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"Brexit" and medicinal products

Some relevant issues in the field of pharmaceutical law after the option to "leave" has won the referendum of 23 of June

It is Friday June 24th, and while writing this CAPSULAS from London, the first thing that comes to my mind is what I wrote in El Global ten days ago: the most important voting this month of June of 2016 is not the General Election that will take place in Spain on Sunday 26th; but the referendum held in the United Kingdom to decide whether to leave or remain in the European Union.

Once we know that the option to leave has won the referendum, many thoughts and questions arise. Modestly, in this special Edition of CAPSULAS, we will try to address some issues related to the impact that the results of the referendum may have in the field of pharmaceutical law.

The famous article 50 of the Treaty on European Union

Article 50 of the treaty on European Union, a great unknown until now for many, states that any Member State may decide to withdraw from the Union in accordance with its own constitutional requirements. Therefore, the decision to withdraw is unilateral, and will be adopted by the United Kingdom in accordance with its own legal and political system.

The result of the referendum is not equivalent to such decision, which the United Kingdom has not adopted yet. When the United Kingdom effectively takes that decision (presumably not before October, after the designation of the new Prime Minister), its government will formally notify it to the European Council.

It shall be then when a process of negotiation of an agreement between the EU and the United Kingdom, which will establish the arrangements and conditions for the withdrawal, will start. The Treaty on European Union states that, to that effect, the agreement will be negotiated in the light of the guidelines provided by the European Council, will require obtaining the prior consent of the European Parliament; and will be finally concluded by the Council.

As we know, the process of adoption of decisions in the EU is complex. In this case, additionally, many aspects will require unanimous consent of all parties involved. It is this context that explains the period of two years usually mentioned in this matter. Article 50 of the Treaty on European Union states that European Treaties shall cease to apply to the withdrawing State from the date of entry into force of the withdrawal agreement or, failing that, two years after the notification of withdrawal. Article 50 also foresees that the European Council, in agreement with the withdrawing State, may unanimously decide to extend this period of two years.

This is why many point out that, presumably, the exit of the United Kingdom will not have effects until the end of 2018. This may be so, but withdrawal could also happen before; and in any event there are several issues affecting legal aspects of medicines that may be wise to consider already as of now.

Norwegian, Swiss and other models

Once the United Kingdom abandons the EU, the relationship between them will depend on the scope of the agreements that are reached. Basically, three possible models are contemplated.

If an agreement similar to the one that the EU has with Norway or Iceland is reached, the impact in the area of EU pharmaceutical legislation and on the application of EU fundamental freedoms of movement (goods, persons, services and capitals) will be fairly low, as the United Kingdom would be integrated in the European Economic Area and, to a large extent, would be bound by EU legislation.

On the contrary, if the parties opt for a relationship like the one that the EU currently has with Switzerland, the implications could be larger as EU rules would not be of general application, and because there would be more possibilities to restrict the free movement of persons between the United Kingdom and the EU.

If the relationship between the United Kingdom and the European Union is similar to the one that the EU has with the USA and other countries with which it has entered into commercial agreements in the framework of the WTO, the gap would be even greater.

In any event, some consequences of Brexit in the area of medicines may already be pointed out.

The headquarters of the European Medicines Agency

At the institutional level, the exit of the United Kingdom from the EU will imply the need to move the headquarters of the European Medicines Agency, which will have to be located in some other city inside the EU. It may be that this circumstance, together with the loss of access to European funds intended for research, makes some companies reconsider having their main headquarters in the United Kingdom. Be it as it may, it seems reasonable to think that non-EU companies that may be considering to start operations in the EU will already be inclined to avoid the United Kingdom as a seat for their headquarters in Europe.

Marketing Authorizations

In this area important matters arise. Holders of marketing authorizations granted through the centralized procedure, if they are domiciled in the United Kingdom, will have to transfer them to companies established in the EU, given that EU pharmaceutical law establishes that the holder of a marketing authorization granted according to EU law has to be established in the EU. It will always be possible to amend EU law in this regard and establish, in some way, that the holder could be established in the United Kingdom but in the current state of the matter, changing

the holder of the marketing authorization would be required.

We understand that in respect of authorizations granted through decentralized or mutual recognition procedures, the United Kingdom could no longer act as reference member State, so a new one will have to be designated.

As regards the validity, in the United Kingdom, of existing authorizations, the British government will be entitled to decide what it deems most appropriate. It is very possible that the United Kingdom will continue to consider those authorizations as valid, but in the future the British medicines agency will play a much different role leading is own national procedures.

EU Directives and Regulations

Once the United Kingdom exits the EU, how EU pharmaceutical law may apply in the United Kingdom remains to be seen. It could well be that the UK legislator decides not to amend all the internal rules that have been approved in the last years when transposing EU Directives. However, EU Regulations will stop being directly applicable. This means that new legislation will have to be adopted in important matters such as clinical trials, orphan medicines or medicines for pediatric use.

And English?

Fortunately, English is an official language in Ireland and in Malta, and they are not leaving the EU. The English language therefore will continue being an official language in the European Union, and using it as a main working language in pieces of European pharmaceutical regulation will still be possible. At least, this is a matter where changes are not to be expected.

Conclusion

In conclusion, the victory of the "leave" option has a very significant impact in the field of pharmaceutical law. Although on the short term no drastic changes are to be expected in the relationship between the EU and the United Kingdom, it is also true that a lot of decisions to be taken henceforth have to consider such future impact.

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