European brief



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Brexit update: "The BMA in Europe" Published

As we approach June 23, when the UK will vote on whether to remain in or leave the EU, the BMA has published its briefing "The BMA in Europe."

Recognising that this is a momentous issue whose result could have huge implications for the medical profession, the briefing highlights the significant impact — intentional or unintended, positive and negative — of EU policy and legislation on the UK's medical profession and the health of the nation.

Given that the referendum coincides with the ARM – where the European Office will be manning a stand – in Belfast (June 20/23) attendees should ensure that they have arranged a postal vote so that their voice is heard on this critical issue. The briefing can be read in full at the link below:

https://www.bma.org.uk/collective-voice/influence/europe/eu-referendum

TTIP (Transatlantic Trade and Investment Partnership) Update

At the conclusion of the 13th round of negotiations, the EC (European Commission) has published a report which details the progress made during this round as well as the proposal on regulatory cooperation in pharmaceuticals made to the US.

Whilst the report details the significant progress made in all 3 pillars of the negotiations – e.g. better access to markets for EU and US firms – equally significant differences still remain with regard to services. The proposal for cooperation in the pharmaceuticals sector aims to help regulators work more closely together to achieve better efficiency and thereby deliver benefits for patients. It also reiterates that both the EU and the US reserve the full right to regulate to achieve public policy objectives and protect human health. Whist we welcome this reiteration, the BMA will continue to monitor this issue and intervene where necessary to ensure that the finalised proposals do not adversely impact upon the NHS.

The EC report and additional background information can be accessed via the following link:

http://trade.ec.europa.eu/doclib/press/index.cfm?id=1501

European Junior Doctors Adopt Position on TTIP

The EJD (European Junior Doctors Permanent Working Group), which represents over 300,000 junior doctors across Europe and of which the BMA is a member, has adopted a position which requests that:

- healthcare services should be excluded from the proposed TTIP agreement and other similar future international trade agreements
- negotiations on future free trade agreements should take account of the impact on health and ensure that health is not damaged by the pursuit of potential economic gain

The support of the EIJD, and the numerous other European organisations which share this position, will be instrumental as we continue to seek the exclusion of public healthcare services from the TTIP and other proposed free trade agreements. Further information about the EJD is available via the following link:

http://juniordoctors.eu/

Provisional Agreement Reached on the Regulation of Medical Devices

A provisional agreement has been reached amongst the EU institutions on the regulation of medical devices and in vitro diagnostic medical devices - which cover a wide range of products, from sticking plasters to hip replacements, and from pregnancy tests to HIV tests. The draft regulations are expected to secure that such devices are safe while allowing patients to benefit from innovative health care solutions in a timely manner. The agreement provides for:

- random inspections on producers after devices have been released onto the market
- stricter checks on notified bodies, which will have to employ medically skilled staff
- an additional safety check for high-risk devices, such as implants or HIV-tests
- an "implant card" for patients, enabling patients and doctors to trace implanted products
- a requirement for medical device manufacturers to provide clinical evidence of the safety of their products, especially in the case of higher risk classes

The EP (European Parliament) is expected to approve the draft regulations in Q3 2016 with those pertaining to medical devices entering into force three years later, and those for in vitro diagnostic medical devices some five years after the EP's approval.

Further information about the draft agreement can be read at the following webpage:

http://www.europarl.europa.eu/news/en/news-room/20160526IPR29427/Safer-medical-devices-MEPs-strike-deal-with-Council

Tightening EU Rules on Advertising to Protect Vulnerable Viewers

Following the analysis of a public consultation (undertaken in 2015) – to which the BMA responded, the EC has published its proposal to revise the EU's Audiovisual Media Services Directive, which regulates Europe's audio-visual media landscape.

The proposal encourages member states to develop self and co-regulatory codes of conduct regarding inappropriate – pertaining to food and beverages containing nutrients and substances with a nutritional or physiological effect, in particular those such as fat, trans-fats, salt/sodium, sugar and alcoholic beverages - audiovisual commercial communications, accompanying or included in programmes with a significant children's audience.

Whilst these proposals reflect the BMA's submission that vulnerable viewers must be protected from such advertising, we will be working with stakeholders and politicians from across Europe to ensure that the revised Directive introduces additional restrictions on related advertising.

The EC's proposals and additional background about this issue can be read at the following link:

http://europa.eu/rapid/press-release IP-16-1873 en.htm

European Court of Justice Approves EU Directive on Tobacco Products

A challenge over the validity of the EU's Tobacco Products Directive had been mounted by Poland, Romania and the tobacco industry but the ECJ (European Court of Justice) has dismissed their concerns and upheld the original directive.

The ruling that the new EU directive is valid means that standardisation of packaging, the future EU-wide prohibition on menthol cigarettes and special rules for electronic cigarettes are all lawful.

The ECJ decision can be read in full via the link below:

http://curia.europa.eu/jcms/upload/docs/application/pdf/2016-05/cp160048en.pdf

MEPs call for a European Alzheimer's Strategy

Recognising that "dementia, and its common form Alzheimer's disease, is a crucial socio-economic challenge that will test the viability of the healthcare services in every single Member State", a group of MEPs has called for "a collaborative approach from the European Commission, the European Commission Group of Government Experts in Dementia and all stakeholders to define a European Alzheimer Strategy." The integral role of the medical professions in tackling this issue is recognised with the "training (of) health professionals to detect the early symptoms of dementia" deemed to be "of prime importance." We will monitor the EC's response to this call for action and, where necessary, work to ensure that the medical profession plays a key role on the development of any such strategy. Further information about this call for action can be read via the link below:

 $\frac{\text{http://francoise-grossetete.eu/wp-content/uploads/2016/04/EP-Open-letter-NL-EU-Presidency-Dementia-conference.pdf}{}$

Scottish Court to Rule on Minimum Unit Pricing

Pending the consideration of new evidence which estimates that alcohol taxes would have to rise by 28% in order to achieve comparable reductions in alcohol-related deaths to a 50p minimum unit price, it is understood that the Scottish Court of Session may be in a position to make a judgment on whether MUP (minimum unit pricing) can be lawfully implemented, by late July/early August 2016. This follows on from an ECJ ruling that it is up to the Scottish courts to decide whether other measures — such as taxation — could protect human life and health as effectively as MUP, while being less restrictive to trade.

Commenting on this news, SHAAP (Scottish Health Action on Alcohol Problems) – with whom the BMA has been working to secure adoption of this legislation - stated that they "remain confident that the case for minimum unit pricing will be conclusive and look forward to this much-needed policy finally being implemented."

The ECJ judgement can be read via the link below:

http://curia.europa.eu/jcms/upload/docs/application/pdf/2015-12/cp150155en.pdf