EFPIA welcomes new EC structure, but others fear threat to data disclosure
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The European pharmaceutical industry federation EFPIA has welcomed the proposed new structure of the European Commission, which includes the transfer of responsibility for medicines and medical device regulation back to the directorate general for industry (DG ENTR).

EFPIA said that commission president-elect Jean-Claude Juncker had "taken on our views and put together all units that are relevant for our business in Europe". These, it said, were previously spread over three directorates general, SANCO (health), MARKT (internal market) and ENTR.

But others are not at all happy with the move. The NGO Health Action International, MEP Glenis Willmott, the campaigning group AllTrials and the public health body EPHA have all criticized the move, describing it as retrograde step that could make it more difficult to find a balance between promoting the industry and protecting public health and hinder efforts to increase the transparency of clinical trial data.

Under plans revealed on Wednesday with the unveiling of the proposed new members of the commission, responsibility for medicines and medical devices is to be moved from DG SANCO – where it was transferred only a few years ago – back to DG ENTR.

This means that the commissioner-designate for industry, the internal market, entrepreneurship and SMEs, Elżbieta Bieńkowska, will now be responsible for relations with the European Medicines Agency (scripintelligence.com, 10 September). Mr Juncker described Ms Bieńkowska's new enlarged portfolio as "the engine house of the real economy".

"The primary purpose of the pharmaceutical industry is to develop and produce innovative medicines that improve the lives of EU citizens," EFPIA declared, noting that the industry "also adds value to the EU through exports and economic activity" and supports R&D in Europe "at the rate of €30bn each year".

It said it was also very pleased with the instructions given in the mission letters sent to the new commissioners-designate, and the fact that pharmaceuticals were mentioned in Mr Juncker's speech. In his letter to Ms Bieńkowska, Mr Juncker said he wanted her to "raise the profile of industry in the economy" and "ensure that Europe maintains its global leadership in strategic sectors with high-value jobs such as the automotive, aeronautics, engineering, chemicals and pharmaceutical industries."

EFPIA welcomed the introduction of vice-presidents overseeing several commission DGs in an effort to reduce "silos" in the commission, and said it had called for the appointment of a dedicated co-ordinator for life sciences in Mr Juncker's cabinet.

"Hard to believe"

But the decision to return medicines and devices to DG ENTR has elicited a chorus of disapproval from health activists and some politicians. Glenis Willmott, the MEP who steered the new clinical trials Regulation through to approval by the European Parliament earlier this year and pushed for strong provisions on trial data disclosure, said the decision was "hard to believe". While Europe's pharmaceutical and medical technology industries were important to the economy, "our first priority must be health", she said.

"When I was negotiating the transparency laws for clinical trial results, it was DG Enterprise that wanted to water the rules down. Now they will be overseeing the European Medicines Agency as it implements the transparency regime, which is frankly concerning," Ms Willmott declared.

In the wake of the PIP breast implant scandal, she continued, "people expect stronger regulation of medical devices, regulation that protects patients. Clearly medical devices should be the responsibility of the health commissioner. This was a bad decision from President Juncker, I hope he will quickly come to his senses and rectify it."

Threat to trial data disclosure?

HAI was equally vocal, saying it was "appalled" by the "opaque and unjustified" decision. As an integral part of enhancing public health, pharmaceuticals belong in the health and consumer portfolio, and moving them to DG ENTR will "put the commercial, profit-driven interests of the pharmaceutical industry, rather than patients and consumers, at the heart of European policymaking on medicines", it said.

Bringing the EMA under DG ENTR was "particularly troubling", as it would "create significant threats to clinical trial data transparency" in the EU. "The EMA had encountered significant opposition to its policy on public access to clinical trial data from the pharmaceutical industry in the last year. Now, the strong opposition from the industry will be more loudly heard by the EMA, and will most likely jeopardize independent review and, ultimately, patient safety."

The European Parliament has yet to give its approval to the college of commissioners, and HAI urged MEPs to "prioritise health over commercial interests and stand against President-elect Juncker's decision to move these units to DG Enterprise and Industry".

"Potential disaster"

The European Public Health Alliance (EPHA) described the move as "a potential disaster", saying that the public health community had reacted with "alarm and disbelief at the ill-thought distribution of responsibilities" among the incoming commissioners. It said the move would threaten Europe's ability to prepare for major health crises "whilst putting the public interest behind the drive for profits in drug authorization procedures". It also complained that the decision was not subject to public debate, the announcement of the portfolios came after the deadline for written questions in parliament, and no explanation was given for the policy shift.

Noting the EMA's efforts to proactively publish clinical study reports under its draft policy on data disclosure, Síle Lane, co-founder of the AllTrials campaign for greater transparency of trial data, said that Mr Juncker "must show that this commitment to clinical trial transparency will not slip following the move of medicines regulations from Health to Enterprise".

Jim Murray, former director of the European consumer organization BEUC, pointed out in a blog that in the new commission, DG ENTR will be responsible for promoting the EU pharmaceutical industry and for commission policy on medicines. "Other DGs will have a say, of course, but DG Enterprise will take the lead and will be the main interlocutor with the industry on medicines and medical devices," Mr Murray said. "This is a good day for the pharmaceutical industry, but a bad day for public health."

The industry, he said, has a strong influence across a wide range of government policies "but typically rather more influence on industry departments – and this is not to imply any impropriety on the part of DG Enterprise. One DG should not combine the lead role for medicines policy with the lead role for the promotion of the pharmaceutical industry. This is not the way to achieve clarity in public health policy. The difficult task of balancing the interests of public health and the (legitimate) interests of the pharmaceutical industry should not take place within the one DG (and should not be well hidden from public scrutiny)", Mr Murray wrote.