Legal and regulatory update

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IMPORTANT OPINION GIVEN BY THE EUROPEAN COURT OF JUSTICE ON SUPPLEMENTARY PROTECTION CERTIFICATES

The Advocate-General of the European Court of Justice (ECJ) has delivered an important opinion that, if adopted by the judges of the court, would mean an extension in the availability of Supplementary Protection Certificates (SPCs) throughout the European Union (EU). In Case C-431/04 *Massachusetts Institute of Technology* (unreported opinion of 24th November, 2005),[1] the Advocate-General proposed a broad interpretation of the definition of the products for which an SPC could be obtained, arguing that a 'combination medicinal product' comprising an active ingredient and an excipient could be considered as a product attracting SPC protection.

Council Regulation 1768/92 (the 'SPC Regulation') provides for the grant of up to five years' additional patent protection for a medicinal product where that product is covered by a basic patent and a marketing authorisation in the country where the SPC is sought. The period of protection is the period between the basic patent filing date and the date of grant of the first market authorisation minus five years and subject to a maximum period of additional protection of five years.

In the SPC Regulation, a product for which an SPC may be granted is defined as the 'active ingredient or combination of active ingredients of a medicinal product'. In this case, an application was made for a product consisting of an active ingredient, carmustine, and an excipient, polifeprosan. It had been found that this excipient increased the efficacy and reduced the toxicity of the active substance by controlling the release of the (cytotoxic) active ingredient from an intra-cranial implant. The German Patent Office refused to grant an SPC on the grounds that there was not a combination of active ingredients and also refused an SPC for the active ingredient alone since this had already been known for a considerable period of time. On appeal, the German Federal Supreme Court referred two questions to the ECJ regarding the interpretation of the definition of product as used in the SPC Regulation.

The Advocate-General took the view that a narrow interpretation as adopted by the German Patent Office would not be consistent either with the broad logic of the SPC Regulation of which it forms part or, above all, with the objectives pursued by the Community legislature. The broad logic of the SPC Regulation is that it is intended to extend the protection conferred by the basic patent. It follows that if the basic patent covers the combination of active ingredient and biologically relevant excipient in the first place, then this coverage must be capable of being extended by the SPC.

Moreover, such an interpretation is, according to the Advocate-General, fully consistent with the objectives of the SPC Regulation. He noted that the objective of facilitating a continuing improvement in public health requires sufficient legal protection to be granted to innovations that allow the therapeutic efficacy of active substances to be increased. He did not believe that it was sufficient simply to extend protection to new active substances, but rather argued that protection should also cover new

applications of existing active substances, including as in this case where used in conjunction with a particularly effective excipient. He also noted that the SPC Regulation seeks to grant legal protection to medicinal products that are the result of long, costly research where that protection is both sufficient to allow pharmaceutical undertakings to cover their investments and equivalent to that enjoyed by other technological sectors. On the other hand, one should be wary of granting protection to every incremental improvement to a product, which would have the effect of stifling generic competition. The Advocate-General did not believe that this was such a situation and found that a combination of the type in question was generally of such innovation that it would merit an extended period of protection.

The final judgment of the ECJ is now awaited, which, if it follows the opinion of the Advocate-General, will represent a useful clarification and indeed expansion of the SPC Regulation.

EUROPEAN COMMISSION SURVEY ON THE FUTURE OF THE EUROPEAN PATENT SYSTEM

The concept of a European patent has been around for some time; however, the desire for a European patent has as yet to overcome the question of languages and more particularly into which languages patents must be translated and the legal effect of such translation. There can be no doubting the commitment of the European Commission to ensure the realisation of their goal of a single European patent, with a unified application process. Current efforts to implement such a system can be traced back almost 10 years. The Commission has now launched a consultation[2] on the Community patent system in what Internal Market Commissioner Charlie McCreevy described as his final effort to have the proposal adopted during his mandate. While it is questionable whether he will realise his aim, the consultation will, however, serve to ensure the idea is kept alive and could bring some solution to the impasse.

The consultation comes amidst growing support for the alternative to the Commission's suggestions, the European Patent Litigation Agreement (EPLA). The EPLA came about as a result of frustration at the lack of progress towards a European patent and the current costs and uncertainty of filing and litigating patents in numerous member states. The EPLA would provide for a centralised patent litigation system for those member states that sign up to the agreement and is seen by some as moving towards a European patent through the 'back door'. The cost of translating patents would also be addressed by the London agreement on translations. Under this agreement countries signed up to the European Patent Convention agreed that where a European patent application is filed in one of the official languages of the EU (English, French or German), the requirement that it be translated into their native language before it can have effect in that country is removed. This would greatly reduce translation costs; it is, however, as with the EPLA, still subject to ratification by the member states before it can take effect. In addition, there is some doubt as to whether the EPLA could in fact be so ratified by EU member states since it seeks to legislate on matters (jurisdiction in civil and commercial disputes), which, according to the Commission, fall within the exclusive competence of the EU.

The consultation is clearly aimed at finding a way to overcome the language issues which caused the last attempt to reach agreement on a European patent to fail in May 2004. In particular Germany and Spain have been reluctant to allow a European patent that is not translated into their respective languages. The concern is that for example a Spanish company may be found liable for infringement of a patent that has never been translated into Spanish. The question is also raised of what should be the outcome where, for

example, the Spanish company has the patent translated, but there is a mistranslation. The issue is a real one especially with such a specialised document and the potential of significant financial consequences for infringing a patent.

In terms of the global market and the competitiveness of the European Union there can be no denying that filing for a European patent and the resulting translation into the languages of the member states is significantly more expensive than applying for a single patent in the USA or Japan. Although this question of cost is one that would need to be addressed in any European alternative, it should be remembered that a patent does not have to be translated into every European language, simply those where the patentee wishes to register a patent. So while it is certainly true that a single European patent would be cheaper than filing in all member states, there is a question as to whether it would be cheaper than filing in just the countries which make up the main European markets for the product in question.

The consultation covers the main points of what should form the basic aspects of a European patent system and whether its achievement should be a priority for the EU. The third question is perhaps the most telling: respondents are asked for their response to the EPLA. This could be seen as opening the door for the EU perhaps to give the EPLA its blessing if the consultation revealed a positive response. This would acknowledge the progress the EPLA seems to have made where the European patent negotiations stalled on the question of language. As much as the Commission would not wish to see it, a situation may well arise that could be characterised as a two-speed Europe, where those who are willing to sign up to the EPLA do so with the European Commission's blessing, and those who are not willing are left behind, may be the only solution. Perhaps this is done in the hope that those who are left behind will eventually see the benefits and thus join the EPLA. The time may have come to acknowledge that two speeds are desirable as the only solution capable of forcing a stalled European patent back on the road to realisation.

FURTHER CHANGES TO UK PATENT LAW

Further changes to domestic patent law were introduced on 1st October, 2005, in the UK. These consisted of certain changes to procedure before the UK Patent Office, such as the arrangements for late payment of renewal fees, ordering security for cost in proceedings before the Patent Office and the rights of co-owners in respect of jointly owned patents together most significantly with a new possibility for the Patent Office to issue opinions on the validity or infringement of a UK patent. Finally, there is now a facility for an inventor of a patented invention to waive their right to be mentioned as the inventor in a patent specification. These amendments to the Patents Act 1977 are part of a package of reforms introduced by the Patents Act 2004.

Following the entry into force of s.74A Patents Act 1977, it is possible for anyone to request an opinion from the Patent Office on whether a particular act constitutes or would constitute an infringement of a UK patent (including a European patent designating the UK) and whether (and to what extent) an invention forming the subject-matter of such a patent is in fact patentable. It should be noted that the validity opinion may consider only whether the requirements of novelty and inventive step have been satisfied and not industrial application and inherent patentability. There is a possibility for the owner of the patent in question or an exclusive licensee to seek a review of such an opinion.

The opinion is not of itself binding for any purpose. However, it seems possible for the parties to a dispute involving the patent in question to agree among themselves that the opinion will be binding upon them for the purposes of

resolving the dispute. That would seem to be the hope of the government which sees this particular reform as a means by which to reduce the cost of patent dispute resolution in the UK, especially for smaller businesses. Indeed the procedure laid down by the Patent Office provides for a simple, purely written process, whereby the person seeking the opinion is required to file a statement of their analysis of the facts of the situation along with supporting documents and then interested parties (including the patent owner and any registered exclusive licensees) are invited to make observations before the Patent Office issues its opinion.

The procedure is also believed to be of use outside the litigation context. The Patent Office suggests that this may occur where a person, before investing resources in a particular activity, wants to find out whether that activity would infringe a patent of which they have become aware. It also suggests that a patent owner might want an opinion about whether newly discovered prior art is relevant to the patented invention, before they decide whether to amend the scope of the patent. The fact that an opinion has been requested is published on the Patent Office website together with the opinions once issued. Consequently, it is questionable whether the procedure is of such use in this context since there is a risk, for example, that a patent owner would be alerted to potentially infringing activity of which it was previously unaware.[3]

The rights of co-owners of a UK-granted patent have been modified so that the consent of all co-owners is now required when amending or applying to amend that patent or for that patent to be revoked, in addition to the granting of a licence under that patent.

The ability of an inventor to waive his or her right to be named as inventor in a patent specification is clearly of use to inventors involved in areas of biotechnological research where there is a risk that members of extremist organisations may seek to target inventors on the basis of publicly available information.

POSSIBLE US SUPREME COURT RULING ON PHARMA SETTLEMENT AGREEMENTS

A recent line of argument in the USA has considered the validity of certain patent litigation settlements on anti-trust grounds and this is now set to reach the US Supreme Court. The argument relates to a series of 'reverse payment' patent settlement agreements between branded and generic pharma companies in which a patent holder makes substantial payments to an alleged infringer. The US Federal Trade Commission (FTC) argues that these agreements are anti-competitive. It has recently petitioned the US Supreme Court to review an appeals court ruling which overturned an earlier FTC finding that these agreements were anti-competitive.

Since the Hatch–Waxman Act was enacted in the USA in the 1980s, generics have been able to obtain approval to sell generic drugs more easily. They must show that their products are 'bio-equivalents' of branded pharmaceutical products and must certify that the new drug does not infringe any of the patents relating to the original drug.

Once approval from the Food and Drug Administration (FDA) is obtained, the generic is given 180 days to exclusively manufacture and sell the generic product before any other entrant will be approved. However, if the patent holder of the branded drug (branded pharma) brings an infringement action against the generic applicant within 45 days of its application, approval of the generics drug is suspended for 30 months. This means that unless the applicant generic transfers its 180-day exclusivity to a competing generic, no other generic can obtain approval for a generic drug until expiry of the 30 months. For the patent holder this effectively means that there is no generic competition during this period.

Particular controversy has arisen in relation to a number of settlement arrangements which have been agreed between patent holders and generics following commencement of patent infringement proceedings by the patent holder. Typically patent litigation gives rise to the alleged infringer making payments to the patent holder to compensate the patent holder for infringement of its valuable intellectual property. However, in patent disputes that have arisen under Hatch–Waxman, settlement agreements have controversially been characterised by:

- 'reverse payments' – essentially the patent holder paying extremely large sums of money to the generic;
- the generic agreeing on delayed entry to the market;
- the generic agreeing not to transfer its 180-day exclusivity to any other drug company, thereby preventing any other generic competitive entry to the market.

Two sharply divided schools of thought have emerged in relation to these settlement agreements. On one side are those who argue that they are anti-competitive, effectively collusive arrangements by which a patent holder pays a large exclusion payment to a generic to keep competition out of the market and therefore to retain (or establish) market power. In particular the debate has focused on the size of payments made to generics as evidence of the anti-competitive nature of these agreements. The argument is that a patent holder that considers that there is genuine infringement of its patent by a generic would only be prepared to make a settlement to the value of anticipated litigation costs of the generic in fighting a patent case. Any payment beyond that amount indicates that a patent holder is not confident of winning its infringement claim and is therefore making a payment to keep competition out of the market. Added to that is the delayed entry component of the settlement agreements which prevents other generics from entering the relevant market and which serves to increase the exclusionary effect of these agreements.

Entirely on the other side of the debate are those who support the intellectual property right position and who consider that these settlement agreements are a legitimate means by patent holders of protecting their intellectual property. Patent rights are by their nature exclusionary, giving the patent holder exclusive rights for a period of time. Although that position is in a sense anti-competitive, this is the accepted exception for intellectual property rights which is necessary to encourage innovation and recovery of investment. In particular the courts that have not regarded the settlements as anti-competitive have held that:

- public policy favours patent settlements;
- they have many efficiency-enhancing objectives;
- they are presumptively valid; and
- they give the patent holder the right to exclude those who infringe its rights in the absence of evidence to the contrary.

Given the divergent views of judicial authorities on these agreements, a US Supreme Court decision on the Schering-Plough case will be important (if it agrees to hear the case) in finally clarifying whether these exclusionary agreements are legitimate or anti-competitive.

In the Schering-Plough case, Schering-Plough initiated patent litigation against two generics (Upsher-Smith and ESI) who had each applied for approval to market a generic version of Schering-Plough's brand-name drug.

Schering-Plough settled with each party in 1997 and 1998 respectively. Broadly the terms of the agreement with the generics included large cash payments to them and delayed market entry.

To date, the Schering-Plough settlement has been reviewed three times – first by the Administrative Law Judge (ALJ) of the FTC who found that the settlements were not anti-competitive, second by the FTC which found that they were anti-competitive and third by the Eleventh Circuit Court of Appeals which reversed the FTC decision and found that the agreements were not anti-competitive. This case therefore highlights the real absence of judicial agreement about the competition law implications of settlement agreements and the need for a clear ruling.

In addition the Supreme Court's view on the kind of competition law analysis which should be applied to settlement agreements will be important. This is because the US courts and FTC have demonstrated little uniformity of approach to such an analysis. In some cases the view has been that settlement agreements are inherently illegal as their effect is to keep generics out of the market (ie 'per se' illegal). Other courts have stated that these agreements are not necessarily illegal but that their pro- and anti-competitive effects need to be weighed (ie 'rule of reason' approach). To add to the confusion the Eleventh Circuit Appeals court recently rejected these approaches and argued that the appropriate test was to examine the scope of the exclusionary potential of the patent, the extent to which the agreements exceed that scope and the resulting anti-competitive effects.

A clear view from the Supreme Court on the correct approach will not only be welcome but is much needed so that pharma companies (both branded and generics) can enter into settlements on terms they know to be acceptable and without the risk of their being found to be party to anti-competitive agreements.

It is interesting to compare the US position with that of the EU. Some aspects of Hatch–Waxman have only recently been enacted into the laws of EU member states (eg the so-called 'Bolar' exemption which allows generics to conduct tests on a patented compound prior to patent expiry without being liable for patent infringement).

Although settlement agreements of the kind evidenced in the USA have largely not been publicised in Europe, the same issues are likely to arise in relation to them. Just as the US anti-trust authorities clearly consider these reverse payment agreements to be anti-competitive, so it is conceivable that the European Commission and other equivalent member state authorities would adopt a similar approach. The European authorities are likely therefore to take a keen interest in any US Supreme Court ruling on this issue if there is one.

One can expect several things in terms of outcome. First, that the Supreme Court grants the FTC petition. If it does not, a good opportunity to obtain clarity on the question of whether reverse payment settlements are a valid defence of intellectual property rights or infringe competition law will have been lost as well as the opportunity to establish the competition law principles on which they should be assessed.

Assuming the petition is granted and a view reached that such pharma agreements are anti-competitive (for example the large reverse payment element), then it will raise serious questions about the acceptability of such patent settlements going forwards. One would assume that in the absence of large payments, generics may be more inclined not to enter into settlements with branded pharma and proceed with patent litigation. On the other hand, the costs of such litigation and relative uncertainty of outcome may deter generics in particular from this course. We therefore await the outcome with interest.

OMNITROPE RECEIVES POSITIVE CHMP OPINION

The Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMEA) has issued a positive opinion on OMNITROPE somatropin human growth hormone (hGH) made by Sandoz. The CHMP found that OMNITROPE has been shown by studies demonstrating comparable quality, safety and efficacy to be similar to a reference medicinal product already authorised in the EU, namely GENOTROPIN somatropin marketed by Pfizer and recommended approval of OMNITROPE for all indications on the GENOTROPIN label. The recommendation has now been passed to the European Commission for formal approval.

If the Commission approves OMNITROPE, it would be the first product marketed under European biosimilar regulations. This possibility was introduced under the 2004 revision of the Community Code on medicinal products for human use.[4] Similar biological medicinal products may be authorised on the basis of appropriate non-clinical and clinical data requirements. This is based on the experience gained with the reference medicinal product, against which appropriate studies and comparisons are made. However, compared with generics, in the case of similar biological medicinal products, substantial additional data, in particular the toxicological and clinical profile, have to be provided. The EMEA has published guidance on the data required and is the process of drafting guidance to cover specific products and categories of products.[5]

The Commission rejected Sandoz's first application using the so-called 'bibliographic' route in 2004 based on a well-established use of the reference product, despite a recommendation for approval from the EMEA in 2003. After seeking judicial review of this decision, Sandoz submitted a second OMNITROPE application in July 2004.

UK HUMAN TISSUE AUTHORITY SETS COMMENCEMENT DATE OF NEW REGULATORY REGIME

The Human Tissue Authority (HTA) has recently announced some important dates in the new regime governing medical research and treatment using human cells and tissues. The HTA is the UK regulatory body established by the Human Tissue Act 2004 to oversee the removal, storage and use of human tissue. This remit includes the regulatory framework mandated by European Parliament and Council Directive 2004/23/EC on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells (the 'Tissues and Cells Directive').

The first date is that on which the Tissues and Cells Directive's regime will enter force in the UK. This has been set for 7th April, 2006. From this date tissue banks storing tissues and cells intended for *human application* or the manufacture of products for human application will require a licence from the HTA. This will include tissue banks for bone, corneas and skin and stem cells taken from adults. Blood and derivative products will be excluded since these are separately regulated.

The HTA will establish a scheme to ensure compliance by licence holders with certain standards. An important feature is the introduction of a traceability requirement, which will also apply to tissues and cells from donors outside of the EU. The HTA is required to ensure that tissue donation in this context takes places place on a voluntary, not-for-profit basis and the Tissues and Cells Directive sets out specific information that must be provided when obtaining informed consent from the donor. All samples obtained must be anonymised, including any data obtained through the processing of the samples. In terms of tissue processing and storage, appropriate quality control procedures are required and must

be supervised by a designated responsible person. Every tissue establishment is required to put in place written agreements with third parties where the agreed activity influences the quality and safety of the tissues, and to make these agreements available on request to the competent regulatory authority.

The European Commission is still in the process of preparing detailed technical requirements concerning:

- accreditation, designation, authorisation or licensing of tissue establishments;
- procurement of human tissues and cells;
- quality systems, including training;
- selection criteria for the donor of tissues and/or cells;
- laboratory tests required for donors;
- cell and/or tissue procurement procedures and reception at the tissue establishment;
- tissue and cell preparation processes;
- tissue and cell processing, storage and distribution;
- direct distribution to the recipient of specific tissues and cells.

These will be applied by the HTA following adoption by the Commission. The legislation giving effect to the Tissues and Cells Directive has not yet been published, but drafts are expected shortly.

Centres storing human tissue for, among other things, *research purposes* will have to be licensed by the HTA by 1st September, 2006. More information on the operation of the licensing scheme including inspection of these tissue collections will be published in April 2006, along with the final versions of the five statutory codes of practice on the main areas within its remit, namely consent, donation of human organs, tissues and cells for transplantation, post-mortem examination, anatomical examinations and removal, collection, retention and disposal of human organs and tissues. These were the subject of a consultation during 2005.

Running throughout this licensing scheme is the fundamental new requirement that the removal, storage and use of human tissue for particular purposes set out in the 2004 Act will require the specific consent of the donor of the tissue given in accordance with the provisions of the Act. These purposes include obtaining scientific or medical information about a living or deceased person which may be relevant to any other person and research in connection with disorders or the functioning of the human body. It should be noted that the definition of human tissue excludes live gametes and embryos since these are regulated under the Human Fertilisation and Embryology Act 1989. In addition, cell lines derived from human tissue are excluded. This consent requirement has not entered force yet, but is likely to take effect no later than September when the licensing scheme starts.

It is important to note that existing holdings as at the date the regime enters effect will be excluded from the consent requirement given the obvious difficult in obtaining retrospective consent. Storage and use of such holdings will still be subject to the statutory codes of practice.

Once these new regimes enter effect, carrying out licensable activities without a licence and removing, storing and using human tissue for the purposes set out above without appropriate consent will be a criminal offence.

EUROPEAN COMMISSION PROPOSES REGIME FOR REGULATION OF ADVANCED THERAPY MEDICINAL PRODUCTS

Despite the plethora of European directives and regulations on medicinal

products and medical devices, a gaping hole remains, and this is the regulation of the application in human medicine of tissue engineered products. The proper regulation of the use of this and other advanced therapies, which include gene therapy and somatic cell therapy, requires expertise at a high level, although such high-level expertise is scarce. These two issues and the desire to improve competitiveness within the EU for advanced therapy products have brought about a proposal for harmonisation of the rules on the marketing and sale in the EU of gene therapy and somatic cell therapy medicinal products and tissue engineered products ('advanced therapies').

The Regulation essentially extends to advanced therapies the powers of regulation and supervision of medicinal products which the EMEA and national regulatory authorities have over medicinal products. Included within these powers are those regulating clinical trials,[6] good manufacturing practice,[7] marketing authorisations[8] (which will be dealt with centrally by the EMEA) and post-authorisation pharmacovigilance.[9] Unfortunately within each of these areas, much of the legislation is still to be written in the form of amendments to existing legislation and new sets of guidelines.

Provisions which are particular to advanced therapies include Article 16 on traceability. Because of the relatively unproven track record of advanced therapies and because these products can be retained in the body longer than conventional medicines, long-term patient follow-up and post-authorisation monitoring are crucial. The Regulation therefore requires that the product used is traceable back to source and also that the recipient of the particular product can be traced.[10]

Advanced therapy medicinal products for the purposes of the Regulation fall into three categories: (i) gene therapy medicinal products, (ii) somatic cell therapy medicinal products (both of these are defined in Part IV of Annex I to Directive 2001/8/EC, as amended) and (iii) tissue engineered products. For this last category the legislators had to go back to the drawing board for a definition. A tissue engineered product is defined as a product that 'contains or consists of engineered cells or tissues and is presented as having properties for, or is used in or administered to human beings with a view to regenerating, repairing or replacing human tissue.'[11]

These advanced therapy products may contain cells or tissues of human or animal origin or both.[12] However, it is the intention that only those advanced therapy products that are prepared 'industrially' are to be regulated. Products prepared in a hospital in accordance with a medical prescription for an individual patient are to be excluded from the scope of the Regulation,[13] although this is mentioned only in the recitals and not in any of the Articles.

The Commission has not specifically either included or excluded the use of embryonic stem cells for medical use. It has taken the position that whether or not these are used is a matter for the country in which the use will take place. If, however, the use of embryonic stem cells is permitted in a particular country, that use must comply with the terms of the Regulation.[14]

The major addition to current regulatory functions is the creation of a Committee for Advanced Therapies (CAT).[15] The CAT is to be a hub of relevant expertise. It will perform the function of being the advisory body for the EMEA on matters relating to advanced therapy products and in particular on matters arising through the operation of the Regulation.

The proposed regulation has to sit within a web of other applicable legislation. Such legislation includes the following:

- The Tissues and Cells Directive on quality and safety for donation, procurement, testing, processing, preservation and distribution of

human tissues and cells:[16] this will continue to govern these particular issues even where the tissues and cells applied to the uses envisaged in the Regulation.[17]

- The Medical Devices Directives:[18] these will be relevant where there is a combined therapy. In these cases the 'device' part needs to meet the requirements of the medical device directives. The CAT is also required to take any CE marking of the device into account when considering whether or not to authorise a product.[19]

- The Clinical Trials Directive:[20] this is specifically extended to tissue engineered products, which were not originally covered in the Clinical Trials Directive. The Commission is also tasked with drawing up detailed guidelines on good clinical practice which will be specific to advanced therapy medicinal products.[21]

The Regulation provides for an EU-wide amalgamation of expertise on advanced therapy products to assist with decision making with respect to matters involving marketing authorisations. Unfortunately, however, areas such as clinical trials and reimbursement are generally dealt with at a national level. Where harmonisation of laws has yet to be achieved, national bodies such as national ethics committees and the national bodies charged with determining reimbursement status and pricing of products will be obliged to make decisions about advanced therapy products without the benefit of the high level of expertise that will be available to the EMEA through the CAT. It remains to be seen whether these national bodies will be able to rise to the challenge of forming good judgments about these products, particularly on their safety and efficacy.

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