'Growing' medicines in plants requires new regulations

February 19 2013

Scientists say amending an EU directive on GMOs could help stimulate innovation in making vaccines, cheaper pharmaceuticals and organic plastics using plants.

In a paper to be published in *Current Pharmaceutical Design*, six scientists from the US and Europe compare risk assessment and regulation between the two continents. They will run a web chat on the subject with Sense About Science from 12-1 on Wednesday 20th February.

In the EU, plant-made pharmaceuticals have to be authorised in the same way as GM agricultural crops. In theory, agricultural crops can be grown by any farmer in the EU once approved. But for crops producing pharmaceuticals this would never actually happen. Drug companies would likely license farmers to grow these crops under controlled, defined and confined conditions.

"We need tight regulations enforced by continuous oversight to encourage investment, while maintaining trust," said Dr Penny Sparrow from the John Innes Centre.

"This will be of high importance, especially in Europe, where the issues surrounding the cultivation of GM agricultural crops remains a contentious concern."

"Plant-made pharmaceuticals challenge two sets of existing EU

regulations and to make progress in this area we need to make sure they are applied sensibly to allow pharmaceuticals to be produced in plants."

Advantages of using plants to produce therapeutic proteins include the ability to produce large quantities quickly and cheaply, the absence of human pathogens, the stability of the proteins and the ease with which raw material can be stored as seed. This could be of huge benefit in developing countries where problems with storage can render vaccines useless.

If seed could be transported to local production and extraction facilities, the technology could also help boost local economies. The technology is also known as "plant molecular farming".

Just one farm growing 16,000 acres of safflower could meet the world's total demand for insulin. But potential cost savings are eliminated under current regulations, set up for GM agricultural crops not pharmaceuticals.

The average cost for having GMOs approved in Europe is estimated at €7-10 million per event, compared to $1-2 million in the US. This helps keep Europe behind in exploiting the potential of these technologies.

"Openness and transparency are needed to develop new regulations that work for the public and for investors," said Sparrow.

"Regulations need to be harmonised across the world, in order to keep advances and competition on a level playing field."

They propose amendments to EU Directive 2001/18 to allow pharmaceutical products from GM plants to be commercialised without needing authorisation to enter the human food or animal feed chain. Instead, the scientists say they should be grown under clearly defined and

enforced conditions to keep the food and animal feed chain 'contamination free'.

As each GM plant moves from the laboratory to scaled-up production in a greenhouse or field, additional oversight is needed to consider issues with environmental release and the ultimate use by humans. Measures can include those adopted in the US, such as limited acreage, confinement, fallow zones and only supplying seed to farmers specifically contracted to grow PMPs.

Dr Sparrow was involved in a collaboration with EU partners to road test the challenges faced by potential investors. They chose the first plant-derived anti-HIV monoclonal antibody to be tested in humans. It was isolated, purified and formulated as a topical saline solution. One result of the project was preparing a regulatory pathway that others could follow to take a product into clinical trials. Another was establishing good manufacturing practices for biologically active proteins expressed in transgenic plants.

Provided by Norwich BioScience Institutes