New EU rules to ensure safety of medical devices

People rely on these devices every day and expect them to be safe and incorporate the latest progress in science and innovation. The current rules on the safety and performance of medical devices in the EU were harmonised in the 1990s. To reflect the substantial technological and scientific progress in this sector over the last 20 years, the Commission proposed to update the rules to improve the safety of medical devices for EU citizens, create the conditions to modernise the sector and to consolidate its role as a global leader.

Why do we need new regulations on medical devices?

Problems with diverging interpretation of the existing rules as well as certain incidents -e.g. with breast implants and metal hips – highlighted the weaknesses of the current legal system and damaged the confidence of patients, consumers and healthcare professionals in the safety of medical devices.

To address this, the Commission proposed two Regulations on medical devices and *in vitro* diagnostic medical devices in 2012. To ensure harmonised application of the rules throughout the EU, the two new Regulations will replace the three existing Directives on medical devices. The new rules significantly tighten the controls to ensure that medical devices are safe and effective and at the same time foster innovation and improve the competitiveness of the medical device sector. The new rules also better reflect the most recent scientific and technological progress and set the gold standard for medical device regulation globally. The revised rules also provide the conditions needed to consolidate the role of the EU in the long-term as a global leader in the sector.

What are the main benefits for patients and consumers?

The new Regulations pave the way to a more patient-friendly environment, where transparency and patients' information and choice are a priority; where patients can benefit from innovative, highly performing devices and new therapies become possible. The new rules introduce:

- **better protection of public health and patient safety**. In particular high-risk devices are going to be subject to stricter pre-market control. Certain aesthetic devices (such as coloured contact lenses or equipment for liposuction) presenting high-risk to consumers and practices such as reprocessing of single-use devices are included in the scope of the new Regulations and made subject to a stricter and more harmonised regime. Rules on clinical evaluation and clinical investigation (and, for *in-vitro* diagnostic medical devices, performance studies) are generally strengthened and stricter requirements on the use of hazardous substances are introduced.

- a comprehensive **EU database** on medical devices (EUDAMED) that will contain a living picture of the lifecycle of all products being available on the EU market. A large part of the information will be made publicly available, including a newly introduced summary of safety and performance for all Class III and implantable devices. The Commission is required to set up the database by spring 2020 and to maintain it thereafter.
- a new **device identification system based on a unique device identifier (UDI)** that will allow easier traceability of medical devices,
- an **'implant card'** for patients containing information about implanted medical devices that will make information easily available and accessible to the particular patient.
- a **robust financial mechanism to ensure patients are compensated** in case they receive defective products. The Regulations require manufacturers to have measures in place to provide sufficient financial coverage in respect of their potential liability. Such financial coverage shall be proportionate to the risk class, type of device and the size of the enterprise. This should allow patients to be rapidly and effectively compensated, also in case of financial bankruptcy of the relevant company.

Which products are affected by the new regulations?

In line with the current system, all medical devices, *in vitro* diagnostic medical devices and their accessories fall under the new regulations. In addition, certain aesthetic products such as coloured contact lenses or equipment for liposuction that need to be just as safe as existing medical devices will also be covered.

Under the new Regulations, both medical devices and *in vitro* diagnostic medical devices are divided into four risk classes. Depending on the risk class of the product, a different conformity assessment procedure is foreseen before the product can be placed on the EU market. In case of medium or high risk classes, Notified Bodies might be involved in the process.

Why did an agreement take so long to reach?

Effective and efficient rules on medical devices are extremely important to ensuring high levels of health and safety protection for EU citizens. At the same time, they are very technical and sensitive, and they had to be considered thoroughly.

After three years of discussions at the expert level, the ministers of all EU countries agreed on 5 October 2015 on the general approach to the medical devices package. The European Parliament and the Council agreed on a final text on 15 June 2016. Based on this agreement and following the legal-linguistic finalisation of the text, the Council voted its first reading position for the two texts on 7 March 2017. The same texts were then adopted without modification by the European Parliament with an early second reading on 5 April 2017, which closed the legislative procedure.

The new rules will now start to apply 3 years after publication of the

Regulation for medical devices and 5 years after publication for *in vitro* diagnostic medical devices. New requirements on Notified Bodies and the provisions of the new governance structure will already be applicable six months after the adoption, therefore by the end of this year.

Will the new rules be able to keep up with the future progress?

The final Regulations contain very important changes to the current system to enable the sector to produce safer and more innovative devices and help address future challenges. The new Regulations contain many provisions to increase security and regulatory certainty (harmonised rules on drug-device combination products, tissue engineering, nanoscience, personalised medicine, substance based devices and genetic tests) and take into account the latest developments in the sector (medical software, apps, cybersecurity).

To help boost innovation in the sector, the EU-wide database on medical devices (EUDAMED), supported by a new device identification system based on a unique device identifier (UDI), will make big sets of data in the field of medical devices available within the EU. By producing more innovative devices, medical device manufacturers will also be able to offer solutions for disease prevention or early diagnosis that will in turn make the healthcare sector more affordable, by for example helping to prevent or reduce hospitalisation.

Will the transition to the new rules create any disruptions to the availability of medical devices? What are the arrangements?

It is crucial to ensure that the new rules enter into force without any unreasonable delays and they do not create any serious disruption of the medical devices supply. The Commission, competent Authorities, Notified Bodies and all other stakeholders will work together to ensure that the transition to the new regime is smooth and successful. The Regulations foresee that certificates issued under the current Directives can remain valid for a certain additional period after the general application date of the two Regulations (3 years after the entry into force for medical devices and 5 years for the *in vitro* diagnostic medical devices). Moreover, a set of exemptions from clinical investigation requirements have been introduced for products placed on the market under the current Directives, provided that their clinical evaluation is based on sufficient clinical data and that they are in compliance with relevant common specifications. These regulatory developments will also create new opportunities for qualified staff. The Commission will work with stakeholder organisations and Member states authorities to organise relevant information and training within their constituencies required to carry out these changes.

How will the governance of the new regulations make the medical devices and *in vitro* diagnostic medical devices safer? How will the market surveillance be improved?

The strengthened European governance of the new system is one of the main improvements. The Regulations introduce:

- a new Medical Device Coordination Group (MDCG), composed of Member States experts and chaired by the Commission;
- increased cooperation between Member States in the field of vigilance and market surveillance;
- a mandatory coordinated assessment of multinational clinical investigations.

As a result, a true European mechanism will be put in place for the regulatory management of medical devices. It will allow more frequent exchange of information, so regulatory decisions by either Member States or Commission can be taken on a more informed basis. Under this new governance, it should be easier to address safety issues and scandals on the EU territory and act quicker whenever required and appropriate.

What will be the role of notified bodies?

Currently, medical devices are not subject to a pre-market authorisation by a regulatory authority. Medium and high-risk devices require a conformity assessment procedure, involving an independent third party known as a 'notified body'. Notified Bodies used to be designated and monitored by the Member States and acted under the control of the national authorities. In 2013, joint assessments of Notified Bodies were introduced, with members from other Member States and the Commission involved in the designation procedure. Under the new framework, the successful experience of the joint assessments is reinforced. Under the new Regulations, independent experts could be required to provide an opinion to the Notified Body on certain high-risk products before the final decision on the certification of the product is taken. This will help a Notified Body to make more informed decisions and stimulate a process of continuous learning. It will help drive innovation while preserving a high level of safety and performance of products.

How will the scrutiny mechanism for assessment of high-risk devices work?

For certain high risk devices, the new Regulations require the Notified Bodies to consult with an expert panel before placing the device on the market. According to this procedure, an expert panel could provide a scientific opinion to the notified body on its assessment of the manufacturer's clinical file. While the notified body would not be bound by the opinion, it would have to provide a justification for not following it. All relevant documents regarding the opinion and the final decision of the notified body would be publicly available in EUDAMED.

What will be the impact of the new rules on the industry? Will they result in additional costs for companies and SMEs in particular?

The medical devices sector is a global leader and a major employer in Europe: it employs more than 500,000 people in over 25,000companies. The sector is driven by small and medium-sized companies (SMEs) and the new Regulations will help the EU industry to maintain and further expand its leadership role on the global scale, by making it more competitive and more solid in a complex global environment. This will be the result of three main factors:

- **simplified administrative procedures** – under the new framework, registration of devices and operators will have to be done only once at the EU level. This is a major change compared to today's situation where in many cases manufacturers might be required to register their products in all Member States where those products are placed on the market.
- **increased legal certainty –** growth and competitiveness build on the existence of a stable set of legal requirements. Contrary to a Directive, a Regulation is directly applicable in all Member States: this will help to avoid varying conditions for patients and industry in different countries. The new texts also include precise and detailed clarifications of the scope of the new rules, a list of clear obligations of relevant economic operators as well as an indication of the specific exemption regimes which apply to certain devices or practices such as in-house devices or reprocessing of single-use devices.
- **increased credibility and reputation of the overall system** – industry's reputation is highly sensitive to the credibility of the EU medical device system as a whole. Various incidents as well as public reports regarding an alleged "uneven approach" among the bodies responsible for certification and approval of medical devices have damaged the confidence of patients and healthcare professionals in the safety of the devices they use every day, while confirming some weaknesses in today's legislation. The new Regulations address the shortcomings of the current legislation and aim to increase the overall confidence in the medical device market.

These advantages should counterbalance the extra costs incurred by companies due to compliance with the higher safety standards and new requirements contained in the new Regulations. Specific needs of SMEs have been addressed in the texts particularly in relation to new requirements on financial coverage for manufacturers, person responsible for regulatory compliance and fees charged by Notified Bodies. This gives a potential boost to SMEs active in this sector.

What are the rules on reprocessing single-use medical devices?

Some devices are intended to be discarded after they have been used once. However, under properly controlled conditions some such devices can be safely reused. The regulation on medical devices contains minimum requirements on reprocessing of single-use medical devices. Reprocessing may only take place when authorised under national law and in accordance with the provisions of the medical devices Regulation. When reprocessing is allowed, the entity that wants to reprocess the device must assume the same obligations as a manufacturer. However, a different regime is applied in the case of reprocessing by health institutions and by third parties on the request of health institutions. Such regime includes compliance of reprocessing with common specifications or national provisions and harmonised standards to be certified by a notified body.

Is the regulation addressing the issue of risks of use of nanomaterials used for medical devices?

The new Regulation on medical devices lays down a dedicated classification rule for devices incorporating or consisting of nanomaterials. The critical factor is the potential for nanomaterials to be in contact with membranes inside the body. Those devices presenting a high or medium potential for such contact will fall under the highest risk class and thus be subject to the most stringent conformity assessment procedures.

For further information

IP/17/847

Opening statement by Federica Mogherini at the Brussels Conference "Supporting the future of Syria and the Region"

Check against delivery!

Welcome to Brussels for this important international conference. First of all let me particularly welcome Secretary General [of the United Nations], António Guterres, also the Prime Ministers of Lebanon, Mr [Saad] Al-Hariri, and Jordan Mr [Hani] Al-Mulki, and my fellow co-chairs, the Foreign Ministers [Foreign Minister of Qatar, Sheikh Mohammed bin Abdulrahman] Al-Thani, [Foreign Minister of Norway, Børge] Brende, [First Deputy Prime Minister and Minister for Foreign Affairs, Sheikh Sabah Khalid Al Hamad] Al-Sabah, [Foreign Minister and Vice Chancellor of Germany, Sigmar] Gabriel and [United Kingdom Secretary of State for Foreign and Commonwealth Affairs, Boris] Johnson, and all of you representing so many countries and international organisations here today.

And let me start by saying that, indeed, today and yesterday are sad days – as there have been hundreds and thousands of days that have been sad, dramatic, horrific, in these last six years. How many minutes of silence we have observed in these six years and how much frustration we have all felt in front of the victims – the children, the innocent people losing their lives.

This is a conference where all of us come together, as international community, to tell the Syrian people that we care for their lives and that we are ready to support the livings, the ones who are still alive, and prevent the lives of those who are at risk inside Syria and in the neighbouring countries. But this is also, I think, a conference where our voice can join the voice of so many Syrians, as the civil society representatives that we will hear in a few minutes. All the Syrian women and men that have only one word to say to us: *"Hudna"* – a ceasefire and peace. And I think we have also

a collective responsibility as international community to be consistent, not only with our humanitarian efforts, but also with our political work, to make sure that peace can be reached in the country with the help and the support of all of us. We have a responsibility to put an end to this war.

We are here in Brussels today with clear purposes and clear reasons. First of all, giving an answer to these Syrians who still hope and believe that peace can be built in their country. Every time I meet with representatives of Syrian civil society – and especially the women if I can say so – I see this mix of desperation and hope. And if they still have hope, I think we have a duty to live up to these expectations to be able to rebuild their own country in freedom, in democracy, in full respect of human lives and rights.

The first thing we have today is obviously condemning all loss of lives and particularly the horrific chemical attack close to Idlib that was yet another reminder – if we needed it any – of the need for us to come together and put an end to this war.

Some in our public opinions might think that the humanitarian effort in this moment is a naive exercise. Ask to the millions of Syrians who live thanks to that humanitarian aid, thanks to that humanitarian support that we are mobilising here and you will realised that this is a must; it is not a naive exercise. It is where peace can be built.

First objective of our work today is this: support the Syrians, inside Syria and in the neighbouring countries and help the living. The people in need – including the most vulnerable, children, women – cannot wait until the war is solved, ended and everything is settled. They need our help right now.

So we must look at the commitments we made in London [*The Supporting Syria and the Region conference*] last year, assess where we have made progress and where progress has been too slow. We must look at the needs for 2017 and raise the necessary funding through our pledges today. And we will look forward to 2018 and 2019 to ensure that we can provide some continuity and predictability to the humanitarian support we give to Syrians. Here in this room I think we have to be very clear on the fact that we are supporting the Syrians and we are supporting them as they hope to build the future of their country.

The European Union has fulfilled its pledge for 2016. We are always the ones that not only pledge but also deliver on our pledge. I can today announce we will also deliver on our pledge for 2017. We are and we will continue to be the first humanitarian donor, the strongest supporter of the people of Syria and of their host countries. Today we commit to maintain similar levels of support, amounting to €560 million for 2018 for Lebanon, Jordan and for the humanitarian work inside Syria and we have the ambition to maintain our level of engagement also in 2019.

What is vital is that humanitarian funding – this humanitarian funding – turns into humanitarian action. And for this to happen, for this money to become something real to the Syrian people and to the hosting communities, we need not only the energy, the passion, the dedication of the humanitarian

workers that put sometimes their lives at risk but also we need to make sure that full access throughout Syria is guaranteed to humanitarian access.

Second objective of this conference is to support the region and to support the future of the region. This is why I am particularly glad to have next to me, the Prime Minister of Jordan [Hani Al-Mulki], the Prime Minister of Lebanon [Saad Al-Hariri], but also representatives of countries like Iraq or Egypt that are hosting in the region a large number of Syrians.

Because the story of the Syrian conflict is the story that affects the entire region and the broader region including Europe, but it is also the story of generosity and solidarity. We cannot just praise the solidarity or commend the solidarity. We have a responsibility to support those who are showing solidarity and make it sustainable in the long term.

The people of Jordan, Lebanon and Turkey deserve all our support, as well as those in Iraq, Egypt and elsewhere who are hosting thousands of Syrian refugees. It is a promise we made in London and we continue to honor our promise. More than half of the overall pledge from the London Conference came from the European Union and our Member States and we have fully delivered on our commitments both financially and through the compacts with Lebanon and Jordan. On top of the humanitarian aid, we are promoting economic growth and jobs for our Lebanese and Jordanian friends, as well as for the refugees because we do not want to see a conflict between the hosting communities and the refugees who are hosted by these communities.

Third objective: make peace possible. Here we are more than 70 countries and organisations. The world is looking at us, the Syrians are looking at us and are expecting us to give a strong push to the political talks in Geneva under the excellent leadership of the UN and the Special Envoy [for Syria, Staffan de Mistura], because it is clear that the best investment for all the people of Syria and for a sustainable future in the region is a commitment to peace – serious, consistent commitment to peace.

The task undertaken in Astana by Russia, Turkey and now Iran, is important, is increasingly urgent – the attack in Idlib makes it even more evident. A mechanism for an implementation of the ceasefire has to be a serious one and we have to put a halt to the continuing breaches committed on a daily basis, some more dramatic than others but the ceasefire is a must. *Hudna, hudna, hudna!*

It also needs a political horizon if it has to be sustainable and you will hear the civil society representatives – they met here in Brussels for four days, we met them yesterday -, they make this point very clear. The people of Syria need progress at the talks in Geneva, they want their country back, they want peace back. We need to have the talks in Geneva moving towards an inclusive credible political transition that builds on UN Security Council Resolution 2254 and on the 2012 Geneva Communiqué.

And I will go even further: only a political solution to the conflict in Syria will allow for a real defeat of Da’esh, Al-Nusra, Al-Qa’ida and all the UN-designated terrorist groups in Syria.

Only a political solution will allow all Syrians to return home without fear of arbitrary detention, torture, executions and child recruitments. Only a political transition can make all Syrians feel home in their own country and be part of a joint effort to give a rebirth to the country.

It is up to the Syrian parties to reach a political agreement and shape the future of their country. But we can collectively contribute to creating the space for them to engage in peace, with political pressure and with the right incentives.

We will hear in the political session the UN Special Envoy Staffan de Mistura on the progress made in the latest round of talks in Geneva. We will also hear from him the latest difficulties and the ways in which we can support his work for real.

All of us, I think, have a responsibility to contribute to a successful outcome of the talks in Geneva. And I want to be very frank: this is the most complex and the most violent conflict in our times. No regional, no global power has the strength to solve it alone. We see many who attempt to worsen it by the day. This will only make the situation worse, not only for the Syrians, but also for the rest of the world. No side can impose one solution on the other. Peace in Syria will require an agreement among local players, but also support from all regional actors and world powers under the auspices of the United Nations.

We, the European Union, are eager to do our part. We have been engaging with the regional actors, all of them, international powers and we believe that there is common ground, but we need serious political will from all.

Fourth objective for today's meeting – and I will close: supporting the future of Syria and of the region.

Today, in Brussels, we can begin to work on one more contribution we can make to make peace possible. Once an agreement is reached, and only once an agreement is reached in Geneva, the reconstruction of Syria will require a massive collective effort. So it is crucial that the international community starts to get ready for that.

Too many times we were unprepared to peace and we did not win the peace even after the conflict was over. We have to start preparing for that day even if today in particular that day seems very far away. It can also be a very strong incentives for the parties and for some regional and international players to see that there is a peace dividend for all the people of Syria, all of them, without any distinction or discrimination, to see that the international community – the European Union for sure – is ready to help them reconstruct and rebuild the future of their country, on the basis of the end of violence and of a political transition that starts.

The future of Syria belongs to Syrians. We all agree on that. Peace and reconciliation is in their hands – has to be in their hands. But today we can send a powerful message to our Syrian friends – women, men, children – : We are on your side, on the side of the Syrian people who are suffering; we are

helping you already, we are ready to help you more for a free, united, inclusive, democratic Syria.

Thank you.

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Last updated: April 2, 2017 at 5:01 pm

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Eurojust: coordination meeting on Berlin Christmas market terrorist attack

On 27 March 2017, Eurojust held a coordination meeting on the case known as the Berlin Christmas market terrorist attack of 19 December 2016, upon the invitation of the National Members of Germany and Italy, and with the

participation of investigating authorities from various Member States and third States. The participants discussed their respective national investigations and agreed to continue their mutual cooperation.

For interviews and further information, please contact:

EUROJUST
Corporate Communications Office
E-mail: media@eurojust.europa.eu
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Note: Due to maintenance in preparation for the move to the new Eurojust premises, the Eurojust website and e-mail system will not be available on 1 and 2 April 2017. We apologise for any inconvenience caused. Thank you.