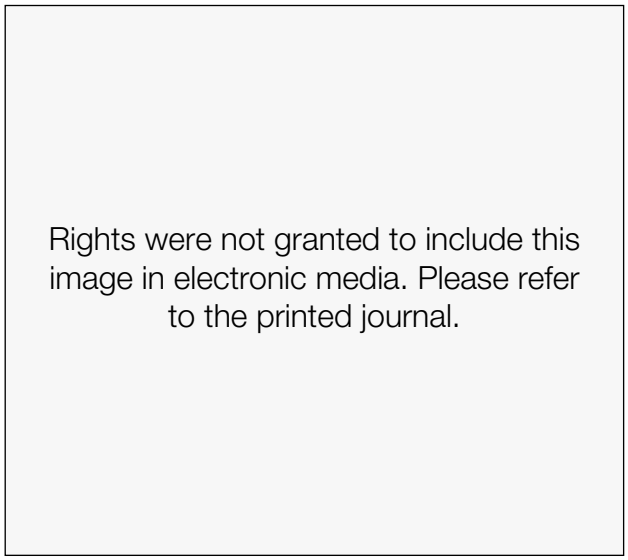
Influenza vaccine shortage hits the USA

The USA will get an additional 375 000 doses of influenza vaccine in January to make up for rapidly diminishing supplies, Tommy Thompson, Secretary General of the US Department of Health and Human Services (HHS) announced on Dec 15. The decision to acquire Chiron's remaining vaccine comes just one week after HHS reported plans to purchase the last remaining doses from Aventis Pasteur. "With this purchase, HSS has acquired remaining stock from both of the manufacturers who produced injectable vaccine for the United States this year", Thompson said.

An unusually early onset of influenza activity, coupled with a large demand for the vaccine, is blamed for the shortages reported all over the USA. Around 80 million doses of the injected vaccine were produced this year—an amount that would ordinarily have been sufficient. However, to cope with increased demand the government has been forced to buy in more supplies. The extra doses from Chiron, along with 100 000 adult doses and 150 000 paediatric doses from Aventis, will be shipped to individual state health departments. Each state's supply will be based upon its population.

The shortage reflects how difficult it is to estimate the number of doses that will be needed during any given year. Vaccine manufacturers look at how many people were vaccinated the year before, and then estimate the number that will be needed for the coming season. The CDC estimates that 185 million people fall into the recommended groups for receiving influenza vaccine, but nowhere near that number ever get vaccinated. On average, the total number of people receiving the vaccine falls somewhere between 70 and 75 million. Last year, manufacturers overproduced and had to scrap 12 million doses of the vaccine, without any reimbursement.

Before Thompson's latest announcement, there were concerns that the US Food and Drug Administration (FDA) would not approve the Chiron purchase, because their product is licensed in the UK, but not in the USA. At a press conference last week, CDC director Julie Gerberding explained that the "situation with Chiron is still under evaluation", and that use of the vaccines was subject to FDA approval.



AP

Some health centres have only a handful of doses remaining

Widespread influenza activity in 24 states underlines the continued need for the vaccine, said Gerberding. "All jurisdictions are reporting 'flu, and it's clear that the epidemic has not peaked this year, although there is some early information suggesting things may be levelling off in some of the states that were hardest hit."

Roxanne Nelson

EU rushes through reduced cell and tissues legislation

Contentious ethical issues that were slowing the progress of European legislation on cells and tissues were swept aside by members of the European Parliament (MEPs) on Dec 16.

The parliament agreed that EU legislation should not "interfere" with national policies on use of germ cells and embryonic stem cells. Furthermore, regulation of transplantation has, in effect, been dropped.

EU Health Commissioner David Byrne conceded that "important differences between organ transplantation and the use of other human substances such as blood, tissues, and cells" would require separate legislation, after there has been "thorough scientific evaluation".

British MEP Caroline Jackson, who chairs the Parliament's committee on public health affairs, admitted that the approved legislative draft is "a bit of a fudge".

Policy on donor compensation will be left to state governments, as will practice on disclosure of donor identity, "notably in the case of gamete donation". National governments will merely be required to "endeavour to ensure that the procurement of tissues and cells as such is carried out on a non-profit basis".

MEPs agreed to concentrate instead on quality control and accreditation issues related to the operation of tissue banks, as indicated in the title of the new Directive on "standards of quality and safety for the donation, procurement, testing, processing, preservation, storage, and distribution of human tissues and cells".

EU institutions want to enact legislation ahead of enlargement of the Union from 15 to 25 nations in 2004. Early application of EU rules to candidate states in central Europe is a key objective. However, concerns about supply of organs persist, not least in light of allegations that "organ theft" occurs in states on the Union's future frontiers.

To cut short legislative procedures, MEPs negotiated behind the scenes with ministers' representatives to secure a mutually acceptable version of Commissioner Byrne's original draft.

German MEP Peter Liese, himself a physician, bravely insisted that the Parliament had secured "considerable improvements" in terms of avoiding the commercialisation of donation, without preventing sale of products derived from cells; banning payment of donors, while authorising compensation; and clarifying rules on imports from non-EU states, to guarantee their traceability.

Arthur Rogers