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The European Commission's Work Programme 2015: Life Sciences

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Europe

The new European Commission's Work Programme for 2015 lists several items of critical importance to companies in the life sciences space.

Below we provide our analysis on what we expect to happen on each of these.

Review of Existing Legislative Proposals

The European Commission has adopted a proposal for a new regulation on veterinary medicinal products (as part of a package of reforms that also address medicated feeds) which is aimed at increasing the availability of such products and reducing the administrative burden for industry. The proposed regulation could serve as a test case for a future recast of the legislation governing human medicines.

Other on-going initiatives that could be shaped by the new policy objectives outlined in the Work Programme include: the proposed regulations governing medical devices and in vitro diagnostic medical devices, which are likely to be intensely negotiated in 2015 following the Council's review of the current proposals; the proposed regulations governing consumer product safety and market surveillance, which would standardize market surveillance requirements across industry sectors and simplify the use of harmonized standards to demonstrate product safety; the proposed regulation on novel foods, which would introduce a more efficient, fully centralized authorization procedure; and the proposed reform of the data protection legislation (see also our e-alert on ICT and Telecoms).

M-Health

While the Commission's Work Programme does not directly address m-health/e-health, it does list several initiatives of a more general nature that may, together with the outcome of the consultation organized by the previous Commission earlier this year, provide a platform for new legislation. These initiatives include a proposed regulation on a Common European Sales Law, the Digital Single Market Package (see our e-alert on ICT and Telecoms), and the Internal Market Strategy for goods and services.

We would encourage pharmaceutical companies interested in m-health, apps and other tools for integrated treatment options with IT aspects to engage in a dialogue with the Commission to steer the process.

Transparency Directive

The Commission recommends withdrawing the 2012 proposed Directive on the transparency of measures regulating the prices of medicinal products for human use and their inclusion in the scope of public health insurance systems, as no agreement between the EU co-

legislators is foreseeable. The proposal will be formally withdrawn once the European Parliament and Council validate the Commission's suggestion.

The pharmaceutical industry expressed strong concerns regarding the EP's first-reading position as it watered down some of the key provisions of the proposal—among them, the maximum time limits for completing and publishing pricing and reimbursement decisions for innovative medicines. Member states have been unable to reach a common position. The withdrawal of the proposal removes the risk of a negative outcome.

Genetically Modified Organisms

The Commission is going to review the existing decision-making process applicable to genetically modified organisms (GMOs). Under the current rules, the Commission drafts a proposal for granting or refusing authorization to place GMOs on the market and to cultivate them in the EU. The Council then has three months to reach a qualified majority in favor or against any such Commission proposal. If no agreement is reached within the deadline, the Commission has the right to adopt its proposal, which is then binding on member states.

Seeing that, over the past years, the GMO issue has raised a heated political debate at the national and supranational levels as well as among several member states, the decision-making process described above is clearly controversial. Some countries strongly oppose the Commission's relatively favorable position towards GMOs and vehemently object to their authorization, in particular with regard to their cultivation. The European Parliament is currently considering in second-reading a Commission proposal to allow member states to opt out of Commission decisions concerning the authorization of GMOs and prohibit the cultivation of such GMOs on their territory. The new review could give more power to member states in the EU approval process for GMOs, especially by allowing a simple majority to block the decision. It is unclear whether this would also apply to white and red biotechnology.

Contact

Please contact Sebastian Vos (Partner, Head of EU Public Policy and Government Affairs practice) should you wish to know more about any of the above issues or wish to discuss how Covington can help.

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