# EU Legal & Regulatory Update – June 2014


## ABSTRACT

UK and European content is compiled and written by Bird & Bird LLP, an international law firm which advises life sciences companies on the full spectrum of legal and commercial issues affecting the industry:

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  - Clinical trials
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- Risk management
- Data protection & privacy issues
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This section is intended to be a synopsis of recent legal developments and is not intended to be exhaustive. If any issue referred to in this section is to be relied on, specific advice should be sought.


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## ORGANISMS NOT CAPABLE OF DEVELOPING INTO A HUMAN BEING ARE NOT HUMAN EMBRYOS


### Rachel Fetches and Toby Sears, London


On 18 December 2014, the Court of Justice of the European Union (CJEU) handed down its judgment holding that an organism that was incapable of developing into a human being did not constitute a human embryo within the meaning of Directive 98/44/EC (Case C-364/13).[1] The CJEU observed that the purpose of the Directive was to regulate patentability of biotechnological inventions and not to regulate research and use of human embryos. It was a matter for the English Court to determine if human parthenotes had the inherent capacity to develop into a human being but if they did not, then they would not be a human embryo within the meaning of the Directive. Any such an organism used for industrial or commercial purposes would in principle be capable of being patented. This Judgment adopted the Opinion delivered by Advocate General Cruz Villalón on 17 July 2014 (previously reported in the January 2015 edition of the Journal of Commercial Biotechnology).

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1 Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions (OJ 1998 L 213, p. 13).

## Background

In April 2013, the English High Court referred a question to the CJEU on the interpretation of Article 6(2)(c) of the Directive. The question asked whether a parthenote, which only contained pluripotent and not totipotent cells and was therefore incapable of developing into a human being, was included in the term "human embryo" under Article 6(2)(c) of the Directive. This arose from the application by International Stem Cell Corporation ("ISC") for a patent claiming methods of producing pluripotent human stem cells from parthenogenetically-activated oocytes and stem cell lines produced according to the methods and another patent claiming methods of producing synthetic corneal or corneal tissue from such pluripotent stem cells. ISC argued that the parthenotes were unable to develop into a human embryo because of genomic imprinting, although ISC acknowledged that this might be possible through extensive genetic manipulation and had amended the claims to exclude such a possibility.

## Judgment

In *Brüstle* (Case C-34/10) the CJEU held that a 'human embryo' included "non-fertilised human ovum whose division and further development have been stimulated by parthenogenesis" as they were "capable of commencing the process of development of a human being just as an embryo created by fertilisation of an ovum can do so." The CJEU noted that whereas in *Brüstle,* written observations presented to the Court stated that parthenotes did have the capacity to develop into a human being, none of the interested parties (which included a number of observations from Member States) in this case disputed that this was not correct according to current scientific knowledge.

The CJEU agreed with A-G Cruz Villalón's Opinion that in order to be classified as a 'human embryo,' a non-fertilised human ovum "must necessarily have the inherent capacity of developing into a human being." Therefore, if an unfertilised human ovum whose division and further development have been stimulated by parthenogenesis did not, in itself, have the inherent capacity of developing into a human being, it would not constitute a 'human embryo' under the Directive.

The case will now come back before the English High Court who will consider the application of the CJEU's Judgment to ISC's patent applications.

# NEW POLICY ON PUBLICATION OF CLINICAL DATA FOR MEDICINAL PRODUCTS FOR HUMAN USE


## Maria-Paz Martens and Nicolas Carbonnelle, Brussels


In October 2014, a new policy on publication of clinical data for medicinal products for human use was unanimously approved by the management board of the EMA. The adoption of this policy forms an important milestone in the on-going debate on access to clinical research, data sharing and transparency.

## Introduction

The new policy governs publication of clinical trial data for medicines that have received a Marketing Authorization (MA) under the centralized procedure as from 1 January 2015. Indeed, applicants for a MA routinely submit such data, composed of clinical reports and Individual Patient Data (IPD) to the EMA under the centralized marketing authorization procedure.

The new policy clarifies the extent to which the EMA will proactively publish these data and under what conditions. It deals with the main concerns relating to the concept of Commercial Confidential Information (CCI) and the protection from unfair commercial use, protecting patient confidentiality as well as the concept of raw data.

This policy is without prejudice to Regulation No 1049/2001 regarding public access to documents. The result of this is that any natural or legal person may continue to submit a request for access to documents to the EMA independently of the proactive publication mechanism established in this new EMA policy.

Importantly, the EMA developed this policy in the absence of any specific legal provision mandating that the EMA must publish such data. Hereby taking into account the views and concerns of a broad range of stakeholders (including patients, healthcare professionals, pharmaceutical industry representatives, researchers, transparency campaigners, academic and public institutions, health technology assessment bodies, and national medicines regulators) and European bodies, who all contributed actively to the development of this new policy.

## Scope of the new policy

The EMA's new policy will only cover clinical data of new MA applications and Article 58 applications of Regulation (EC) No 726/2004 (medicines that are intended exclusively for markets outside the European Union) submitted to the EMA after 1 January 2015 and does not apply to clinical data that the EMA holds for applications received under the centralized procedure before that date.

For post-authorization procedures for existing centrally authorized medicinal products, the effective date will be 1 July 2015 for extension of indication and line extension applications that have been submitted as of that date.

Therefore, according to this policy, data will only start to become accessible once the final decision on a given procedure has been reached by the European Commission, which implies a timeframe of approximately 18 months.

## Main features of the new policy

In accordance with the policy, the EMA will provide access to clinical reports primarily redacted by the Marketing Authorization Holder (MAH). In limited circumstances these reports may be redacted prior to publication, the objective being a publication of the documents around the time of the Commission decision granting or refusing the MA/post-authorization submission outcome.

The redaction mechanism foresees that the reports may only be subject to redaction when needed to protect specific elements which qualify as CCI. The EMA will have the final say in case of disagreement on what will be redacted, following a consultation with the MAH. Importantly, the new policy provides an extended list of documents potentially containing CCI for partial redaction.

The policy is accompanied by newly developed Terms of Use (ToU) and access rules. The Annexes of the policy contain (i) copies of the ToU, (ii) details of information contained in clinical reports that may be CCI and (iii) the process for publishing clinical reports.

Two sets of ToU are available depending on the intended use of the information contained in the clinical reports:

- Any user may have view-only access to the clinical reports for general information purposes (non-commercial, including non-commercial research purposes) following a simple and limited registration process; or
- Formally identified users to the EMA may download clinical reports solely for academic and non-commercial research purposes. These data may not be used to support a MA application or extensions or variations to a MA nor to make any unfair commercial use of the clinical reports.

A Q&A document was published together with the final policy.

## Stepwise implementation of the new policy

The first stage of implementing the new policy will involve the publication of clinical data relating to clinical reports only. There will be no access to so called raw data. This will however, be reviewed by the EMA in a second phase in which various aspects in relation to IPD, including finding the most appropriate way to make IPD available in compliance with privacy and data protection laws, will be analyzed.

# EU DATA PROTECTION REGULATORS CLARIFY SCOPE OF 'HEALTH DATA' AND CHAMPION EXPLICIT CONSENT FOR DATA PROCESSING IN THE CONTEXT OF SCIENTIFIC RESEARCH.


## Frank Simons, the Netherlands


While medical researchers find innovative ways[2] to gain valuable insights from large amounts of medical data, European data protection regulators have clarified their views[3] on the scope of the definition of personal health data and on the processing thereof in the context of historical, statistical and scientific research.

The regulators – unified in the Article 29 Working Party (the "Working Party") – wrote[4] to the European

2 http://www.bbc.co.uk/news/science-environment-31166170.

3 The Article 29 Data Protection Working Party's criteria for health data may be found at: http://ec.europa.eu/justice/data-protection/article-29/documentation/other-document/files/2015/20150205_letter_art29wp_ec_health_data_after_plenary_annex_en.pdf.

4 A copy of the letter is available at: http://ec.europa.eu/justice/data-protection/article-29/documentation/

Commission in reaction to a recent Commission consultation[5] concerning mobile health (mHealth) devices and apps, but their views have wider implications.

## Health data

Pointing to the proposed definition in the draft EU Data Protection Regulation,[6] the Working Party explains that 'health data' in the context of data protection regulation is a much broader term than 'medical data'. In the Working Party's view, 'health data' includes *inter alia* 'information derived from the testing or examination of a body part or bodily substance, including biological samples' and any information about 'disease risk' and about 'the actual physiological or biomedical state of the data subject independent of its source.'

For data to qualify as 'health data,' it need not necessarily relate to 'ill health.' Whether data about a person's physiological or biomedical state is within the 'healthy' limit or not is not relevant. Moreover, in the Working Party's view, even personal data not directly related to a person's health may qualify as health data if processed with the purpose of identifying disease risks - for example as part of big data analysis of exercise habits or diet.

The broad definition of 'health data' championed by the Working Party implies that data being processed in the context of life sciences research may unexpectedly qualify as personal health data in the eyes of data protection regulators, and be subject to a stricter than usual data protection regime.

## Explicit consent

In particular, the requirement for explicit consent from the data subject, commonly required for processing of health data outside the scope of the provision of healthcare to patients, may become of particular relevance in a research context.

Whereas the current EU Data Protection framework allows national legislators and regulators relative flexibility in applying a lighter regime for further processing of personal data for historical, statistical and scientific research purposes, the European Parliament has proposed to amend the new draft EU Data Protection Regulation with a strict consent requirement for such processing.

The Working Party now calls for this strict consent requirement to be also applied under the current regulatory framework for the further processing of personal health data for research purposes. In this regard the Working Party specifically expresses its concern about the introduction of the notion of a lighter data protection regime for pseudonymised data. According to the Working Party, the use of pseudonymised data is, in itself, not sufficient to justify a lighter regime.

Whether the Commission will respond to the Working Party's call, and whether the European Parliament's proposal will be included in the Data Protection Regulation is uncertain. It is clear, however, that the use of personal health data, including in the context of historical, statistical and scientific research, is on the agenda of data protection regulators.

other-document/files/2015/20150205_letter_art29wp_ec_health_data_after_plenary_en.pdf.

5 See: http://ec.europa.eu/digital-agenda/en/public-consultation-green-paper-mobile-health.

6 A copy of the draft regulation may be accessed here: http://ec.europa.eu/justice/newsroom/data-protection/news/120125_en.htm.