European news

Janssen: why transparency is essential to the health of our industry

Jane Griffiths, company group chairman for Janssen EMEA and chairwoman of the EFPIA executive committee, talks openly to Pharmafocus

The pharmaceutical industry is moving forward, working together to ensure patients have access to new and innovative medicines.

However, more must be done to meet society's huge unmet medical need and to enhance society's perception of the value we bring. We need to live up to the high standards we have set ourselves.

Despite the great value that pharmaceutical companies bring to public health and individual patients, as well as the contribution they make to the European economy, the reputation and perception of the industry as a whole has long been an issue.

Just as we strive to harness the best science for the benefit of patients, we also endeavour to enhance our efforts in the area of clinical trial data transparency – especially because demands for disclosure have never been higher.

As a company, we believe that greater clinical trial data sharing for the advancement of science and medicine is the right thing to do, and I think there will be a coalescing of the industry to move that topic forward.

In fact, we are seeing movement in this direction with some recent clinical trial data sharing announcements. Whilst we believe this is the right thing to do, it involves a number of complex issues and so, contrary to what some may think, it is not straightforward to achieve. For example, we have to be constantly vigilant about maintaining patient confidentiality. We also need to ensure that we do not compromise existing partnership agreements.

Perceived lack of transparency can be a barrier to open dialogue and being a trusted industry.

If people believe things are being withheld or hidden, then the sooner that transparency can be established the better.

I believe that it will break down barriers if the industry is seen to be more transparent, and I'm quite sure that by the end of this year and into next year, you will see more transparency commitments from companies.

In my role as chairwoman of the European Federation of Pharmaceutical Industries and Associations (EFPIA) executive committee, I have first-hand experience of the EFPIA Transfer of Value Code. This was adopted by the EFPIA Statutory General Assembly in June last year, and establishes a code on the disclosure of transfers of value from pharmaceutical companies to healthcare professionals and healthcare organisations.

The Code is the current major pan-European transparency initiative for the industry, in addition to similar transparency initiatives in countries across Europe.

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Data disclosure

There is currently ongoing discussion over the transparency of clinical trial data. At Janssen, in January we announced a novel agreement with Yale School of Medicine's Open Data Access Project (YODA) to share data from our clinical trials to enhance public health and advance science and medicine.

Under this agreement, YODA will serve as an independent body to review requests from investigators and clinicians seeking access to clinical trial data from Janssen, and will make decisions on sharing data.

This is the first time any company has collaborated with a completely independent third party to review and make final decisions regarding every request for clinical data, and we believe it sets a new industry standard in ensuring all requests for clinical data are reviewed in a systematic and objective way that protects patient privacy and confidentiality.

In order not to compromise competitiveness, we believe it is important that data relating to new medicines, in the early stages of development pre-license, are granted an exception: so data will only be available on medicines that have been granted a licence by the US Food & Drugs Administration and/or the European Medicines Agency.

But, for all licensed medicines and medicines that are already protected by patents, there is more we can do to disclose data.

It has long been acknowledged that the success of the industry in delivering life-saving medicines is due in part to healthy competition.

Furthermore, we are fully engaged with experts and stakeholders to integrate their views on the development of measures to collate commercially confidential information and to ensure patient confidentiality is not compromised.

Clinical trials are conducted according to the same scientific and ethical standards, irrespective of the country. At Janssen, we ensure the highest ethical standards are applied to everything we do – and we apply these standards globally. We conduct our trials across the globe, in multi-centre studies, not only because this is required by regulators but also because it is medically appropriate in respect to future users of our medicines.

Most regulatory authorities will only approve medicines if a percentage of the trial population is from their native country or region. Every trial protocol that is set up is posted on a website, clinicaltrials.gov. Furthermore, every clinical research programme ultimately will be in the public domain after the approval of a medicine.

Our collaborations

At Janssen we can see the value of collaborations in helping us achieve better outcomes for patients, and we have increased the number of collaborations we have with universities and small biotech companies.

In EMEA we have set up Janssen Healthcare Innovation, an entrepreneurial group within Janssen R&D, with the aim of developing cutting-edge health solutions designed to modernise healthcare delivery as well as improve patient outcomes.

Additionally, there are the Johnson & Johnson Innovation Centres in California, Boston and London, each focussing on developing research partnerships in their region.

These centres are aimed at fostering collaboration between small biotechs, university research establishments, funders and ourselves. Collaboration between pharmaceutical companies is on the increase and is likely to stay that way. For example, there is a lot of sharing of science, particularly in areas such as Alzheimer's, which has proved to be a challenging disease to tackle.

Moreover, through Transcelerate Biopharma, Janssen is working with 15 other pharmaceutical companies to simplify and accelerate the drug development process, so that we can get innovative medicines to patients as soon as possible.

We have also created the Janssen Health Policy Centre, a new initiative to encourage healthcare debates that will address ways in which the healthcare expectations of patients and broader society can be better met in the future.

It will establish multi-stakeholder forums for open discussions with key groups – public health specialists, healthcare providers, caregivers, policy makers, health economists and patient advocacy groups.

The debates will be based on data and health policy related reports.

The insights gained by the Janssen Health Policy Centre will offer a holistic healthcare perspective and provide pragmatic recommendations to benefit society at large.

Mutual trust

Society itself is increasingly being driven by transparency and a more open dialogue on all topics. We have made progress but there is much more we can do as a company and as an industry.

Our stakeholders have asked us to become more transparent and accessible. They want an even stronger commitment to demonstrate ethical behaviour in everything we do.

We want results for patients and for public health. It is only by developing medicines with high medical value, and in an ethical manner, that we will change perceptions and be recognised for the value we create for society. In order to achieve this, we need mutual trust.

I want to emphasise the importance of experts and expertise. We have to trust the people in charge, the academics in the various committees of our national and regional public health authorities.

We rely on them to put things in perspective, to weigh the benefits and risks.

At Janssen, our dedication to finding solutions for unmet medical needs is extremely high.

For example, our portfolio of medicines to treat life-threatening conditions – including HIV, cancer and hepatitis C – as well as many other acute and chronic conditions, mean we dramatically improve and enhance the lives of thousands of patients every day.