Proposal for a Regulation of the European Parliament and of the Council amending Regulation (EC) No. 469/2009 concerning the supplementary protection certificate for medicinal products

Opinion on the proposed Art.3 notification and required information

1. Executive summary

1.1 Pinsent Masons studied the impact of the proposed notification of information required by generic and biosimilar companies and the consequences it would have on the functioning of the proposed legislation.

1.2 According to Recital 12 of the proposed Regulation, the purpose of the proposed notification is to provide safeguards to help the holder of an SPC to enforce its protection in the Union against illicit diversion onto the Union market during the term of the certificate.

1.3 This opinion sets out a number of reasons why generic and biosimilar companies should not be expected to disclose to a relevant authority to publish on a publicly accessible register and/or to the SPC holder the information listed below, which has long been recognised as being commercially sensitive and confidential.

1.3.1 **Art.3(a) – The name and the address of the maker:** Disclosure of this information will undermine the HMA and EMA guidance referred to below and provides advanced notice to competitors of commercial intentions and could lead to blocking/searching of manufacturing sites on the basis of assumptions, causing delays to manufacture.

1.3.2 **Art.3(b) - The address, or addresses, of the premises where the making is to take place in the relevant Member State**: Both the HMA and EMA recognise that manufacturing sites are commercially confidential information. The disclosure of such information could lead to blocking/searching of manufacturing sites on the basis of assumptions, causing delays to manufacture and potentially impacting manufacturing jobs if those sites become difficult to use.

1.3.3 **Art.3(d) - The number of the authorisation granted in accordance with Article 40(1) of Directive 2001/83/EC or Article 44(1) of Directive 2001/82/EC for the manufacture of the corresponding medicinal product or, in the absence of such authorisation, a valid certificate of good manufacturing practice as referred to in Article 111(5) of Directive 2001/83/EC or Article 80(5) of Directive 2001/82/EC covering the premises where the making is to take place:** Both the HMA and EMA recognise that manufacturers of (a) the medicinal products and (b) the active substances and the sites of manufacture are commercially confidential information. The disclosure of either authorisation numbers granted in accordance with Article 40(1) of Directive 2001/83/EC or Article 44(1) of Directive 2001/82/EC for the manufacture of the corresponding medicinal product, or certificates of good manufacturing practice, will necessarily relate to specific manufacturing sites and will identify the manufacturer. This will undermine the HMA and EMA guidance. The points raised above with regard to Art.3(a) and (b) apply equally here.

1.3.4 **Art.3(e) - The intended start date of making in the relevant Member State:** A pharmaceutical company (innovator or generic) would never be required to disclose to any of its competitors this information as it provides advance notice of commercial intentions and could be used to obtain a commercial advantage and/or cause harm to the concerned pharmaceutical company, leading to a distortion of the competition between the company disclosing this information and its competitors.

1.3.5 **Art.3(f) - An indicative list of the intended third country or third countries to which the product is to be exported:** Similarly this information is part of a

business plan and therefore confidential and sensitive and would never be disclosed by any pharmaceutical company as it will lead to a distortion of competition. The fact marketing authorisations have been obtained in third countries (of which the innovator is likely to be aware) would be adequate indication that a pharmaceutical company may export to / sell there and then it is up the innovator to monitor the market in these countries.

1.4 The disclosure of the above mentioned commercially confidential information to the SPC holder and/or other competitors would act against the disclosing company's interests as there are a number of ways that this information (considered as being part of a business plan) could be misused, undermining the strategic positions or ability to compete. Indeed the information could be misused leading to damage the company would suffer as a result of the information being known to competitors.

1.5 The proposed notification of the required information would strongly question and limit the intended usage of the manufacturing waiver and therefore act against the spirit of the proposed legislation.

1.6 There are numerous exemptions to patent/SPC infringement, such as the so-called “Bolar exemption”, which can be relied on as defences where appropriate – and for which there is no requirement for prior notification of confidential commercially sensitive information to a competitor. This shows that the notification is not needed.

1.7 Canada has recently adopted a comparable export waiver and has implemented it without requirements for notification.

1.8 It is strongly questionable that a notification is required. If a notification was nevertheless to be adopted, it should be noted that the information currently requested in the proposed notification is clearly not consistent with and goes beyond the need for safeguards as set out in Recital 12 of the proposed Regulation, namely to help the holder of an SPC to enforce its SPC in the Union against illicit diversion onto the Union market during the term of the SPC.

1.9 It is also questionable that the “*the person doing the making*” (Article 2(b)) should necessarily be the person providing the notification, given that this would require disclosing the name and address of the maker, and would therefore raise the same issues as Article 3(a), 3(b) and 3(d).

1.10 In the hypothetical case of illicit divergence, the SPC holder still has the right to object and, if appropriate, to seek injunctive relief if product manufactured under the waiver is diverted and sold in another SPC protected country leading to commercial harm to the SPC holder.

1.11 Directive 2004/48/ of 29 April 2004 on the enforcement of intellectual property rights and its national implementations already provide for the appropriate reliefs and evidence means in that respect. In third countries, national marketing authorisations obtained by generic or biosimilar companies, of which the innovator should be aware, is an adequate indication that a company may export to / sell there. It is then up to the innovator to monitor the market in said third country and, if appropriate, it can make use of reliefs available under national law in those countries.

1.12 Finally regarding the potential risk of diversion, the Falsified Medicines Directive offers the possibility to track medicines present within the EU and provide the necessary tool to address the objective of Recital 12.

2. Background

2.1 In February 2017 the Commission published its Inception Impact Assessment Optimising the Internal Market's industrial property legal framework relating to SPCs and patent protection research exemptions for sectors whose products are subject to regulated market authorisations.

2.2 On 5 October 2017 the Commission published the study *'Assessing the economic impacts of changing exemption provisions during patent and SPC protection in Europe'* conducted by Charles River Associates. This report showed that an SPC manufacturing waiver could:

- create 20,000-25,000 additional manufacturing jobs in Europe by 2025;
- increase the net sales for the EU based pharmaceutical industry by €7.3 to €9.5 billion by 2025;
- ensure faster entry of generic and biosimilar competition in the EU after SPC expiry - thus improving access for patients;
- enable savings in pharmaceutical expenditures of €1.6 to €3.1 billion thanks to competition; and
- generate, together with a broader Bolar exemption, additional EU active pharmaceutical ingredient sales of €211.8 to €254.3 million by 2030, creating an additional 2000 jobs in the sector.

2.3 A public consultation followed between 12 October 2017 and 4 January 2018.

2.4 On 28 May 2018 the Commission published its proposal for a Regulation to amend Regulation (EC) No. 469/2009 concerning the supplementary protection certificate for medicinal products (the "SPC Regulation") together with an impact assessment. The Proposal states that the preferred option is to introduce a targeted and narrow exception from the SPC Regulation:

- it introduces an exception, to enable manufacturers of generics and biosimilars to manufacture such medicines for the purpose of exporting them outside the EU during the SPC protection term;
- it is accompanied by important 'anti-diversion' safeguards, notably a requirement to notify, ex ante, such manufacturing to independent national public bodies (which will hold the relevant information in a publicly accessible register) along with labelling requirements for products that are exported and due diligence requirements on the manufacturer vis-a-vis persons in its supply chain; and
- the exception will apply only to SPCs that have not yet been granted and only after a transitional period to accommodate pending applications.

2.5 In light of this preferred option, proposed wording is provided by the Commission to amend the SPC Regulation in order to incorporate the manufacturing waiver for export. The following provisions are relevant to this opinion:

2. The certificate referred to in paragraph 1 shall not confer protection against a particular act against which the basic patent conferred protection if, with respect to that particular act, the following conditions are met:

(a) the act comprises:

(i) making for the exclusive purpose of export to third countries; or

(ii) any related act that is strictly necessary for that making or for the actual export itself;

(b) the authority referred to in Article 9(1) of the Member State where that making is to take place ('the relevant Member State') is notified by the person doing the making ('the maker') of the information listed in paragraph 3 no later than 28 days before the intended start date of making in that Member State;

…

3. The information for the purposes of paragraph 2(b) shall be as follows:

(a) the name and address of the maker;

(b) the address, or addresses, of the premises where the making is to take place in the relevant Member State;

(c) the number of the certificate granted in the relevant Member State, and identification of the product, by reference to the proprietary name used by the holder of that certificate;

(d) the number of the authorisation granted in accordance with Article 40(1) of Directive 2001/83/EC or Article 44(1) of Directive 2001/82/EC for the manufacture of the corresponding medicinal product or, in the absence of such authorisation, a valid certificate of good manufacturing practice as referred to in Article 111(5) of Directive 2001/83/EC or Article 80(5) of Directive 2001/82/EC covering the premises where the making is to take place;

(e) the intended start date of making in the relevant Member State;

(f) an indicative list of the intended third country or third countries to which the product is to be exported.

3. Opinion

3.1 The legal opinion is provided in relation to five aspects of the notification of information under Article 3 which, in order for a company to rely on the manufacturing waiver, would require the disclosure of commercially sensitive information to not only the SPC holder but also to independent national regulatory bodies to hold on a publicly accessible register.

3.2 These are:

(a) the name and address of the maker;

(b) the address, or addresses, of the premises where the making is to take place in the relevant Member State;

(d) the number of the authorisation granted in accordance with Article 40(1) of Directive 2001/83/EC or Article 44(1) of Directive 2001/82/EC for the manufacture of the corresponding medicinal product or, in the absence of such authorisation, a valid certificate of good manufacturing practice as referred to in Article 111(5) of Directive 2001/83/EC or Article 80(5) of Directive 2001/82/EC covering the premises where the making is to take place;

(e) the intended start date of making in the relevant Member State; and

(f) an indicative list of the intended third country or third countries to which the product is to be exported.

3.3 The above information might collectively be considered to be part of business plans and strategies, the disclosure of which would harm the competitiveness of companies seeking to make use of the manufacturing waiver, making it ineffective.

3.4 The issue is protecting the commercial value of the information prior to that happening, i.e. by avoiding giving advance notice of commercial plans. At present, companies never have to publicly divulge the above information in advance of launching their products. The requirement to do so would have a significant dissuasive effect regarding the use of the

manufacturing waiver and the possible commercial harm caused by doing so may prohibit a company's ability to make use of it at all.

3.5 Whilst some of the same considerations discussed below apply to more than one of the above pieces of information and collectively they may be more commercially valuable than each item being disclosed separately, it is useful to consider each of them individually too because the reasons why they are commercially sensitive may differ.

4. Protection of secrets

4.1 This information is secret in the sense that it is guarded from competitors.

Trade Secrets

4.2 Directive (EU) 2016/943 of the European Parliament and of the Council of 8 June 2016 on the protection of undisclosed know-how and business information (trade secrets) against their unlawful acquisition, use and disclosure (**"The Trade Secrets Directive"**) harmonises and formalises the protection of trade secrets across the EU. It came into force on 9 June 2018. It states that:

*'**trade secret'** means information which meets **all** of the following requirements:*

(a) it is secret in the sense that it is not, as a body or in the precise configuration and assembly of its components, generally known among or readily accessible to persons within the circles that normally deal with the kind of information in question;

(b) it has commercial value because it is secret; and

(c) it has been subject to reasonable steps under the circumstances, by the person lawfully in control of the information, to keep it secret.

4.3 This Directive introduces a unified definition of a trade secret which reflects the definition set out in TRIPS and other national legislation (e.g. the US Defend Trade Secrets Act 2016), reflecting a global move towards greater recognition and protection of trade secrets. In its recitals the Trade Secrets Directive states:

(2) "*Businesses, irrespective of their size, value trade secrets as much as patents and other forms of intellectual property right. They use confidentiality as a business competitiveness and research innovation management tool, and in relation to a diverse range of information that extends beyond technological knowledge to commercial data such as information on customers and suppliers, business plans, and market research and strategies…By protecting such a wide range of know-how and business information, whether as a complement or as an alternative to intellectual property rights, trade secrets allow creators and innovators to derive profit from their creation or innovation …"* (emphasis added).

4.4 Here, confidential information is placed on the same level as other, protectable/registerable IP rights and, in the context of this Directive, is intended to include 'soft' trade secrets like business plans and commercial strategy. Further and perhaps more relevantly, the Recitals state at (3) that the unlawful acquisition of trade secrets "*compromises legitimate trade secrets holders' ability to obtain first-mover returns from their innovation-related efforts*" (emphasis added). The information required under the manufacturing waiver notification process would certainly hinder a company's ability to leverage the element of surprise and would*, inter alia,* permit competitors to make vexatious claims in order to cause delays to market entry (see further below).

4.5 Trade secrets are very diverse and if companies did not have secrets it would be harder for them to exist and benefit from their particular strategies and commercial philosophy; being key to their competitiveness.

4.6 As reflected in the definition outlined above, to be protected by the Trade Secrets Directive it is necessary to have a direct nexus between the secrecy of the information and its commercial value. In order to assess the commercial value of these pieces of information individually, or collectively as part of a business plan or strategy, it is necessary to consider the potential for use of the information by an unauthorised or non-entitled recipient (i.e. misuse or unlawful use) or an unrelated third party obtaining access to it on a public register. It is clear that other companies having knowledge of the information could act upon it to their own commercial advantage and to the detriment of the company to whom the information relates. Hence there is undoubtedly commercial value attached to this information, but the actual value will differ for each product.

4.7 In considering whether information meets the requirements outlined in the Directive and therefore qualifies for protection as a trade secret, it will be necessary to consider for example:

- the secrecy of the information (that is the degree to which the information is known within the business and/or externally (presumably not the latter));
- the commercial value of the information;
- the resources required to develop the information and the ease with which third parties could legitimately replicate or obtain the information.
- the degree to which the commercial value is derived from the secrecy of the information (that is the "direct nexus" referred to above); and
- the practical measures taken by the lawful owner of the information to keep the information secret (that is, evaluating whether 'reasonable steps' have been taken to protect the secrecy of the information). This typically includes an evaluation of whether documents are marked as confidential, the restrictions upon access, how the information is used (e.g. if it is licensed, the scope of the licence), the security and sophistication of the physical and digital repositories etc.

4.8 The Recitals of the Directive suggest that the definition as drafted should be construed broadly such that it covers business information in which there is a legitimate interest in preserving confidentiality and where disclosure would harm the interests of the person controlling it such that it "*undermines that person's…strategic positions or ability to compete*".

4.9 We have set out below ways in which the information could be misused leading to damage the company would suffer as a result of the information being known to competitors.

4.10 Once disclosed under the proposal for notification, a company would no longer be able to treat the information as a trade secret, even though it is commercially sensitive and the company could be harmed by the information being released, because it will no longer be confidential.

5. Commercially Confidential Information - Marketing Authorisation Applications

5.1 Notification in the context of the proposed manufacturing waiver is not for the purposes of the regulators use but is to be put into the public domain. As a result, secret information about business plans will lose its status as a trade secret and/or confidentiality and it will not be possible to recover any compensation for the harm caused as a result of that disclosure to the public.

5.2 In some instances it is required to disclose secret / commercially confidential information to regulators and companies do so because it is necessary and proportionate, for example in the context of applying for a marketing authorisation. However, there is clear guidance (see below) that information which is commercially confidential will be treated as such by the

regulator and will not be disclosed to others, for example as a result of Freedom of Information Act requests. There is no such provision in the current proposal.

6. **Application of the above considerations to the information to be provided**

Article 3(a) The name and the address of the maker;

6.1 The maker is defined in Article 2(b) as *"the person doing the making"*. Disclosure of the name and address of the person(s) doing the making would amount to disclosure of information in relation the country(ies) of manufacture and the manufacturing sites and as such would raise the same issues as those described below in relation to Article 3(b), e.g. it would undermine the HMA and EMA guidance, provide advanced notice to competitors of commercial intentions and could lead to blocking/searching of manufacturing sites on the basis of assumptions, causing delays to manufacture.

Article 3(b) The address, or addresses, of the premises where the making is to take place in the relevant Member State;

Considered Commercially Confidential Information by HMA/EMA

6.2 The *"HMA/EMA Guidance Document on the identification of commercially confidential information and personal data within the structure of the marketing authorisation (MA) application - release of information after the granting of a marketing authorization"* – states clearly that the manufacturers of (a) the medicinal products and (b) the active substances and the sites of manufacture (see the tables in the document, in particular 2.5.2 and 2.5.3 – in accordance with principles 3.1.3 and 3.4) are "Commercially Confidential Information" ("**CCI**") as is a "Flow-chart indicating all manufacturing and control sites involved in the manufacturing process of the medicinal product and the active substance". Anything else which contains "names of sites" is also deemed CCI. As a main rule, this information cannot be released (and would be redacted).

6.3 "Commercially Confidential Information" means *"any information which is not in the public domain or publicly available and where disclosure may undermine the economic interest or competitive position of the owner of the information"* (emphasis added) (see 1. on page 2/40) Reference is made to *"HMA/EMA Recommendations on transparency approved in November 2010 – Recommendations on release of information with regard to new applications for medicinal products before and after opinion or decision on granting of a marketing authorisation (EMA/484118/2010)"*.

6.4 The document was prepared in November 2010 by the HMA and EMA agreeing to lay down a common approach on what should be considered as commercially confidential. The objective was to facilitate a common and consistent approach across the EEA when dealing with requests for access to documents. The guidance document is intended to be a consensus document agreed by the whole Network of National Competent Authorities of the EEA for the release of information regarding medicinal products for human use. It is clear in light of this guidance that the address, or addresses, of the premises where the making is to take place in the relevant Member State would not be disclosed by regulatory bodies across the EEA. Such information is commercially confidential.

6.5 It appears that the basis for this is that the validation of the manufacturing process in accordance with Good Manufacturing Practice is itself confidential. Validation must cover all manufacturing sites used for production of the marketed product. This could include different entities and would disclose commercially sensitive information as to commercial relationships and how companies set up their manufacturing and supply chains.

Trade secret (as a component of a business plan)

6.6 By disclosing the addresses of manufacturing sites prior to product being sold, there are a number of ways in which this information could be misused by the SPC holder and/or other competitors. Assuming it has been publicly accessed (i.e. through the contemplated public

register) and the regulator does not attempt to impose conditions on access to the register, there is no restriction on what an SPC holder (or another competitor) can do once in receipt of the information. It could for example engage in litigation strategies designed to prevent manufacture from taking place in relation to the product in question and/or future products generally or of a similar type. This would firstly cause delays in availability of medicines and access to patients, and would also be to the commercial disadvantage of the company providing the information and it would be likely to suffer financial losses as a result, such as the loss of first mover advantage and, in countries where they are available, inappropriate and disruptive seizures of evidence (e.g. *saisie-contrefaçon* in France*)*.

6.7 This information will be used for purposes going beyond the actual purpose of the notification as set out in Recital 12:

6.7.1 It will inform the SPC holder where to seek an interim injunction to temporarily shut down production of the product in question. In some countries an interim injunction can be sought on an *ex parte* basis, giving no opportunity for an alleged infringer to respond to the allegations, and in others an interim injunction can be granted relatively easily, even if the rights in question are invalid secondary patents or the defendant company has a non-infringement position because there is limited consideration of the merits. It ought to be straightforward for the company to indicate in response that it is only manufacturing for export under the SPC manufacturing waiver but it would be an additional hurdle it would have to overcome and there would be a cost in defending itself in such an action. The information could lead to vexatious interim injunction applications where the value of the drug market in the non-SPC country/ies is such that it is worth the right holder making such an application to frustrate and delay generic or biosimilar production (even if only for a short while – each day is valuable).

6.7.2 It could mean that large portfolios of secondary process and formulation patents (and utility models where available) could begin to be sought and enforced during the SPC term (even if they are invalid or not infringed) because in many countries a mere assertion can be sufficient to obtain interim injunctions stopping manufacture.

6.7.3 It could mean the SPC holder (which is likely to market other products) uses the information relating to manufacturing sites in respect of other potential generic or biosimilar product launches too. Generics and/or biosimilars may have one or only a handful of manufacturing sites. Once an innovator knows where a manufacturing site is based it may target that country for interim injunctions and evidence seizures with regard to a different products in order to delay generic entry. There would be costs incurred by the generic or biosimilar company having to defend such an application simply to demonstrate that a product is not produced there.

6.7.4 It may encourage the innovator to seek customs seizures of API where these are relatively easy to request, in order to delay the generic or biosimilar company's ability to commence manufacture.

Article 3(d) The number of the authorisation granted in accordance with Article 40(1) of Directive 2001/83/EC or Article 44(1) of Directive 2001/82/EC for the manufacture of the corresponding medicinal product or, in the absence of such authorisation, a valid certificate of good manufacturing practice as referred to in Article 111(5) of Directive 2001/83/EC or Article 80(5) of Directive 2001/82/EC covering the premises where the making is to take place;

6.8 The disclosure of either authorisation numbers granted in accordance with Article 40(1) of Directive 2001/83/EC or Article 44(1) of Directive 2001/82/EC for the manufacture of the corresponding medicinal product, or certificates of good manufacturing practice, will necessarily relate to specific manufacturing sites and will identify the manufacturer. This will raise the same issues as those described above in relation to Article 3(b), e.g. it would undermine the HMA and EMA guidance, provide advanced notice to competitors of

commercial intentions and could lead to blocking/searching of manufacturing sites on the basis of assumptions, causing delays to manufacture.

6.9 Under the HMA and EMA guidance this information would not be disclosed by regulatory bodies across the EEA. Similarly, based on the commercially confidential nature of this information, such disclosure under the proposed Article 3 notification is not justified either.

Article 3(e) The intended start date of making in the relevant Member State;

6.10 This information is something which a pharmaceutical company (innovator or generic) would never be required to disclose to any of its competitors. There are a number of reasons why this information is kept secret and some examples of how it could be used by competitors to obtain a commercial advantage and/or cause harm to a notifying company seeking to bring a product to market are set out below.

Innovator producing/selling the drug	Generic or biosimilar competitors with an interest in producing their own generic version of the drug
Provides the innovator with information as to when it could seek a (vexatious) PI and when (roughly) the notifying company is aiming to launch in the non-SPC country/ies.	Provides generic or biosimilar competitors with information as to (roughly) when the notifying company is aiming to launch based on knowledge of their own manufacturing timelines. Each generic or biosimilar will want to be first to market.
Provides the innovator with an indication as to whether the notifying company is likely to be applying for a tender in non-SPC countries and when i.e. if the manufacturing start date is around 6 months before a tender is due to take place in another country.	Provides generic or biosimilar competitors with information as to whether the notifying company is likely to be applying for a tender in key markets and this may encourage or discourage a generic or biosimilar competitor from applying for a tender and alter its tendering strategy including the price offered etc. It would also provide information as to how many EU competitors might be submitting tenders.
This information combined with the date of first launch in the non-SPC countries for the particular product will provide the innovator company with an indication as to when this particular generic or biosimilar company starts to manufacture products in advance of a launch. This information could be applied by the innovator companies for other products to allow them to time a (vexatious) PI application and/or seizure of evidence application such that these are made when manufacturing is in progress.	Provides generic or biosimilar competitors with a strong indication as to whether the company intends to seek to clear the way of blocking patents in key European jurisdictions, if the manufacturing date is some time earlier than day 1 in an export country. Given known timings re. court diaries etc the generic or biosimilar competitor could have an indication as to when to expect a national litigation to start.
It would never be possible for a Europe based generic or biosimilar company to have alternative strategies to access the market, even if there are no patents in the destination country or if there are only weak secondary process or formulation patents (which might be invalid and/or not infringed and may or may not be enforced). In order to manufacture in its own facilities for export, the innovator company will always know that launch is intended soon if the company notifies it of the date it will start manufacturing (and the destination countries).	If the manufacturing start date is particularly early this could indicate to a generic or biosimilar competitor that the notifying company has reached a confidential agreement with the innovator, negating the need to clear the way. The very fact that such an agreement has been reached is commercially sensitive information and confidential. Each generic or biosimilar wants to be first to market. This information may encourage the generic or biosimilar competitor to approach the SPC holder for their own agreement, increasing the competition to the notifying company when they launch.

Article 3(f) An indicative list of the intended third country or third countries to which the product is to be exported;

6.11 A pharmaceutical company would never be required to disclose its intended countries of sale to a competitor. This information is commercially sensitive and confidential as being part of a business plan. The fact that marketing authorisations have been obtained in third countries (of which the innovator is likely to be aware) would be adequate indication that a company may export to / sell there and then it is up to the innovator to monitor the market in said third country and, if appropriate, it can make use of appropriate reliefs available under national law in those countries.

6.12 We set out below potential ways in which this information could be used by competitors:

6.12.1 This information combined with the information relating to manufacturing sites will divulge the likely transportation route from manufacturing site to destination country. If this route is through countries where PIs are regularly granted, including for goods in transit (potentially on an ex parte basis) or customs seizures can be easily achieved, this could lead to vexatious PI/customs seizure/evidence seizure applications by the innovator in these countries to try to delay entry of the generic or biosimilar product into third country markets.

6.12.2 If the generic or biosimilar company discloses the third countries it plans to sell its product in, the innovator company may use this information to focus its marketing efforts in those particular countries (including concentrating efforts on, for example, brand equalisation deals in those countries) to limit the sales to be made by the generic or biosimilar company, even before the launch of the concerned generic or biosimilar products.

6.12.3 If the generic or biosimilar company discloses the third countries it intends to focus sale of its product in, in response to this information competitor generic or biosimilar companies may increase their marketing efforts in those particular countries, leading to a distortion of competition and a competitive disadvantage to the Europe based notifying company.

Article 2(b) A notification provided by the person doing the making

6.13 Article 2(b) requires the notification to be provided by "*the person doing the making* '*(the maker')*". If the company doing the manufacturing always has to be the person providing the notification, it will *de facto* disclose its name and address, which would amount to disclosure of information in relation the country(ies) of manufacture and the manufacturing site(s).

6.14 As discussed above, manufacturing sites are commercially confidential information according to the HMA/EMA and providing the SPC holder and/or generic/biosimilar competitors with such information would be detrimental to the company's business planning and compromises the company's legitimate commercial interests.

7. **Other considerations relevant to the nature of the notification proposed**

7.1 If a product is diverted into an SPC protected member state for sale (which is unlikely), the SPC holder will become aware very quickly and will be able and entitled to enforce its rights, seeking evidence seizures where it is permitted and obtaining interim relief as appropriate, on the basis of Directive 2004/48/ of 29 April 2004 on the enforcement of intellectual property rights and its national implementations. The implementation in February 2019 of the Falsified Medicines Directive 2011/62/EU put in place a tracking system that could enable competent authorities of member states to enhance the controls on trade in medicines and make them more easily identifiable. This should avoid the alleged re-importation situation which is of concern to innovators.

7.2 On the contrary, there are no safeguards for the generic or biosimilar manufacturer which would be concerned about the risk of misuse of the information provided (i.e. for any other purpose than helping the SPC holder to enforce the SPC against illicit diversions of the product onto the Union market), competition distortion, vexatious claims and seizures aimed at causing difficulties and delays in manufacture and export outside Europe as well as the potential for requests for more and more commercially confidential information about supply chain activities and business plans.

7.3 Canada has implemented an export manufacturing waiver within its Patent Act at section 115(2): *"it is not an infringement of the certificate of supplementary protection for any person to make, construct, use or sell the medicinal ingredient or combination of medicinal ingredients for the purpose of export from Canada".* No notification requirement is imposed.

7.4 Throughout Europe there are a number of exemptions to infringement of patents (and/or SPCs/paediatric extensions) which require no notification to the right holder (let alone to direct generic or biosimilar competitors). This maintains the ability to undertake commercial activities which have been exempted from infringement by statute, without the knowledge of competitors. Such exclusions have been identified as activities which can be undertaken without causing any real commercial harm to a right holder and, if necessary, the exemptions would be relied on as a defence to an infringement allegation.

7.5 As identified by the Impact Assessment, SPC holders will not suffer harm by use of a manufacturing waiver which allows export outside the EEA so this too would be better implemented as an exemption to patent infringement requiring no notification. Similarly, if the waiver extended to manufacturing for launch on day 1, SPC holders would not suffer any greater harm than if product is manufactured outside the EEA to be imported upon SPC expiry.

7.6 By way of example, Article 10(2) of Directive 2001/83/EC, as amended by Directive 2004/27/EC provides for a "Bolar Exemption" [1] according to which conducting the necessary studies and trials with a view to the application of paragraphs 1-4 of Article 10[2] and the consequential practical requirements shall not constitute an infringement of a patent or SPC.

7.7 In the UK, under Section 60(1)(a) of the UK Patents Act 1977, it is an infringement to make, dispose of, offer to dispose of, use, import, or keep a product in the UK which infringes a registered patent. Examples of exemptions which apply to this Section of the Act and are relevant to the pharmaceutical industry are:

7.7.1 Section 60(5)(b) - an act which would constitute infringement of a patent will not do so if it is done for experimental purposes relating to the subject-matter of the invention (the "Experimental Use Exemption" or "research exception");

7.7.2 Section 60(5)(i) of the UK Patents Act which implements the "Bolar Exemption" states that such actions will not constitute an infringement to the extent they consist of either:

(a) acts done in conducting a study, test or trial which is necessary for and is conducted with a view to the application of paragraphs 1 - 4 of Article 10 of Directive 2001/83/EC, as amended by Directive 2004/27/EC; or

(b) any other act which is required for the purpose of the application of the above.

[1] the Bolar Exemption was introduced to address uncertainty regarding bioequivalence and stability studies to obtain an abridged MA under Directive 2001/83/EC, as amended by 2004/27/EC.
[2] Article 10(1) to 10(4) of the Directive relates to the circumstances in which pre-clinical trial and test results need to be provided to the competent authority when obtaining a Market Authorisation for that product. Such tests include physico-chemical, biological, microbiological, toxicological, pharmacological test and clinical trials (Article 8(3)(i) of the Directive).
Article 10(6) states that necessary studies and trials carried out with a view to the application of 10(1) to 10(4) shall not be regarded as contrary to patent rights (i.e. not amount to acts of infringement).

7.7.3 Section 60(6D) states that for the purposes of section 60(5)(b), anything done in or for the purposes of a medicinal product assessment which would otherwise constitute an infringement of a patent for an invention is to be regarded as done for experimental purposes relating to the subject-matter of the invention ("the New Experimental Use Exemption").

7.7.4 Use of these exemptions requires no notification whatsoever. There is no obvious basis why the same approach cannot be applied to the SPC manufacturing waiver.

8. Conclusion

8.1 This opinion sets out a number of reasons why generic or biosimilar companies would wish to resist disclosing the following information to a relevant authority to publish on a publicly accessible register and/or sharing it with the SPC holder:

(a) the name and address of the maker;

(b) the address, or addresses, of the premises where the making is to take place in the relevant Member State;

(d) the number of the authorisation granted in accordance with Article 40(1) of Directive 2001/83/EC or Article 44(1) of Directive 2001/82/EC for the manufacture of the corresponding medicinal product or, in the absence of such authorisation, a valid certificate of good manufacturing practice as referred to in Article 111(5) of Directive 2001/83/EC or Article 80(5) of Directive 2001/82/EC covering the premises where the making is to take place;

(e) the intended start date of making in the relevant Member State;

(f) an indicative list of the intended third country or third countries to which the product is to be exported.

8.2 This opinion clearly shows that this information is unnecessary to the proper operation of the waiver for both generics (and biosimilar) companies and originators, is not consistent with the purpose of the proposed notification, goes beyond any notification regime in existence at present and could distort trade and hinder competition.