Medical Device Regulation formally adopted by European Parliament

Dear President,
Dear Board members,
Dear ADDE members,

The European Parliament has adopted the Medical Device Regulation (‘MDR’) during its second reading on April 5th, 2017 (see press release attached). The Parliament’s vote constitutes the final step in the legislative process for the adoption of the MDR and confirms the informal political agreement that was reached with the Council and the Commission in May 2016.

The MDR will enter into force on the twentieth day after its publication in the Official Journal of the European Union, and shall, apart from few exceptions, apply from three years after its entry into force. As the publication of the MDR is anticipated in the near future, the MDR is expected to fully apply from mid-2020.

Attached you can also find the recommendation for second reading of the European Parliament’s ENVI Committee. It contains a short justification on the basis of which the ENVI Committee recommends to endorse the MDR without further amendments.

We will keep you informed of any future developments and will provide you with the relevant documents as soon as they become available.

Sarah

The ADDE Flash has been prepared for information purposes only and is not intended as legal advice.

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Medical devices: more safety, more traceability

Stricter rules to ensure that medical devices such as breast or hip implants are traceable and comply with EU patient safety requirements were backed by MEPs on Wednesday. MEPs also approved laws to tighten up information and ethical requirements for diagnostic medical devices, e.g. for pregnancy or DNA testing.

Both proposals had been informally agreed with the Council.

"The metal-on-metal hip scandal highlighted weaknesses in the current system. So we’ve introduced much stricter requirements for the bodies that authorise medical devices, and will insist that particularly high risk devices, such as implants, joint replacements or insulin pumps, be subject to additional expert assessments before they can be authorised.", said medical devices rapporteur Glenis Willmott (S&D, UK).

Stronger post-market surveillance, more information to patients

“We’ve also agreed a much stronger system of post-market surveillance so that any unexpected problems are identified and dealt with as soon as possible”. “With the PIP breast implants scandal, many women simply didn’t know if they had received defective implants or not. So we’ve also introduced a Unique Device Identification system to help trace patients, who will also be given an implant card, which they can use to access information via a publicly accessible database”, Ms Willmott added.

Learning the lessons of the breast and hip implants scandals

The rules provide for:

• random inspections of producers’ facilities after devices have been placed on the market,
• stricter controls on notified bodies, which will have to employ medically skilled people,
• an additional safety checking procedure for high risk devices, such as implants or HIV tests. Not only a notified body, but also a special committee of experts, will check that all requirements are met,
• an "implant card" for patients, enabling patients and doctors to track which product has been implanted, and
• clinical evidence of medical device safety to be provided by manufacturers (as for medicines), especially in the case of higher risk classes.

"Pre-market scrutiny of high-risk devices was a priority for the Parliament so I’m particularly pleased that we successfully pushed for this and that these devices will now undergo additional assessment from expert panels", Ms Willmott concluded.

A separate law will also ensure that the new rules also apply to in-vitro diagnostic medical devices, i.e. those that are not in direct contact with the patient, but provide health information, such as HIV, DNA or blood testing devices.

“We learned the lessons of scandals such as that of defective breast implants”, said rapporteur on in-vitro diagnostic medical devices Peter Liese (EPP, DE).

“Problems have occurred in other areas too, e.g. with stents that are implanted into the brain or unreliable HIV tests. The new regulation is good for patients, puts an end to...}
fraudulent and shady producers and thus also strengthens respectable producers”, he added.

**Ethical requirements for DNA testing**

The legislation would also require EU member states to inform patients of the consequences of DNA tests.

"DNA tests can have severe consequences for patients’ lives and they should not be carried out without proper information and counselling. Member states pointed out that this is first of all their responsibility and that they will therefore accept EU rules only to a certain extent. It is important that member states fulfil this obligation. We will be very vigilant on this question", said Mr Liese.

**Further information**


**Political groups**


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***II

RECOMMENDATION FOR SECOND READING


Committee on the Environment, Public Health and Food Safety

Rapporteur: Glenis Willmott
Symbols for procedures

* Consultation procedure
*** Consent procedure
****I Ordinary legislative procedure (first reading)
****II Ordinary legislative procedure (second reading)
****III Ordinary legislative procedure (third reading)

(The type of procedure depends on the legal basis proposed by the draft act.)

Amendments to a draft act

Amendments by Parliament set out in two columns

Deletions are indicated in bold italics in the left-hand column. Replacements are indicated in bold italics in both columns. New text is indicated in bold italics in the right-hand column.

The first and second lines of the header of each amendment identify the relevant part of the draft act under consideration. If an amendment pertains to an existing act that the draft act is seeking to amend, the amendment heading includes a third line identifying the existing act and a fourth line identifying the provision in that act that Parliament wishes to amend.

Amendments by Parliament in the form of a consolidated text

New text is highlighted in bold italics. Deletions are indicated using either the ▌ symbol or strikeout. Replacements are indicated by highlighting the new text in bold italics and by deleting or striking out the text that has been replaced.

By way of exception, purely technical changes made by the drafting departments in preparing the final text are not highlighted.
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DRAFT EUROPEAN PARLIAMENT LEGISLATIVE RESOLUTION


(Odinary legislative procedure: second reading)

The European Parliament,

– having regard to the Council position at first reading (10728/4/2016 – C8-0104/2017),
– having regard to the opinion of the European Economic and Social Committee of 14 February 2013¹,
– having regard to its position at first reading² on the Commission proposal to Parliament and the Council (COM(2012)0542),
– having regard to Article 294(7) of the Treaty on the Functioning of the European Union,
– having regard to Rule 67a of its Rules of Procedure,
– having regard to the recommendation for second reading of the Committee on the Environment, Public Health and Food Safety (A8-0068/2017),

1. Approves the Council position at first reading;
2. Notes that the act is adopted in accordance with the Council position;
3. Instructs its President to sign the act with the President of the Council, in accordance with Article 297(1) of the Treaty on the Functioning of the European Union;
4. Instructs its Secretary-General to sign the act, once it has been verified that all the procedures have been duly completed, and, in agreement with the Secretary-General of the Council, to arrange for its publication in the Official Journal of the European Union;
5. Instructs its President to forward its position to the Council, the Commission and the national parliaments.

¹ OJ C 133, 9.5.2013, p. 52.
SHORT JUSTIFICATION

Procedure


Parliament adopted its first reading position on 2 April 2014, however, negotiations with the Council did not start until the autumn of 2015 when on 5 October 2015 the Council adopted a General Approach in view of commencing early second reading negotiations with Parliament which began on 13 October 2015 under the Luxembourg Presidency.

Following ten rounds of negotiations in total, the Parliament and the Council reached a political agreement on 25 May 2016 under the Dutch Presidency. The agreed text was subsequently endorsed with an overwhelming majority by the ENVI Committee on 15 June 2016. On the basis of the committee's approval, the Chairman of the Committee undertook in his letter from 16 June 2016 to the Chair of Coreper to recommend to the plenary to approve Council’s position at first reading without amendment. Following legal-linguistic verification, Council adopted its first reading position confirming the agreement on 7 March 2017.

Content

The medical device regulatory system in Europe was shaken by a number of device scandals that exemplified the existing weaknesses and stressed the urgent need to tighten up the loose ends in the framework. The Commission proposal and the subsequently agreed text for a new regulation replacing all existing directives seek to efficiently address these weaknesses while still maintaining and strengthening the current approval system.

The initial Commission proposal was a solid starting point which was further strengthened by the subsequent amendments by Parliament and Council. New additional provisions and structures will fill in the gaps and increase the levels of protection of public health and safety while ensuring clear rules with regard to the roles and obligations of all actors operating on the market, without stifling the innovation that is an essential element of this industry.

In this respect, your Rapporteur would like to highlight in particular the following elements of the agreed text:

Special Procedure for certain High Risk Devices

Expanding on the Commission’s initial proposal for a scrutiny mechanism for Class III devices, the co-legislators introduced a provision (Article 54) for a second-level check, a special procedure during the conformity assessment and before certification (Section 5.1 of Annex IX), of the highest risk devices of class III implantable and class IIb active devices administering or removing a medicinal product. The procedure involves the independent assessment by a special expert panel (Article 106). In an overall decentralised system of
conformity assessment and certification in Europe, this new provision aims to ensure that when it comes to the highest risk devices there is an additional level of supervision on EU level conducted by experts re-evaluating the clinical evaluation assessment reports of the notified bodies for such devices.

Manufacturers’ Liability

Given recent experience with defective devices and the consequences for affected users, an aspect that was extremely important for Parliament to be addressed in the new regulatory framework, and that was missing from the Commission proposal, was manufacturers’ liability insurance. This was also linked with frequent cases where patients were unable to access the relevant information in order to prove a causal link between defect and damage, as required by the Product Liability Directive. To this end, a compromise was reached with the Council whereby under Article 10, on manufacturers’ obligations, a provision was added requiring that manufacturers should, in a manner that is proportionate to the risk class, type of device and the size of the enterprise, have measures in place to provide sufficient financial coverage in respect of their potential liability under the above Directive. In addition, further rules were agreed concerning the facilitation, by a competent authority, of the provision of information to persons who may have been injured by a defective device.

Substances that are carcinogenic, mutagenic or toxic for reproduction and substances having endocrine disrupting properties

Parliament’s first reading position amendment to the Commission proposal provisions on these substances in Annex I called for a total ban for certain concentrations of these substances in certain devices subject to a range of derogations. Although such full ban was unacceptable to both the Council and the Commission due to the potential impact on industry and issues of implementation, the agreed text significantly strengthens what was initially proposed and paves the way for encouraging manufacturers to seek substitution of these substances since the permission for their use above a certain concentration would only be possible subject to manufacturers providing a strictly defined justification (Annex I, section 10.4)

Clinical Investigation/Evaluation - alignment to Clinical Trials regulation

Building on existing provisions in the current directives on conducting clinical investigations for medical devices (the equivalent of clinical trials in the field of medicinal products), the new regulation lays down detailed provisions for the entire process with clearly defined rules and obligations on manufacturers, sponsors, participating subjects and the relevant authorities (Chapter VI and Annex XV). Given that the Clinical Trials Regulation was agreed and adopted ahead of the medical devices regulation, the negotiated text sought to align the latter as much as possible including all provisions related to informed consent, ethics committees, incapacitated subjects, minors, pregnant women, transparency and a provision for the mandatory application of the coordinated assessment procedure (where investigations are conducted in more than one Member State) seven years after the date of application of the current regulation.

Reprocessing of single use devices
Legal provisions did not exist under the medical devices directive with regards to reprocessing of single use devices apart from an obligation for the Commission to produce a report on this practice and in light of it submit a proposal if deemed appropriate. Establishing common provisions on a divergent practice in the Member States appeared challenging, however, the legislators found a common solution, also supported by the Commission, which for the first time channels the practice, sets obligations and ensures a level of safety for the use of reprocessed devices. The agreed text stipulates that reprocessing may only take place if allowed under national law and is in accordance with Article 17 of the current regulation, however, Member States may go beyond these provisions in further restricting or prohibiting this practice on their territory. Reprocessors are to be considered the manufacturer of the reprocessed device and should accordingly assume the obligations of manufacturers. Under certain circumstances, Member States may apply exceptions from the rules for devices reprocessed within health institutions. The Commission is tasked with producing common specifications for reprocessing of single use devices.

**Notified Bodies provisions**

One of the major amendments to the old system is the strengthening of the provisions on the designation, organisation, monitoring and expertise of the Notified Bodies (NBs) conducting the conformity assessment and certification for all devices on the Union market. Chapter IV and Annex VII address all aspects of these procedures. Some of the additional provisions introduced by Parliament and agreed by the Council relate to the permanent availability of sufficient administrative, technical and scientific personnel of NBs for them to successfully conduct their conformity assessment activities. The joint assessment at designation, continuous monitoring and annual re-assessment of NBs with on-site audits, including unannounced visits, is another measure to ensure the continued quality of expertise and observation of legal requirements by all NBs in the Union. A major improvement to the new legislation to be stressed is that notified bodies are obliged to do unannounced inspections on the production site. For high-risk devices, it is no longer sufficient to just check the papers but controls have to be on the spot. This is in your rapporteur’s view the most important improvement that will avoid scandals in future. Last but not least, to provide for a level-playing field and transparency among them all in the different Member States, a new provision initiated by Parliament now requires that NBs establish lists of standard fees charged for conformity assessment procedures, which are made public.

**Vigilance and Post-Market Surveillance**

Apart from strengthening the authorisation procedures, one of the key pillars of the new proposal is an enhanced overall system for traceability of devices, vigilance and post-market surveillance to ensure constant monitoring and swift reaction should problems arise (Chapter VII). In addition to the Commission proposal, the co-legislators introduced an obligation for manufacturers, proportionate to the risk class of the device, to plan, establish, document, implement, maintain and update a post-market surveillance system for each type of device in order to gather, record and analyse all relevant data associated with the safety of the device throughout its lifecycle. Similar to medicinal products, periodic safety update reports were introduced for all risk classes but Class I, and for the higher risk classes these need to be updated at least annually. The co-legislators also oblige Member States to take the necessary measures to encourage and empower healthcare professionals, users and patients to report suspected serious incidents at national level using harmonised formats.
**Recommendation**

As Council’s first reading position is in conformity with the agreement reached during the interinstitutional negotiations, your Rapporteur recommends endorsing it without amendments.
### Title

### References
10728/4/2016 – C8-0104/2017 – 2012/0266(COD)

### Date of Parliament’s first reading – P number
2.4.2014 T7-0266/2014

### Commission proposal
COM(2012)0542 - C7-0318/2012

### Receipt of Council position at first reading announced in plenary
16.3.2017

### Committee responsible
ENVI 16.3.2017

### Rapporteurs
Date appointed
Glenis Willmott 16.10.2012

### Discussed in committee
20.3.2017

### Date adopted
21.3.2017

### Result of final vote
| +: | 54 |
| --: | 3 |
| 0: | 1 |

### Members present for the final vote
- Marco Affronte
- Margrete Auken
- Pilar Ayuso
- Zoltán Balczó
- Ivo Belet
- Biljana Borzan
- Paul Brannen
- Soledad Cabezón Ruiz
- Nessa Childers
- Birgit Collin-Langen
- Mireille D’Ornano
- Miriam Dalli
- Seb Dance
- Angélique Delahaye
- Ian Duncan
- Stefan Eck
- Bas Eickhout
- José Inácio Faria
- Karl-Heinz Florenz
- Francesc Gambús
- Gerben-Jan Gerbrandy
- Jens Gieseke
- Julie Girling
- Sylvie Goddyn
- Françoise Grossetête
- Jytte Guteland
- György Hölvényi
- Anneli Jääätteenmäki
- Benedek Jávor
- Josu Juaristi Abaunz
- Karin Kadenbach
- Kateřina Konečná
- Urszula Krupa
- Giovanni La Via
- Peter Liese
- Valentinias Mazuronis
- Susanne Melior
- Miroslav Mikolášik
- Massimo Paolucci
- Piermicola Pedicini
- Pavel Poc
- Julia Reid
- Frédérique Ries
- Michèle Rivasi
- Annie Schreijer-Pierik
- Davor Škrlec
- Renate Sommer
- Estefanía Torres Martínez
- Nils Torvalds
- Adina-Ioana Vălean
- Damiano Zoffoli

### Substitutes present for the final vote
- Nikolay Barekov
- Nicola Caputo
- Stefano Maullu
- Gesine Meissner
- Elżbieta Katarzyna Lukacijewska

### Substitutes under Rule 200(2) present for the final vote
- Jan Keller
- Arne Lietz

### Date tabled
23.3.2017
# FINAL VOTE BY ROLL CALL IN COMMITTEE RESPONSIBLE

<table>
<thead>
<tr>
<th>Party</th>
<th>Names</th>
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<tr>
<td><strong>ALDE</strong></td>
<td>Gerben-Jan Gerbrandy, Anneli Jääteenmäki, Valentinas Mazuronis, Gesine Meissner, Frédérique Ries, Nils Torvalds</td>
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<tr>
<td><strong>ECR</strong></td>
<td>Nikolay Barekov, Ian Duncan, Julie Girling, Urszula Krupa</td>
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<tr>
<td><strong>EFDD</strong></td>
<td>Pierincola Pedicini</td>
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<tr>
<td><strong>GUE/NGL</strong></td>
<td>Stefan Eck, Josu Juaristi Abaunz, Kateřina Konečná, Estefanía Torres Martínez</td>
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<tr>
<td><strong>NI</strong></td>
<td>Zoltán Balczó</td>
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<tr>
<td><strong>PPE</strong></td>
<td>Pilar Ayuso, Ivo Belet, Birgit Collin-Langen, Angélique Delahaye, José Inácio Faria, Karl-Heinz Florenz, Francesc Gambús, Jens Gieseke, Françoise Grossetête, György Holvényi, Giovanni La Via, Peter Liese, Stefano Mauullu, Miroslav Mikolášik, Annie Schreijer-Pierik, Renate Sommer, Adina-Ioana Vălean</td>
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<tr>
<td><strong>S&amp;D</strong></td>
<td>Biljana Borzan, Paul Brannen, Soledad Cabezón Ruiz, Nicola Caputo, Nessa Childers, Miriam Dalli, Seb Dance, Jytte Guteland, Karin Kadenbach, Jan Keller, Arne Lietz, Susanne Melior, Massimo Paolucci, Pavel Poc, Damiano Zoffoli</td>
</tr>
<tr>
<td><strong>VERTS/ALE</strong></td>
<td>Marco Affronte, Margrethe Auken, Bas Eickhout, Benedek Jávor, Michèle Rivasi, Davor Škrlec</td>
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<tr>
<td><strong>EFDD</strong></td>
<td>Julia Reid</td>
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<tr>
<td><strong>ENF</strong></td>
<td>Mireille D’Ornano, Sylvie Goddyn</td>
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<th>Party</th>
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<tbody>
<tr>
<td><strong>PPE</strong></td>
<td>Elżbieta Katarzyna Łukacjewska</td>
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**Key to symbols:**
- **+**: in favour
- **-**: against
- **0**: abstention