HEADING IN A DIFFERENT DIRECTION?

The European Medicines Agency’s Policy on the Public Release of Clinical Trials Data
Contents

List of Abbreviations

Executive Summary

Introduction

Section 1: Regulatory Data Protection: An Overview
  1.1 Introducing regulatory data protection
  1.2 The context: The rising cost of drug development and R&D
  1.3 Regulatory data protection: What does it protect and how?
  1.4 The growing availability of regulatory data protection

Section 2: A Break from the Past? EMA’s New Policies and Existing EU and International Practices
  2.1 Existing practices in the EU
  2.2 Existing practices in the United States
  2.3 Existing practices in Canada
  2.4 Existing practices in Australia

Section 3: Unintended Consequences? The Global Implications of EMA’s Policy: An Illustrative Scenario Analysis
  3.1 From commercially confidential to publicly available: The context
  3.2 The Australian scenario

Section 4: Conclusions and Recommendations

Tables and figures
  Figure 1: European R&D spending (€ million) in Europe between 1990 and 2011
  Table 1: International use of RDP

The Global Intellectual Property Center

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List of Abbreviations

ANDA  Abbreviated New Drug Application
CCI    Commerically Confidential Information
CTs   Clinical Trials
DRA   Drug Regulatory Authority
EMA   European Medicines Agency
EU    European Union
FDA   U.S. Food and Drug Administration
IP    Intellectual Property
NAFTA North American Free Trade Agreement
NIH   National Institutes of Health
NOC   Notice of Compliance
R&D   Research and Development
RDP   Regulatory Data Protection
TGA   Therapeutic Goods Administration
TRIPS Trade Related Aspects of Intellectual Property Rights
WIPO  World Intellectual Property Organization
WTO   World Trade Organization
Executive Summary

This briefing paper was commissioned by the U.S. Chamber of Commerce’s Global Intellectual Property Center (GIPC). Its purpose is to examine and compare the draft guidelines issued in 2013 by the European Medicines Agency (EMA), titled “Publication and Access to Clinical-Trial Data,” with existing practices in the European Union (EU) and internationally regarding regulatory data protection and data transparency initiatives.

The paper has as its conceptual starting point the unique situation that arises when a biopharmaceutical product is submitted and evaluated for market approval. Specifically, the fact that the trade secrets and data generated by a biopharmaceutical innovator in the pursuit of developing a new product or technology is (prior to the product being allowed to enter a given market) required to be deposited with a governmental or regulatory body for evaluation. Under these circumstances, the regulatory or governmental body charged with evaluating these trade secrets and data becomes a custodian of them. In return, this body grants a form of protection and a commitment not to release or rely on the information submitted by the innovator in its evaluation of other product applications unless authorized to do so by the innovator.

The core question examined in this paper is where control over these deposited trade secrets and data—which have not been created by the relevant regulator or governmental body—resides. Does it reside with the regulator and evaluator of the trade secret or with the innovator who invested the time, financial resources, and effort to create the actual secret? This question is at the heart of how regulatory agencies such as the EMA are shaping their disclosure and transparency policies on submitted biopharmaceutical tests and clinical data.

The paper looks at the legal and conceptual basis for providing terms of data protection and the different core elements that make up a pharmaceutical regulatory data protection (RDP) framework and examines current international practices as they relate to RDP, the protection of submitted regulatory test data, and regulatory disclosure and transparency initiatives. Case study analysis of the clinical trials and data transparency and disclosure policies in place is provided for four major markets: the EU, United States, Canada, and Australia.

The paper makes four key findings.

First, that the EMA guidelines on data transparency are a break from preceding EMA practices, in which the release of clinical test data and related information did not take place. The agency’s change in policy raises fundamental questions about its views on the inherent confidentiality of the data submitted to it as part of a market authorization application as well as its role as a custodian of this information.
Second, the paper finds that while drug regulatory authorities in all the case-studied countries are considering and consulting on the issue of increasing clinical trial transparency, no country is seeking to emulate EMA’s policy in full. The U.S. Food and Drug Administration (FDA) in its “Transparency Initiative” launched in 2010, made a clear distinction between the manner and, more important, the extent to which “summary” versus “non-summary” clinical trials data would be published and placed in the public domain. Although the agency’s most recent (June 2013) consultations are not as clear, they nevertheless still differ significantly from the EMA’s. Other countries’ proposed initiatives are also cognizant of the need to balance greater clinical trials transparency with the need to protect proprietary and confidential information. For example, the Australian drug regulatory authority TGA (Therapeutic Goods Administration) in its own transparency proposals is not proposing to proactively publish this information. The agency is also statutorily obliged to consult with the owner of the information prior to the disclosure or publication of the information.

Third, the EMA’s proposed policies also stand in stark contrast to those initiatives taken by the private sector and research-based biopharmaceutical manufacturers. Beginning in 2014, members of the European and American biopharmaceutical trade associations EFPIA and PhRMA have committed to increasing transparency and release of information and data relating to their clinical research. These initiatives include enhanced data sharing with scientific researchers, making publicly available synopses of clinical study reports as well as a renewed commitment to seek publication of all clinical research results regardless of the research outcome.

Finally, the new transparency policies put in place by the EMA may have unintended consequences and result in placing commercially confidential information into the public domain not only in the EU but also internationally. A number of countries and legal jurisdictions predicate the protection of information on that information not already being in the public domain. Generally speaking, multinational and international biopharmaceutical manufacturers obtain such protection independently in each legal jurisdiction in which they wish to operate. Manufacturers must apply for marketing authorization in each jurisdiction. The publication of large volumes of clinical trials and test data submitted as part of a marketing authorization application in one country or jurisdiction risks putting into the public domain a significant amount of information that may be used by applicants in other jurisdictions as part of new market authorization applications for the same product or technology. Consequently, mechanisms such as RDP that are contingent on the information submitted in a marketing authorization application being protected and not publicly available, may not be available to manufacturers as a result of the EMA’s disclosure of the same or similar information. The case of Australia provides a scenario that illustrates the potential for this to happen.
Introduction

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The core question examined in this paper is where control over these deposited trade secrets and data—which have not been created by the relevant regulator or governmental body—resides. Does it reside with the regulator and evaluator of the trade secret or with the innovator who invested the time, financial resources, and effort to create the actual secret? This question is at the heart of how regulatory agencies such as the EMA are shaping their disclosure and transparency policies on submitted biopharmaceutical test and clinical data.

This paper consists of four sections.

Section 1 gives an overview of RDP regimes. It looks at the legal and conceptual basis for providing terms of data protection and the different core elements that make up an RDP framework. This section also provides a legislative overview of the growing number of countries that have introduced RDP regimes.

Section 2 examines current international practices as they relate to RDP, the protection of submitted regulatory test data, and regulatory disclosure and transparency initiatives. Case study analysis of the clinical trials and data transparency and disclosure policies in place is provided for four major markets: the EU, United States, Canada, and Australia. This section includes an examination of the EMA draft policy explaining the policy’s objective and design.
Section 3 provides an illustrative scenario analysis of how the new transparency policies put in place by the EMA may have unintended consequences and result in placing commercially confidential information into the public domain not only in the EU but internationally.

Section 4 provides conclusions and recommendations.
Section 1: Regulatory Data Protection: An Overview

1.1 Introducing regulatory data protection

Recognized internationally for the first time in international agreements by the North American Free Trade Agreement (NAFTA) and the Trade Related Aspects of Intellectual Property Rights (TRIPS) agreement, RDP is a specific type of intellectual property (IP) right (the nature and extent of RDP as an IP right is discussed below).

The subject matter of RDP is the data gathered in the process of drug development and marketing approval. Each proposed new medicine has to undergo a complex and lengthy process of selection, testing, and development in order to make it safe for human use and effective in terms of treatment. A potential medicine will be constantly examined and evaluated during its development to maximize its effectiveness and minimize any side effects. Following initial testing, using computers and test-tube methods, and testing the molecule on animals, a promising compound typically begins three phases of clinical trials on an increasingly wide range of people, to analyze its effects on the human body and its absorption, distribution, metabolism, and excretion. Pre-clinical research on new compounds is carried out in a company’s laboratory, using a wide variety of techniques. Promising compounds are then studied in animals to investigate effects that cannot currently be predicted from the computer and test-tube studies.

Clinical assessments in humans are carried out following strict guidelines and are divided into four phases:

- **Phase I**: A small number of healthy volunteers are given the compound to determine mainly that the drug is safe for human use.
- **Phase II**: A small number of patients are given the medicine to assess its efficacy and safety and to ensure that there are no unacceptable side effects.
- **Phase III**: A large number of patients, usually thousands, take the medicine under supervision over a defined period of time, with the results used to establish efficacy. If the results prove satisfactory in terms of efficacy and safety, the data gathered are presented to the medicines evaluation authorities and, after review and discussion, a marketing authorization is issued. Alternatively, additional studies may be requested.
- **Phase IV or post-marketing studies**: Following the grant of marketing authorization, the newly authorized medicine is studied in large numbers of patients in hospitals and clinics to further assess its clinical effectiveness.
Safety assessment studies are initiated after the medicine has been made available for doctors to prescribe and to help identify any unforeseen side effects. These studies may involve many thousands of patients. Physicians’ databases are also used to identify medicine safety issues and to explore the potential for new or better use of medicines, once the product is available for prescription.

1.2 The context: The rising cost of drug development and R&D

The importance of RDP and protecting data submitted to a drug regulatory authority (DRA) as part of the marketing approval process is illustrated by the significant increases in cost and complexity in biopharmaceutical research and development (R&D) over the past three decades.

The costs and time required for the accumulation and compilation of the data included in a biopharmaceutical registration file have been constantly rising. In 1979, the total cost of developing and approving a new drug stood at $138 million. Almost 25 years later, in 2003, this figure was estimated to have rocketed to $802 million.¹ A more recent estimate points to the total cost of drug development being approximately $1,506 million.² Significantly, different stages of R&D do not contribute equally to the composition of total cost. For biopharmaceuticals, the clinical component is the most costly and has increased the most. For example, clinical trials from Phase I to III account for approximately two-thirds of the total cost of bringing a medicine to the market, even though they do not represent the longest period of drug development.³

In addition to cost, there is also the challenge of successfully developing new medicines and technologies, and the length of time spent on developing a drug. On average, only one to two of every 10,000 synthesized, examined, and screened compounds in basic research will successfully pass through all stages of R&D and go on to become a marketable drug. Furthermore, it takes between 10 and 15 years from the filing of a new patent to the day when a new medicine finally becomes available for patients to use.⁴

These challenges in cost and time have led to a significant increase in expenditure on R&D by the biopharmaceutical industry. Figure 1 shows the total amount of R&D expenditure in Europe in the period 1990–2011.
1.3 Regulatory data protection: What does it protect and how?

Considering the vast financial resources and extensive time needed to acquire and prepare clinical trials (CTs) data for registration, these data can be viewed as proprietary know-how belonging to biopharmaceutical companies. Under article 39.3 of the TRIPS agreement, the World Trade Organization (WTO) requires that member states protect these data from “unfair commercial use.”

RDP allows the data owner to prevent third parties, such as generic manufacturers or biosimilar companies, from relying on these data by a manufacturer of a follow-on product to obtain marketing approval for a fixed period of time, that is, for the RDP term. It is aimed at protecting and safeguarding the proprietary know-how and information included in drug marketing registration files against any type of unfair commercial use.

RDP is separate from other forms of IP rights used to protect pharmaceutical innovation such as patents. Unlike patents, the legal and economic rationale for RDP is based on the concept of trade secrets. A trade secret is defined by the World Intellectual Property Organization (WIPO) as “broadly speaking, any confidential business information which provides an enterprise a competitive edge.” WIPO further states that the “unauthorized use of such information by persons other than the holder is regarded as an unfair practice and a violation of the trade secret.” Unlike the social trade-off within a
Heading in a Different Direction?

patent system—whereby the need to provide incentives for innovation through the granting of a form of exclusivity to an innovator is balanced by ensuring full public access to the innovation—for RDP, there is a different type of trade-off. Here the trade-off is the demand that biopharmaceutical companies provide data on the safety and efficacy of a new medicine as part of their marketing authorization application in exchange for regulators treating these data as a trade secret. In contrast to other industries, the trade secrets and data generated by a biopharmaceutical innovator in the pursuit of developing a new product or technology are (prior to the product being allowed to enter a given market) required to be deposited with a governmental or regulatory body for evaluation.

Compared with the form of protection provided by patents, RDP is not as comprehensive, mainly because it does not legally prevent other companies from generating their own registration data. RDP legislation in the EU, United States, Canada, and other major jurisdictions (and in international agreements) as a rule does not apply to cases where a second applicant (whether a generic or an innovator) provides their own test data. In such cases, the originator may not prevent marketing approval for “newcomers” by invoking RDP. Rather, the marketing of the applied-for product, may be prevented only if there is a valid patent on the relevant product.

Layers of protection

By definition, the data included in the registration file of a pharmaceutical product are disclosed to the health regulatory authorities. Without these data, a drug cannot be approved for market use. This in turn means that the term “unfair commercial use” is ultimately linked to the responsibility of the relevant DRAs for protecting these data.

Generally speaking, there are two layers to the responsibility of health regulatory authorities to protect biopharmaceutical registration data against unfair commercial use: nondisclosure and nonreliance.

Nondisclosure aims to ensure that rival companies (usually generic companies) do not gain access to the registration file of the original product.

Nonreliance aims to prevent a generic substitute relying on and benefiting from an approved registration file in order to compare it to the chemical and toxic levels of the substitute, for example through bioequivalence tests. The concept of nonreliance is for a fixed term, which is the RDP term.

Generally speaking, the layer of reliance has been the basis for different interpretations and discussions as to what constitutes unfair commercial use of submitted clinical data. This has been the case in developed mature markets as well as emerging and developing countries. For example, up until the mid-2000s, Canadian biopharmaceutical regulations provided little actual protection for clinical data submitted during the market approval process. As is detailed below in the case study analysis of Canada, a 1998 court ruling found that Canada’s RDP regime’s market exclusivity did not apply in
most cases when a generic producer applied for market approval because the usual approval process of a generic drug did not include actual examination and, hence, a “direct reliance” on the innovator’s data. Instead, most cases were deemed to involve only an “indirect reliance,” that is, the regulator relied on a previously submitted application only as part of the new drug’s approval process, in which case RDP was deemed not to apply at all. In 2006, the Food and Drug Regulations were officially amended and Canada introduced stronger measures, increasing the period of protection from five years to a standardized eight years with the possibility of a six-month extension if a drug was for pediatric use. During this time period, there is also a six-year no-filing period during which generic producers cannot file a notice of compliance (NOC) application.

1.4 The growing availability of regulatory data protection

RDP is increasingly being offered in a number of emerging and middle-income countries. For instance, Russia was one of the most recent high-profile countries to commit to the introduction of a six-year RDP term as part of its accession to the WTO. The growth in the number of markets introducing an RDP framework is a reflection of the value of offering protection for submitted clinical test data and how offering RDP encourages biopharmaceutical investment and the introduction of new products. Table 1 gives an overview of countries that have pharmaceutical RDP regimes in place. The table is a mix of developed and emerging markets. It specifies the length of the provided RDP term, disclosure requirements in the relevant RDP legislation, and legislative source.

Table 1: International use of RDP

<table>
<thead>
<tr>
<th>Country</th>
<th>Length of RDP term</th>
<th>RDP Non-disclosure</th>
<th>Legislative source</th>
</tr>
</thead>
<tbody>
<tr>
<td>Australia</td>
<td>5 years</td>
<td>Yes</td>
<td>25A Data Exclusivity Provision of Therapeutic Goods Act (Cth) 1989.</td>
</tr>
<tr>
<td>Canada</td>
<td>8 years</td>
<td>Yes</td>
<td>Section C 08.004.1 Food and Drug Regulations.</td>
</tr>
<tr>
<td>Chile</td>
<td>5 years</td>
<td>Yes</td>
<td>Article 89 through 91 Law 19,039 on Industrial Property (as amended by Law 199,996).</td>
</tr>
<tr>
<td>China</td>
<td>6 years</td>
<td>Yes</td>
<td>Article 35 Regulations for Implementation of Drug Administration Law of the People’s Republic of China (Decree of the State Council No. 360).</td>
</tr>
<tr>
<td>Colombia</td>
<td>5 years</td>
<td>Yes</td>
<td>Article 1 through 5 Data Protection Decree No. 2085 - September 19, 2002.</td>
</tr>
<tr>
<td>Egypt</td>
<td>5 years</td>
<td>Yes</td>
<td>Article 55 through 62 Intellectual Property Law No. 82 (2002).</td>
</tr>
<tr>
<td>EU (current policy)</td>
<td>10 years</td>
<td>Yes</td>
<td>Directive 2001/83/EC.</td>
</tr>
<tr>
<td>EU (EMA proposed policy)</td>
<td>Unchanged</td>
<td>No</td>
<td>For EMA policies see: Publication and access to clinical-trial data.</td>
</tr>
</tbody>
</table>
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<table>
<thead>
<tr>
<th>Country</th>
<th>Duration</th>
<th>Exempt</th>
<th>Legal Basis</th>
</tr>
</thead>
<tbody>
<tr>
<td>Honduras</td>
<td>5 years</td>
<td>Yes</td>
<td>Article 19 through 24 Decree No. 16-2006, Law on Application of Free Trade Treaty between the Dominican Republic, Central America and the United States.</td>
</tr>
<tr>
<td>Japan</td>
<td>8 years</td>
<td>Yes</td>
<td>Article 14-4 Medical Devices.</td>
</tr>
<tr>
<td>Jordan</td>
<td>5 years</td>
<td>Yes</td>
<td>Article 8 Trade Secrets and Unfair Competition Law, No. 15 (2000).</td>
</tr>
<tr>
<td>Malaysia</td>
<td>5 years</td>
<td>Yes</td>
<td>Regulation of the Control of Drugs and Cosmetics Regulations 1984.</td>
</tr>
<tr>
<td>Mexico</td>
<td>5 years</td>
<td>Yes</td>
<td>Article 86bis Industrial Property law (as amended).</td>
</tr>
<tr>
<td>Morocco</td>
<td>5 years</td>
<td>Yes</td>
<td>Article 15.10 Measures Related to Certain Regulated Products.</td>
</tr>
<tr>
<td>New Zealand</td>
<td>5 years</td>
<td>Yes</td>
<td>23B and 23C Medicines Act 1981 No.118.</td>
</tr>
<tr>
<td>Oman</td>
<td>5 years</td>
<td>Yes</td>
<td>Article 34 Sultanic Decree No. 38/2000, The Law of Trademarks, Trade Data, Undisclosed Trade Information and Protection from Unfair Competition.</td>
</tr>
<tr>
<td>Peru</td>
<td>5 years</td>
<td>Yes</td>
<td>Legislative Decree 1072 (Protection of Undisclosed Test Data or Other Undisclosed Data Related to Pharmaceutical Products).</td>
</tr>
<tr>
<td>Russia</td>
<td>6 years</td>
<td>Yes</td>
<td>Part 6, Article 18 of Federal Law No. 61-FZ On Circulation of Drugs.</td>
</tr>
<tr>
<td>Singapore</td>
<td>5 years</td>
<td>Yes</td>
<td>Chapter 176 Medicines Act.</td>
</tr>
<tr>
<td>Switzerland</td>
<td>10 years</td>
<td>Yes</td>
<td>Section 3, Article 17 Decree on Medications</td>
</tr>
<tr>
<td>Taiwan</td>
<td>5 years</td>
<td>Yes</td>
<td>Article 40-1 and 40-2 Pharmaceutical Affairs Law.</td>
</tr>
<tr>
<td>Ukraine</td>
<td>5 years</td>
<td>Yes</td>
<td>The Law of Ukraine- On Amending Article 9 of the Law of Ukraine &quot;On Medicines.&quot;</td>
</tr>
<tr>
<td>United States</td>
<td>5 or 12 years</td>
<td>Yes</td>
<td>Federal Food, Drug, and Cosmetic Act, Section 505 [21 U.S.C. 355] (c) and (3)(F), Public Health Service Act, Section 351 (42 U.S.C. 262).</td>
</tr>
<tr>
<td>Vietnam</td>
<td>5 years</td>
<td>Yes</td>
<td>Article 128 Intellectual Property Law.</td>
</tr>
</tbody>
</table>

As suggested in the preceding subsection, the discussion as to what constitutes reliance and the interaction between RDP and the approval of generic applications is still a matter of debate in many emerging and developing country markets. In these countries, the RDP environment is still guided by a triangle of actors: regulator, innovator, and generic. And it is within this context that debates over the extent and coverage of RDP are had.

In contrast, the debate in developed countries has evolved and now encompasses the public interest in reviewing and accessing submitted data and information as part of the market authorization process. The transparency of this material (by both regulators and companies) is a topic of intense policy and legal debate.
Section 2 will, through case study analysis of four developed markets, examine current international practices as they relate to RDP, the protection of submitted regulatory test data, and regulatory disclosure and transparency initiatives.
Section 2: A Break from the Past? EMA’s New Policies and Existing EU and International Practices

RDP regimes have been in place in many developed economies for a number of years. The EU’s current regime has been in place since 2003 and RDP was introduced in the United States in 1984. As Table 1 illustrated, a growing number of middle income and emerging markets have also introduced pharmaceutical RDP regimes. And RDP has also been enshrined in numerous international treaties and agreements such as TRIPS, NAFTA, and bilateral treaties.

The purpose of this section is to describe current international practices as they relate to RDP, the protection of submitted regulatory test data, and the disclosure of this information. Case study analysis is provided of the RDP regimes and the disclosure policies in place in four major markets: the EU (including an analysis of the new EMA policy), United States, Canada, and Australia.

2.1 Existing practices in the EU

RDP legislation in the EU is provided by Article 10 of Directive 2004/27/EC (amending 2001/83/EC). This Directive was finalized in December 2003 and came into effect in May 2004. Prior to 2003–04, RDP was provided through Directive 2001/83/EC but legislation was not harmonized between EU members, and the term of protection varied between 6 and 10 years. The 2004 amendments harmonized the term of protection according to the 8+2+1 formula. According to this formula new pharmaceutical products are entitled to eight years of data exclusivity, two years of marketing exclusivity (in which generic companies would be allowed to submit bio-equivalence tests), and an additional year of protection for new indications of existing products. This is explained in article 10 of Directive 2001/83/EC. This means that the only clinical trial data a generic company needs to submit in its application for market authorization are from bio-equivalence studies. In other words, a generic company is able to rely on the information generated by the innovator instead of producing its own clinical data. However, the 8+2+1 formula for RDP created by the EU does not allow generic companies to apply this pathway until eight years have passed from the initial authorization of the reference product. This period of protection is also provided to biologics.

The EU also provides a separate exclusivity period for orphan drugs. This period is determined based on the product’s characteristics and commercial viability and ranges from 6 to 12 years. There is an
additional period of two years of exclusivity available (10+2) for orphan medicines developed for pediatric use through Regulation (EC) No. 1901/2006 (Paediatric Regulation).12

Nondisclosure

Regarding the nondisclosure of test data to the public, up until the recent changes in the EMA’s disclosure policies (which emanated from a 2007 request for public access to documents submitted as part of a marketing authorization application), the nondisclosure element of the EU’s RDP regime was clear and undisputed. Guided by Regulation 1049 of 2001 (regarding public access to European Parliament, Council, and Commission documents), the EMA did not release to the public documents contained in or as part of a marketing authorization application, because these were judged as being of a confidential nature.13 This changed in 2010 when the EMA shifted its position following a ruling by the European Ombudsman and began actively developing new policies and guidelines, culminating in the publication of the 2013 draft policy discussed separately below. Yet crucially neither the legal nor the regulatory framework changed during the time period. As stated in the April 2013 European Court of Justice (ECJ) orders suspending the EMA’s release of clinical trials data in AbbVie, Inc., AbbVie Ltd v European Medicines Agency and InterMune UK Ltd, InterMune, Inc. and InterMune International AG v European Medicines Agency, this change in EMA policy has not been the result of a change in rules and laws or a judicial ruling. Instead, this change in the agency’s position has been guided solely by a change of the EMA’s interpretation of those relevant rules and laws:

before the EMA amended its policy on disclosure of clinical study reports, the EMA itself classified those reports as confidential and refused to disclose them to third parties under Regulation No 1049/2001. Moreover, although the EMA has stated that the contested decision is based on its new policy on access to documents, it should be noted that the lawfulness of that policy, which has been in place since 2010, has not yet been ruled on by the European Union courts. Furthermore, the EMA expressly recognises that, in the present case, it is the first time since its new policy was implemented that an MA holder has requested the suspension of operation of a decision to disclose such reports under Regulation No 1049/2001.[Emphasis added]14

This is a significant point because it raises fundamental questions over the legal and statutory basis for the EMA’s shift in policy. At the very least this policy change constitutes a clear and direct break from past practices. Furthermore, in a broader context not only is this shift in the agency’s position a clear break from past EMA policies, but as discussed below it also contrasts starkly with existing international practices.

EMA’s proposed policy

First published in June 2013, the draft policy “Publication and Access to Clinical-Trial Data,” was the sum of work that had begun within the EMA in 2012.15 Following a consultation process and submission of comments, the draft guidelines are set to be implemented in the first half of 2014.
The stated objective of the draft policy is to increase access to data and scrutiny of EMA decisions without compromising personal privacy or long-term incentives for biopharmaceutical R&D. Two main principles guide the policy.

The first principle is that increased transparency will lead to greater efficiencies in drug development and medical research. The agency states that:

Access to CT data in an analysable format will benefit public health in [the] future. It will make drug development more efficient by establishing a level playing field that allows all drug developers to learn from past successes and failures, and it will enable the wider scientific community to make use of detailed and high-quality CT data to develop new knowledge in the interest of public health.

Second, the EMA states that greater transparency will bring the agency and its regulatory powers closer to patients: “The Agency also takes the view that a high degree of transparency will take regulatory decision-making one step closer to EU citizens and patients, and promote better-informed use of medicines.”

The policy includes a significant, if at times contradictory, discussion about clinical data submitted by applicants and commercially confidential information (CCI). Regarding the protection of CCI, the draft policy states that “The Agency respects and will not divulge commercially confidential data or information. In general, however, CT data cannot be considered CCI; the interests of public health outweigh considerations of CCI.” [Emphasis added].

Similarly, in describing the categories to be used for publication, the policy states that “if a document is deemed to contain CCI, it will not be made available under the policy.” However, the policy in the preceding paragraph implies that only a small number of clinical trials data and documents “can contain CCI … [and] this information will only be deemed CCI in duly justified cases.”

Yet despite its narrow interpretation of the meaning of CCI, the proposed framework also seeks to ensure future investment in biopharmaceutical research and development:

A sustained and high level of bio-pharmaceutical research activity is a precondition for future improvements in public health. The policy has no intentions to negatively impact on the incentives to invest in future bio-pharmaceutical R&D; it is designed to guard against unintended consequences, e.g. breaches of intellectual property rights that might disincentivise future investment in R&D.

In this context, the draft policy aims to continue to safeguard protected know-how in as much as it is important for incentivizing investment in biopharmaceutical R&D. Specifically, the document states that disclosure will not be allowed “where [it] may undermine the legitimate economic interest of the owner of the information,” including with regards to trade secrets and commercial confidences.
Yet as described for the categories of publication, CCI would comprise only very specific elements of the studies, mainly details about the product itself, that is, bioanalytical characterizations, in vitro tests, and other studies that do not involve patients.24

Apart from data designated as commercially confidential, as long as a document does not contain personal patient information (i.e., it only covers aggregate data) the EMA will consider that the document is acceptable to be “open access.” Individual data sets or related “raw” data25 will not be made available unless personal details are removed (or patients are “de-identified”) and only to registered parties who agree to specific terms related to appropriate use.

Having provided an overview of the existing practices in the EU and the EMA’s proposed policy, this paper now moves to an analysis comparing what the EMA is proposing with the regulatory practices that have prevailed in three key markets, as well as current transparency initiatives in those markets.

2.2 Existing practices in the United States

RDP legislation in the United States is provided by section 505 [21 U.S.C. 355] (c) of the Federal Food, Drug, and Cosmetic Act. This legislation states that:

If an application submitted under subsection (b) [ANDA] of this section for a drug, no active ingredient (including any ester or salt of the active ingredient) of which has been approved in any other application under subsection (b) of this section, is approved after September 24, 1984, no application may be submitted under this subsection which refers to the drug for which the subsection (b) application was submitted before the expiration of five years from the date of the approval of the application under subsection (b) of this section.26

Through this law, the United States model provides a five-year period of exclusivity—that is, five years will elapse between the approval of the original drug and the approval of a generic version that is based on the abbreviated new drug application (ANDA) procedure. The U.S. RDP regime provides for five years until an ANDA can be submitted (four years if it includes a patent challenge). In addition, the U.S. model also grants three years of exclusivity until an ANDA can be submitted, to new indications of existing drugs involving new clinical trials and investigations. A period of six months additional add-on pediatric exclusivity is also available under section 505A.

The United States has a separate and distinct term of protection for biologics. The Biologics Price Competition and Innovation Act of 2009 provides 12 years of data protection to biologics (i.e., 12 years until a biosimilar can be approved), with no filing of biosimilar applications for the first 4 years and an extra 6 months (added to both the 4 years and the 12 years) for submission of studies on pediatric use.27
As in the EU, the United States also provides a separate market exclusivity term to incentivize research into orphan drugs. The term used is that of seven years.\(^{28}\) An additional period of six months add-on pediatric exclusivity is also available.

**Nondisclosure**

The transparency and public disclosure of pharmaceutical test data and clinical trials information have also been addressed in the United States. Since 2007, biopharmaceutical innovators are obliged by section 801 of the Food and Drug Administration Amendments Act to register an increasing number of clinical trials and submit results information to the ClinicalTrials.gov website, an online resource maintained by the National Institutes of Health (NIH). The FDA has also launched separate policies in this area to further transparency more generally as well as specifically regarding clinical trials.

For example, as part of its wider “Transparency Initiative” the FDA has raised the issue of disclosure of anonymized test and clinical data submitted to the agency. Launched in 2009, this initiative included the creation of a task force that examined public perceptions of the FDA; the agency’s policies on public disclosure of information; and its relationship with regulated parties.\(^ {29}\) The review of existing public disclosure policies included an examination of disclosure policies in relation to both investigational clinical trials data and safety and effectiveness data submitted as part of a marketing authorization application.\(^ {30}\) As part of this review, the FDA published 21 draft policy proposals. These draft proposals included specific proposals on the release of both summary and non-summary safety and effectiveness test data submitted during a marketing authorization application. The relevant draft proposals are numbers 16 and 17. Together they provide a picture of how the FDA viewed disclosure and transparency policies.

Proposal 16 relates to the public disclosure of summary safety and effectiveness data. It reads:

> FDA should disclose relevant summary safety and effectiveness information from an investigational application, or from a pending marketing application, if the Agency concludes that disclosure is in the interest of the public health, which includes when FDA believes it is necessary to correct misleading information about the product that is the subject of the application.[Emphasis added]\(^ {31}\)

From this it is clear that in the FDA’s view, only summary, and not full, information should be disclosed. Although it is not equally clear under what specific circumstances the agency would make such disclosures (“in the interest of the public health” is not defined) the suggestion is that this would happen only under specific circumstances such as when there is “misleading information” about a product in the public domain.

In contrast to proposal 16, proposal 17 relates to “non-summary” disclosures. It reads:
FDA should convene a group of internal and external stakeholders to discuss the possible uses of non-summary safety and effectiveness data from product applications, the circumstances under which it would be appropriate for sponsors to disclose non-summary safety and effectiveness data from applications submitted to FDA, and if appropriate, the format and the method by which disclosure should occur. Unlike proposal 16, this proposal does not put forward an action point or new disclosure policy by the FDA. Instead, the proposal calls for further discussion with internal and external stakeholders. In the accompanying section stating the rationale and reasoning for this position, the FDA argues that, unlike the disclosure of summary information, a different balance must be struck regarding the potential disclosure of non-summary data. The agency states that:

A different balance may be struck with respect to the disclosure of non-summary safety and effectiveness information. A blanket policy against disclosure of this type of information may not be justified because there are significant public health benefits associated with the disclosure of this information, including reducing the costs and increasing the efficiency of research. But given the nature of the information, other factors may weigh more strongly here. For example, the timing of any disclosure, the potential uses for this information, the means by which disclosure would occur, and the impact disclosure may have on innovation, may lead to a different balance. [Emphasis added] From these draft proposals it is apparent that the FDA clearly distinguished between the public release of summary versus non-summary data, taking a cautious and piecemeal approach to the latter. However, in follow-on announcements and policy initiatives, the FDA’s position is less clear. In the most recent consultation (“Availability of Masked and Deidentified Non-Summary Safety and Efficacy Data”) from June and October 2013, the question is not whether or not the public disclosure of non-summary data is desirable, but rather the most effective manner in which it should be carried out and whether or not regulatory changes are required for the FDA to carry this out. Nevertheless, even in this most recent public pronouncement, the FDA’s objective appears to be limited to the potential publication of aggregated and anonymized data for the purposes of clinical meta-analysis. Moreover, these transparency policies are still being discussed and far from being finalized or implemented.

2.3 Existing practices in Canada

RDP in Canada is provided by C.08.004.1 of the Canada Food and Drug Regulations. These regulations state:

If a manufacturer seeks a notice of compliance for a new drug on the basis of a direct or indirect comparison between the new drug and an innovative drug, the manufacturer may not file a new drug submission, a supplement to a new drug submission, an abbreviated new drug submission or a supplement to an abbreviated new drug submission in respect of the new drug
before the end of a period of six years after the day on which the first notice of compliance was issued to the innovator in respect of the innovative drug; and (b) the Minister shall not approve that submission or supplement and shall not issue a notice of compliance in respect of the new drug before the end of a period of eight years after the day on which the first notice of compliance was issued to the innovator in respect of the innovative drug.\(^{36}\)

Up until the late 2000s, Canadian regulators had in place a relatively limited RDP model, providing little in the way of concrete protection for clinical data submitted in the market approval process. The then Food and Drugs Act, which defined periods and types of exclusivity, stated that if in the event the Minister of Health, who is responsible for the market approval of drugs, in the course of approving a generic drug made use of existing clinical data submitted by an innovator—by examining or relying on it to approve the generic—the Minister could not issue a notice of compliance to the generic applicant for a period of five years after an NOC had been issued for the original drug. This meant that innovators in effect were granted a period of five years of RDP from the date of having a drug approved for sale and obtaining an NOC. However, this regulation was neutralized by a 1998 federal court ruling in *Bayer Inc. v Canada (Attorney General)*. Here the judge ruled that the five-year period of RDP did not apply in most cases when a generic producer is applying for an NOC because the usual approval process of a generic drug did not include actual examination and, hence, a “direct reliance” on the innovator’s data. Instead, most cases were deemed to involve an “indirect reliance,” that is, the regulator only relied on a previous submitted application as part of the new drug’s approval process, in which case RDP was deemed not to apply at all.

In 2006, the Food and Drug Regulations were officially amended and Canada introduced the above-cited stronger measures, increasing the period of protection from five years to a standardized eight years with the possibility of a six-month extension if a drug was for pediatric use.\(^{37}\) During this time period, there is also a six-year no-filing period during which generic producers cannot file an NOC application. In addition, the phrasing of the new regulations effectively neutralized the Bayer ruling making reliance alone—not examination and reliance, as was the case in the old regulations—enough grounds for data protection.

**Nondisclosure**

As in the EU and United States, the transparency and public disclosure of pharmaceutical test data and clinical trials information has also been raised in Canada. Health Canada has been examining this issue since the mid-2000s with the view of increasing transparency and public access to clinical trials data and information. In 2005 and 2006, the department held a number of consultations and established an external working group to advise the agency on a course of action.\(^{38}\) Health Canada was also urged by a parliamentary report published in 2012 by the Standing Senate Committee on Social Affairs, Science, and Technology to increase clinical trials transparency through the mandatory registration of clinical trials and publication of descriptive clinical trials data.\(^{39}\)
In 2013, Health Canada launched its “Clinical Trials Database.” The database lists all trials authorized by Health Canada, and is administered by the agency. In November 2013, the agency issued a notice that data and information relating to the investigational testing of medical devices would also be publicly available on request.\(^\text{40}\)

Guided by the Access to Information Act and section 20 exemptions relating to third-party information, Health Canada does not have a wide-ranging policy of releasing clinical trials data submitted together with a market approval application. Section 20 specifically points to trade secrets and confidential information as qualifying exempt third-party information:

Subject to this section, the head of a government institution shall refuse to disclose any record requested under this Act that contains

(a) trade secrets of a third party;
(b) financial, commercial, scientific or technical information that is confidential information supplied to a government institution by a third party and is treated consistently in a confidential manner by the third party…
(c) information the disclosure of which could reasonably be expected to result in material financial loss or gain to, or could reasonably be expected to prejudice the competitive position of, a third party; or
(d) information the disclosure of which could reasonably be expected to interfere with contractual or other negotiations of a third party.\(^\text{41}\)

The most recent Health Canada annual report (2011–12) on Access to Information requests confirms that third party exemptions are the second most used grounds for refusal to disclose requested information. In the 2011–12 period, this exemption was applied 571 times.\(^\text{42}\) There have been calls for a change in policy with increased disclosure of non-summary information and clinical trials. Indeed, Health Canada has been criticized for invoking this exemption and interpreting the meaning of section 20 too narrowly.\(^\text{43}\)

### 2.4 Existing practices in Australia

RDP in Australia is guided by section 25A of the Therapeutic Goods Act 1989. This section states that market authorization authorities “must not use information about other therapeutic goods that is protected information” in the course of evaluating a drug authorization application.\(^\text{44}\) Protected information is defined and considered as protected under the following circumstances:

(a) the information was given to the Secretary in relation to an application to register therapeutic goods (the new goods):
   (i) not being therapeutic devices; and
   (ii) consisting of, or containing, an active component; and
(b) the information is about the active component and is not available to the public; and
The European Medicines Agency’s Policy on the Public Release of Clinical Trials Data • 22
Crucially, the draft policy does make exception to the release of information in cases of an “overriding public interest.” The draft policy also points to a time element and to the fact that trade secrets and commercial confidential information will need to “retain their quality of confidence.” Local Australian legal analysis suggests that what the TGA is proposing is a fundamentally different approach to the disclosure of confidential information and pharmaceutical test data than the EMA’s approach. For example, when releasing information the TGA will publish only limited amounts of data and the agency is statutorily obliged to consult with the owner of the information prior to disclosure or publication. In its description of procedures relating to the ad hoc release of information based on freedom of information requests, the TGA states that when the issue of commercially confidential information arises, “the TGA will always consult that third party under section 27 of the FOI Act where it is proposing to release the documents and will often do so even if it is not proposing to release the documents.”
Section 3: Unintended Consequences? The Global Implications of the EMA’s Policy: An Illustrative Scenario Analysis

Given the size and international heft of the EMA, any new policy adopted by the agency will generate international interest and potential duplication. The same applies to its clinical trials transparency initiative. As the following brief scenario analysis illustrates, the new transparency policies put in place by the EMA may have unintended consequences and result in placing commercially confidential information into the public domain not only in the EU but also internationally.

3.1 From commercially confidential to publicly available: The context

A number of countries and legal jurisdictions predicate the protection of information on the protected information not already being in the public domain. Generally speaking, multinational and international biopharmaceutical manufacturers obtain such protection independently in each legal jurisdiction in which they wish to operate. Manufacturers must apply for marketing authorization in each jurisdiction. As has been explained, a fundamental part of the market authorization approval process is the submission of clinical test data proving the safety and efficacy of a given product or technology. For a variety of reasons, not all markets are entered into at the same time. Consequently, a product may be launched in some markets many years after it has been approved for sale in another. Yet the product must generally still go through a similar market approval process prior to being approved.

The publication of large volumes of clinical trials and test data submitted as part of a marketing authorization application in one country or jurisdiction risks putting into the public domain a significant amount of information that may be used by applicants in other jurisdictions as part of new market authorization applications for the same product or technology. Consequently, mechanisms (such as RDP) that are contingent on the information submitted in a marketing authorization application being protected and not publicly available, may not be available to manufacturers as a result of the EMA’s disclosure of the same or similar information. The case of Australia provides a possible scenario to illustrate the potential for this to happen.
3.2 The Australian scenario

As explained above, section 25A of the Australian Therapeutic Goods Act provides protection only for information provided to the drug regulatory authorities as part of a registration application as long as it is not available to the public or in the public domain. If the relevant information is in the public domain, it is no longer considered as being of a commercial nature. Indeed, the TGA has itself stated that information that is in the public domain cannot be considered commercially confidential.

Significantly, this includes information made public by the disclosure of regulatory agencies in other countries and jurisdictions. For example, in its 2010 AusPAR guidance document, the TGA states that “Information that is already in the public domain is not considered as commercially confidential. For example, the prior publication of an evaluation outcome from an overseas regulator would be considered information already in the public domain” [Emphasis added].

Significantly, local Australian legal analysis suggests that there are scenarios whereby a market approval application for an equivalent product could be made during the exclusivity period for a registered product if the relevant protected information is in the public domain. Under such a scenario, RDP protection would not be available.

The implications of the EMA’s disclosure and transparency policy were identified as a significant challenge by the Australian authorities in their own review of the potential for the Australian authorities introducing such procedures. The 2013 draft report of the Pharmaceutical Patents Review commissioned by the Parliamentary Secretary for Innovation recognized the challenge of balancing the desirability of putting into the public domain data submitted during a market approval process with protecting commercially confidential information. The review stated that:

Unlike other forms of intellectual property where a period of exclusivity is provided in return for public disclosure, the data protected by data protection remains confidential indefinitely. This is despite the data having value to pharmaceutical researchers involved in the development of other pharmaceuticals and research directed towards a better understanding of complex medical conditions and responses to drugs. Opening these data for further research would not commercially disadvantage the sponsor, with respect to the drug registered by TGA, and could be of substantial public health benefit. It thus makes sense, in principle, that these data should be publicly available. … However, any proposal to make data publicly available should be addressed in an internationally coordinated way because a country publishing company data unilaterally would face the risk that companies would not seek regulatory approval in that country. At present, data are only eligible for data protection if they have not previously been put in the public domain. This requirement is common to many jurisdictions. If Australia alone were to make otherwise confidential data publicly available this may make such data ineligible for protection in other jurisdictions. [Emphasis added]

Significantly, this review draws attention to the scenario that is potentially unfolding with the proactive publication of clinical trials data by the EMA. As stated, given that Australian RDP
legislation protects only information that is not in the public domain, the EMA’s publication of clinical trials data puts this information in the public domain, thereby opening up the possibility that this information loses its confidential character. The result is that manufacturers who have a marketing authorization in the EU and are subsequently applying for marketing authorization for their products and technologies in Australia may not be given RDP as a result of all or portions of their submitted data to the EMA having been published by the agency as a result of its new transparency initiative.

Other countries in addition to Australia make RDP contingent on the information submitted being undisclosed or not in the public domain. For example, the Malaysian Directive of Data Exclusivity states that the “Directive is to protect the undisclosed unpublished and non-public domain pharmaceutical test data, the origination of which involves a considerable effort, submitted as required to the Director of Pharmaceutical Services for the purpose of scientific assessment…” [Emphasis added].

The EMA’s publication of clinical trials data puts this information in the public domain and raises uncertainties about whether or not the information retains its confidential or undisclosed character in countries such as Malaysia.
Section 4: Conclusion and Recommendations

The move toward greater transparency and coordination in the design and conduct of clinical trials is a worthy goal. It represents part of wider efforts to optimize the increasingly complex and costly ecosystem in which research and development in the biopharmaceutical field is carried out. Regulators, scientists, and research-based biopharmaceutical manufacturers all have an interest in increasing the availability of data and information about current and past biopharmaceutical R&D. The fundamental question is, what is the best way of achieving this goal?

The EMA proposal has laid out a path toward reaching this goal. This path takes a proactive approach to the publication of clinical test data and related information. It is based on a perception and definition of overriding public interest in this information being in the public domain. This path is a stark contrast and break from preceding EMA practices in which the release of this information did not take place. The agency’s change in policy raises fundamental questions about its views on the inherent confidentiality of the data submitted to it as part of a market authorization application as well as its role as a custodian of this information.

Although drug regulatory authorities in all the case-studied countries in this paper are considering and consulting on the issue of increasing clinical trial transparency, no country is seeking to emulate EMA’s policy in full.

As detailed above, the FDA in its “Transparency Initiative” launched in 2010 made a clear distinction between the manner and, more important, the extent to which “summary” versus “non-summary” clinical trials data would be published and placed in the public domain. While the agency’s most recent consultations are not as clear, nevertheless they still differ significantly from EMA’s.

Other countries’ proposed initiatives also consider the need to balance greater clinical trials transparency with the need to protect proprietary and confidential information. For example, the Australian drug regulatory authority (TGA), in its own transparency proposals, is not proposing to proactively publish this information. The agency is also statutorily obliged to consult with the owner of the information prior to the disclosure or publication of the information.

The EMA’s proposed policies also stand in stark contrast to those initiatives taken by the private sector and research-based biopharmaceutical manufacturers. Beginning in 2014, members of the European and American biopharmaceutical trade associations EFPIA and PhRMA have committed to increasing transparency and release of information and data relating to their clinical research. These initiatives
Heading in a Different Direction?

include enhanced data sharing with scientific researchers, making publicly available synopses of clinical study reports, as well as a renewed commitment to seek publication of all clinical research results regardless of the research outcome.

Finally, the new transparency policies put in place by the EMA may have unintended consequences and result in placing commercially confidential information into the public domain not only in the EU but also internationally. A number of countries and legal jurisdictions predicate the protection of information on the protected information not already being in the public domain. Generally speaking, multinational and international biopharmaceutical manufacturers obtain such protection independently in each legal jurisdiction in which they wish to operate. Manufacturers must apply for marketing authorization in each jurisdiction. The publication of large volumes of clinical trials and test data submitted as part of a marketing authorization application in one country or jurisdiction risks putting into the public domain a significant amount of information that may be used by applicants in other jurisdictions as part of new market authorization applications for the same product or technology. Consequently, mechanisms (such as RDP) that are contingent on the information submitted in a marketing authorization application being protected and not publicly available may not be available to manufacturers as a result of the EMA’s disclosure of the same or similar information. The case of Australia provides a scenario that illustrates the potential for this to happen.

The EMA’s initiative aspires to the goals of transparency and public access, which is both merited and valuable. At the same time, it is also important to note that at least two other components of the biopharmaceutical R&D ecosystem—maintaining the privacy and confidentiality of patient data and protecting the intellectual property rights and trade secrets generated in the clinical trial phases—are part of the puzzle, and a balance among all of these pieces must be achieved. As currently constructed and compared to past EMA practice and existing international practices, the EMA’s proposals appear to fall short of that goal.
Notes

3 Ibid.
5 EFPIA (European Federation of Pharmaceutical Industries and Associations) (2012), *The pharmaceutical industry in figures*, Brussels.
6 WTO, TRIPS agreement, Part II—Standards concerning the availability, scope and use of Intellectual Property Rights, Section 7: Protection of undisclosed information, Article 39(3).
8 Ibid.

By way of derogation from Article 8(3)(i), and without prejudice to the law relating to the protection of industrial and commercial property, the applicant shall not be required to provide the results of pre-clinical tests and of clinical trials if he can demonstrate that the medicinal product is a generic of a reference medicinal product which is or has been authorised under Article 6 for not less than eight years in a Member State or in the Community. A generic medicinal product authorised pursuant to this provision shall not be placed on the market until ten years have elapsed from the initial authorisation of the reference product. The first subparagraph shall also apply if the reference medicinal product was not authorised in the Member State in which the application for the generic medicinal product is submitted. In this case, the applicant shall indicate in the application form the name of the Member State in which the reference medicinal product is or has been authorised. At the request of the competent authority of the Member State in which the application is submitted, the competent authority of the other Member State shall transmit within a period of one month, a confirmation that the reference medicinal product is or has been authorized together with the full composition of the reference product and if necessary other relevant documentation. The ten-year period referred to in the second subparagraph shall be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorisation holder obtains an authorisation for one or more new therapeutic indications which, during the scientific evaluation prior to their authorisation, are held to bring a significant clinical benefit in comparison with existing therapies.
13 For full details of the relevant guiding regulations and interpretation see: “Order of the President of the General Court,” Case T-44/13 R, AbbVie, Inc., AbbVie Ltd v European Medicines Agency (EMA), European Court of Justice, April 25, 2013.
14 Ibid.
16 Ibid. pp.1–2.
Heading in a Different Direction?

The European Medicines Agency’s Policy on the Public Release of Clinical Trials Data

17 Ibid., p.1.
18 Ibid.
19 Ibid., p. 2. There has been some discussion and debate in the EU about what constitutes CCI, for example, in 2007 draft policy issued by the EMA, *Principles to be applied for the deletion of commercially confidential information for the disclosure of EMEA documents* (EMEA/45422/2006). It is unclear exactly how this draft policy would apply within the new proposed framework on transparency of CT data. See also: EMA, Heads of Medicines Agencies (HMA) (2010), *HMA/EMA guidance document on the identification of commercially confidential information and personal data within the structure of the marketing authorisation application – Release of information after the granting of a marketing authorisation*, http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/03/WC500124536.pdf.
20 Ibid. p. 4.
21 Ibid.
22 Ibid., p. 2.
23 Ibid., p. 3.
24 Ibid., pp. 4, 10–11.
25 “Raw data” refers to data sets and case reports on individual patients, as well as supporting material such as Statistical Analysis Software programmes and records (Ibid., p. 4).
27 In the period following passage of the legislation, there was some debate on the issue—President Obama has issued a proposal to cut the period to seven years. In response, a bipartisan group of at least 50 in Congress sent the President a letter urging him to maintain the 12-year period set out in the legislation. See: MedPage Today, 2011, “Lawmakers defend Biologics’ 12-year exclusivity,” October 18, http://www.medpagetoday.com/Washington-Watch/Washington-Watch/29108.
32 Ibid.
33 Ibid.
35 Food and Drug Regulations, C.08.004.1, Ministry of Justice, 2013.
36 Ibid., (3)(a).
37 Government of Canada, Regulations Amending the Food and Drug Regulations (Data Protection).
39 Senate Standing Committee on Social Affairs, Science and Technology (2012), *Canada’s clinical trial infrastructure: A prescription for improved access to new medicines*, pp. 23–24.
40 Senate Standing Committee on Social Affairs, Science and Technology (2012), *Canada’s clinical trial infrastructure: A prescription for improved access to new medicines*, pp. 23–24.
44 Therapeutic Goods Act 1989, s25A.
45 Ibid.
49 Ibid.
50 Ibid.
52 Ibid.
54 Ibid., subsection 2(b).
58 Ibid.