

## EU – Mercosur in principle trade agreement

### Impact for MedTech Industry – Preliminary Analysis

Brussels – 5th August 2019

#### Introduction

The EU and Mercosur have been working on a trade agreement for the last decade. On July 1<sup>st</sup> 2019 the agreement in principle between the EU and the four Mercosur members (Brazil, Argentina, Paraguay and Uruguay) [was released](#).

The Commission and Mercosur both believe that this will be a foundational trade agreement, covering over 770 million people and substantially facilitating trade between the two blocks.

#### Key aspects of the agreement

**The agreement is expected to substantially reduce tariffs between the EU and Mercosur** – though an essential part of the agreement (especially considering that Mercosur historically has had relatively high tariffs) Medical Technology generally benefits already from very low to non-existent tariffs and therefore is not directly impacted by this change. However, the import and export of materials used in manufacturing can be subject to substantial tariffs and this agreement may make the supply of materials between the EU and Mercosur for manufacturing more interesting.

**Key aspects of trade are facilitated through the agreement**, including definition of rules of origin (determines which products can benefit from the agreement), facilitation of trade and customs clearance. While the Medtech sector will benefit with simplified and at times automated customs clearance procedures, there are a number of specific aspects which can have a much more concrete impact on the MedTech sector.

#### EU – Mercosur Trade in Medical Technology

**Public Procurement** - The principle of non-discrimination in public procurement will apply to all the signatories – this means in practice that Brazil would not be able to discriminate against EU products as part of its public procurement process. It is expected that both sides will be bound to follow transparency principles with regards to the actual public procurement process. This would be a most welcome development as both lack of transparency and discrimination in favor of local manufacturers has been seen in Mercosur economies in the past within the MedTech sector.

**Technical Barriers to Trade** – The agreement in principle lays out mechanisms which would allow alignment in conformity assessment processes – specifically called out are electromagnetic compatibility and electrical safety as well as restriction of hazardous substances which has also an impact on our sector. The principles of conformity assessment could in principle also be extended to medical devices overall. In particular local testing of medical devices has been a matter of concern within Mercosur – the agreement providing a new mechanism to resolve such issues.

**Services** – A far more open framework should be setup by this agreement for services – including investment and manufacturing sectors which are explicitly called out. Details on how this would apply to the medical technology sector are not immediately available but given the growing importance of services in the medical devices sector this is an area which will be followed closely.

**Dialogues** – There is to be a dialogue on tackling Anti-microbial resistance between Mercosur and the EU – This is a matter which is of direct concern to many of our members and we would welcome the opportunity to be a part of this dialogue. Furthermore, additional dialogues may be initiated on subjects of common interest in the future.

**Transparency** – This section is particularly important when it comes to good regulatory practice principles. For a sector which is subject to a high level of regulatory scrutiny, having transparency in regulatory principles helps to ensure a consistent and predictable access to market.

## Next steps – Ratification and implementation

Before the agreement can enter into force it needs to be ratified. All four national parliaments of Mercosur will need to ratify the agreement and within the EU the European Parliament as well as national parliaments (and in some cases regional parliaments – depending on the regional competences) will also need to ratify the agreement. This process can take over a year and may result in specific exemptions being proposed to the agreement.

## References

Agreement in principle between the EU and Mercosur:

[http://trade.ec.europa.eu/doclib/docs/2019/june/tradoc\\_157964.pdf](http://trade.ec.europa.eu/doclib/docs/2019/june/tradoc_157964.pdf)

Commission information on the EU-Mercosur Trade Agreement

<https://ec.europa.eu/trade/policy/in-focus/eu-mercosur-association-agreement/>