body, because the sharing of such data may assist the further development of medicine, while on the other hand it may make the individual vulnerable so that the interests of society and the individual come into conflict, and therefore calls on the Commission, with due regard for the inalienable rights of human beings, to regulate the use and storage of information gathered using such devices, with particular reference to innovation and research;

Or. hu

Amendment 114

Margrete Auken

on behalf of the Verts/ALE Group

Draft opinion

Paragraph 17 a (new)

Draft opinion

Amendment

17a. considers that the only possible owner of the data should be the patient and that by no means should it be allowed to sell data generated by robotics in the

health sector;

Or. en

Amendment 115
Margrete Auken
on behalf of the Verts/ALE Group

Draft opinion
Paragraph 17 b (new)

Draft opinion

Amendment

17b. Insurance companies or any other service provider should not be allowed to use e-health data to introduce discriminations in the setting of prices, as this would contradict the fundamental right for access to the highest attainable standard of health;

Or. en

Amendment 116
Nikolay Barekov

Draft opinion
Paragraph 18

Draft opinion

Amendment

18. Research Ethics Committees (REC) should take into account the ethical questions raised by the development of medical robotic devices and CPS in many areas of healthcare and assistance to disabled and elderly people. Issues such as equality of access to robotic preventive health care, the privileged patient-doctor care relationship, and the susceptibility of patients with special needs such as children to developing an emotional attachment to

18. Research Ethics Committees (REC), ***which should include health practitioners working day-to-day as well as philosophers and religious representatives***, should take into account the ethical questions raised by the development of medical robotic devices and CPS in many areas of healthcare and assistance to disabled and elderly people. Issues such as equality of access to robotic preventive health care, the privileged

robots should be given due consideration.

patient-doctor care relationship, and the susceptibility of patients with special needs such as children to developing an emotional attachment to robots should be given due consideration.

Or. fr

Amendment 117
Ádám Kósa

Draft opinion
Paragraph 18

Draft opinion

18. Research Ethics Committees (REC) should take into account the ethical questions raised by the development of medical robotic devices and CPS in many areas of healthcare and assistance to disabled and elderly people. Issues such as equality of access to robotic preventive health care, the privileged patient-doctor care relationship, and the susceptibility of patients with special needs *such as* children to developing an emotional attachment to robots should be given due consideration.

Amendment

18. Research Ethics Committees (REC) should take into account the ethical questions raised by the development of medical robotic devices and CPS in many areas of healthcare and assistance to disabled and elderly people. Issues such as equality of access to robotic preventive health care, the privileged patient-doctor care relationship, and the susceptibility, *in particular*, of patients with special needs (*for example people with disabilities*), *but not only them* (*for example children, lonely people, etc.*), to developing an emotional attachment to robots should be given due consideration.

Or. hu

Amendment 118
Ádám Kósa

Draft opinion
Paragraph 18 a (new)

Draft opinion

Amendment

18a. considers that it should be adopted as a principle that people who are integrated with CPS systems and people without such devices are equal, and in

this context it is necessary to study such issues as what makes a human being human, what distinguishes human beings from robots, and in what ways they differ from roboticised people (or people integrated with CPS systems), and whether indeed they do so differ, and the rights of human robots (which for example are capable of learning and have emotions or knowledge).

Or. hu

Amendment 119
Jasenko Selimovic

Draft opinion
Paragraph 18 a (new)

Draft opinion

Amendment

18a. encourages the Research Ethical Committees and the Commission to start a reflection in order to develop a code of conduct for researchers/designers and users of medical CPS, that should be based on the principles enshrined in the Union's Charter of Fundamental Rights (such as human dignity and human rights, equality, justice and equity, benefit and harm, dignity, non-discrimination and non-stigmatisation, autonomy and individual responsibility, informed consent, privacy and social responsibility as well as the rights of the elderly, the integration of persons with disabilities, the right to healthcare, and the right to consumer protection) and on existing ethical practices and codes.

Or. en

Amendment 120
Margrete Auken
on behalf of the Verts/ALE Group

Draft opinion
Subheading 8 a (new) and paragraph 18 a (new)

Draft opinion

Amendment

Liability

18a. Acknowledges that robotics can introduce a high level of uncertainty regarding responsibility and liability issues. Therefore is of opinion that an interim solution could be to consider the one(s) who find economic benefits in this business should be held liable by default in case of injuries due to a dysfunction of the robot and responsible for proper disposal of electric and electronic waste generated;

Or. en

Amendment 121
Margrete Auken
on behalf of the Verts/ALE Group

Draft opinion
Paragraph 18 b (new)

Draft opinion

Amendment

18b. Is of the opinion that the mere existence of these technologies should not be translated into a review minimising industrial risks to health, such as nuclear risk, with the argument that it would make possible to avoid exposing humans to dangerous conditions: the high dependency of these technologies on energy supply makes them extremely vulnerable and unreliable in an emergency situation such as a natural or industrial accident in energy supply, a terrorist attack or war.

Or. en