

# Data Sharing Review

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## Consultation paper on the use and sharing of personal information in the public and private sector

### List of questions for response

We would welcome responses to the following questions set out in this consultation paper. Please follow the question order as set out in the consultation paper, leaving a blank response box for any questions not answered.

Please email your completed form to [contact@datasharingreview.gsi.gov.uk](mailto:contact@datasharingreview.gsi.gov.uk)

Alternatively you can send a hard copy response to:

**Data Sharing Review Secretariat**  
**5.26 Steel House**  
**11 Tothill Street**  
**London**  
**SW1H 9LJ**

Thank you.

### Section 1: Background

Question 1. Please explain what your interest in information sharing is. If you have an active involvement in personal information sharing, we would be grateful for the following information:

- What kinds of personal information do you collect, hold and share?
- How do you collect, hold and share such personal information?
- For what purposes do you collect, hold and share such personal information?

Comments:

Novartis is a leading global pharmaceutical company, developing and providing medicines across a range of medical therapeutic areas and products. The main relevance of this consultation to Novartis UK's business is the impact of current and prospective data sharing and protection legislation upon clinical research and practice. The responses in this paper apply to Novartis Pharmaceuticals UK.

Since the Data Protection Act came into force, Novartis has stored patients data electronically for the purposes of complying with medicinal product regulations (medical information, pharmacovigilance, reporting to regulatory authorities). These purposes include risk monitoring such as pharmacoepidemiology studies, and maintaining accurate drug safety profiles. All data stored by Novartis is subject to a full ethics committee review and approval as to which data may be collated, in what form, and the detailed terms of consent to be given by patients, as also complies with the law governing patient consent. These data

will usually be anonymised (except where there is a requirement under pharmaceutical regulations to waive anonymity), and will also be subject to strict password, and other security controls. These data are sent to Novartis by clinical trial investigators as well as primary and secondary care physicians and other healthcare professionals in accordance with NHS Governance and procedures. Data collected will usually take the form of medically relevant criteria such as age, gender and ethnicity. The data are reviewed cumulatively by allocating a structured, sequential case number. Data will rarely be shared across Departments within Novartis, and in the limited cases the information shared will normally be restricted to small data elements such as that required for enquiry handling and medical information across local clinical research groups.

In the case of individual case safety reports (ICSRs) however, details of both the patient and source of the report will normally be included, as required by law. Data elements for ICSRs can include sensitive information such as the patient's name (or at least, initials) and contact details, as well as age, weight, height, gender and ethnicity. More sensitive data may also be held, such as individual specific details such as patient's medical history, family and social history. For example, whether a patient has suffered from alcohol or drug addiction, or has a history of such condition in the family. In cases of adverse reaction reports, information will also be shared with a third party (usually public) bodies, such as the MHRA. In such cases, patient data are stored both individually and cumulatively, but not in a format that could be recognisable as patient-specific. In turn, such bodies will publish details of these reports in the form of aggregate data, so subject identities will remain anonymous.

Like other private sector companies, Novartis also stores data regarding its employees, suppliers and customers, in accordance with law and its policies, for purposes necessary to the conduct of its business.

Novartis has specific policies and procedures to regulate the sharing of clinical trial and any other personal information within the Group to ensure compliance with local laws as well as with Novartis policy.

## **Section 2: Scope of personal information sharing, including benefits, barriers and risks of data sharing and data protection**

Question 2. What in your view are the key benefits of sharing personal information to individuals and society? Please provide examples.

Comments:

The benefits of such data sharing to companies such as Novartis include the furtherance of best-achievable standards for both the risk/benefit of medicines as well as health economics and statistical analysis. Examples of this are: extending our ability to stratify data, through analysing and comparing patient demographics such as age, gender, weight, or body mass index. Such analyses allows us to identify particular 'at risk' groups, or perhaps in the future to identify pharmacogenetic markers, where for example a specific patient group may demonstrate an increased susceptibility to an adverse reaction to a drug. In such cases, it is clearly of huge benefit for Novartis and other bodies to use shared data to compare across physical criteria in order to swiftly and thoroughly overcome such patient safety issues.

Question 3. What in your view are the key risks of sharing personal information to individuals

and society? Please provide examples.

Comments:

The increased recording, storing and possibly sharing of patient information between the public and private sector may in theory present risks of creating additional exceptions to individuals' right to absolute privacy. There is clearly a balance to be struck between the recognition and protection of patients' privacy and the greater public interest of developing drugs that will be safe and effective to use. At present, Novartis feels that the current flexible framework of law and self-regulation by the pharmaceutical industry as well as by Novartis policies in place, does achieve this balance.

Question 4.

Comments: Within the pharmaceutical industry there are few risks and greater opportunities for data sharing, largely as a result of the investments made by the industry in IT, database management and training as well as policy formulation. The areas of risk which Novartis has encountered regard the manner in which local councils sell information to private businesses which do not self-regulate for the protection of personal and other data to the standards to which other sectors have. Other areas of risk include the supply (possibly sale) of personal data by councils to political parties or politicians.

Another area of risk is the lack of harmonisation between public and private sector as to how information is collated and controlled. Data Protection Authorities could for example 'kite mark' relevant database software and hardware products that are available.

The reason for such view is that the lack of harmonisation leads to significant variations in the manner in which data is shared, the form in which and the means by which it is shared.

Novartis believes there would be greater trust in sharing of personal and other information between the public and private sector, if there were greater transparency and consistency in the manner in which such data is collated, stored and shared, by the public sector, as well as greater communication about the benefits of doing so and of sharing that information in a controlled and secure manner with the private sector.

Question 5.

Comments: Novartis believes that the data currently held by the NHS Business Services Authority (about products actually purchased by the NHS as well as NHS contractors' services which are funded by the NHS), should be shared (possibly for a fee) with the pharmaceutical industry and the general public. Clearly defined controls as to the level of granularity of such data would be agreed with relevant authorities and trade associations or professional bodies.

The reasoning for this is that the NHS is not benefiting from a source of income and a level of transparency which would encourage the taxpayer to be aware of the importance of contributing to a publicly-funded healthcare service. The data is only made available to the public sector, save for information which is provided under Freedom of Information Act requests (which generate a cost for the public sector without a corresponding source of income).

Question 6.

Comments: Novartis is not aware of private organisations which hold too much data or personal information: the costs of collating, storing and controlling data which is not necessarily required for private sector businesses are prohibitive.

Question 7. Please provide examples of cases where you believe the sharing of personal information between two or more bodies would be beneficial, but where it is not currently taking place. Please explain as fully as possible why information is not being shared, detailing what the barriers to the sharing of personal information are – e.g. legal, cultural, financial, institutional – and how these barriers can be overcome.

Comments:

The barriers that currently exist towards sharing personal information can place burdensome limitations upon companies such as Novartis. For example, the subsequent use ('secondary use') of data for purposes other than that to which the subject originally consented for data to be used, can lead to difficulties.

One area where the additional sharing of personal information would be beneficial is in confidential correspondence between pharmaceutical companies such as Novartis and Government bodies such as the MHRA. Such bodies correspond daily on issues such as individual case safety reports. However, they cannot currently reveal either the source or full patient details of cases received, which can on occasion impede upon research. For example, if a doctor or pharmacist has contacted both the MHRA and the pharmaceutical company to report a patient's adverse reaction to a drug, even a request to confirm that the case reported to the company is the same as that which the external body is enquiring about specific patient or source details cannot either be confirmed or denied. Thus assumptions may be drawn, but cannot be proven.

Similarly, if a pharmaceutical company were to be contacted by an individual doctor, pharmacist or other third party reporting that a particular patient group had demonstrated an adverse effect, this could present a challenging dilemma. If, as is the case under the current legislation, the company are unable to gain any further information concerning these effects or details of the patient group, the company are faced with two options. Either the drug could be restricted from certain groups of patients considered at risk while further research is carried out (hindered of course, by the fact that the data of those patients potentially

exhibiting adverse reactions cannot be used) with all the primary and secondary marketing implications that this carries, or the company can ignore the warning and be exposed to future litigation for negligence.

Question 8.

Comments: Novartis has not identified a specific issue on such sharing.

### **Section 3: The legal framework**

Question 9. In your view, how well does the DPA work? Please outline the DPA's main strengths and weaknesses and any proposals for changes you would like to see made, including suggestions for their implementation.

Comments:

Novartis ensures that it remains clear and up-to-date in terms of how complying with the DPA affects research plans and opportunities in the UK, and how other forms of data protection legislation impact upon our information policies. From our perspective, the Data Protection Act works well, being similar to other data protection legislation and previously existing Codes of Conduct governing other disciplines such as medical and market research.

The benefits of the DPA from the perspective of Novartis include the additional guidance in acting responsibly and credibly, and more importantly, being seen to be acting as such. Patients expect – and have the right to expect – responsible data management from an organisation the size of Novartis, and it is patient confidence which is often key to clinical research.

Weaknesses remain not in the implementation of the Data Protection Act but rather in the understanding of this legislation in the private sector. Despite the fact that the DPA has been in place for a decade, there are many in the pharmaceutical industry who remain unsure how certain pieces of data can be used, and in which circumstances. For this reason, guidance would be welcome on these grey areas such as secondary usage of patient information, in order to ensure that the current legislation is understood fully by members of the pharmaceutical sector.

Overall, Novartis feel that further restrictions could compromise beneficial research projects. For example, if Novartis were prevented from carrying out even a basic analysis of patient data then this could compromise studies in areas such as pharmacoepidemiology. This in turn would jeopardise the speed and levels of safe and effective drugs being produced for patients in the UK.

Question 10. In your view, how well do public authorities and private organisations adhere to the second principle of the DPA? How valuable do you believe the second principle is? Please provide examples and the reasoning behind your response.

Comments:

While the vast majority of companies within the pharmaceutical sector do adhere to the Second Principle, the potential for use of shared or previously gathered data is now growing. As a result, the technical capabilities are now there for pharmacoepidemiological studies to

be carried out based upon previous studies and stored data. While the primary purpose of collecting and storing such data is to test for drug safety, secondary benefits of such data could be gained through further research based on this existing data and findings.

For example, in the case of a product causing adverse reactions, the drug may be assessed across the patient group using such personal data. Clinical trials or pharmacoepidemiological studies could be run to locate the pharmacogenetic marker, and product safety improved without having to restrict the use, or even withdraw a drug that may significantly benefit a patient group. However, it is recognised that information stored cannot currently be used for any purpose other than that for which the patient has originally given consent.

Question 11.

Comments: Novartis has not identified a specific barrier.

Question 12.

Comments: None – the current combination of law and self-regulation operates well in the pharmaceutical sector.

Question 13.

Comments: The current diversity in how EU Directive 95/46/EC has been implemented and interpreted in the EEA leads to incremental costs for the pharmaceutical industry which could be reduced.

Question 14.

Comments: Novartis would be happy to consider this in detail if specific proposals as to the type of identity authentication which could be used were made.

Question 15.

Comments: Novartis has not identified a burden which affects its business to a significant extent..

#### **Section 4: Consent and transparency**

Question 16. Is it clear whether and when you need individuals' consent to share information about them? Are you clear about the form that consent should take? Please provide examples. Please provide details of any initiative you have been involved in that has been based on consent.

Comments:

Novartis considers that legislation and other international documents provide clear standards on the requirements of patient consent and the storing of their data. Doctors are specifically trained in this area, and pharmacists are also keenly aware of the issues around consent.

Rare difficulties usually manifest themselves at the beginning of the data-gathering process if a patient fails to communicate to a doctor their failure to understand the degree of geographic transmission of data. For example, a doctor can explain to a patient how the DPA may affect the use and possible onward distribution of his or her details, (in the form of an anonymised ICSR) – possibly across as many as 80 different countries worldwide..

Some patients request further information subsequent to communicating consent.

Question 17.

Comments: A requirement for requiring specific written consent is already the standard in the context of clinical trial data and Novartis has made significant investments to comply with this.

Question 18.

Comments The public sector could generate a specific charter as to how it implements the principles of the DPA in the public sector.

Question 19.

Comments: The Framework code of practice is helpful but it is not clear how all public sector authorities are complying with it.

### **Section 5: Technology**

Question 20. What impact in your view have technological advances had on the sharing and protection of personal information? Please provide examples.

Comments:

Electronically stored information clearly allows for easier access and easier sharing, but with such increased access there is a greater emphasis upon protecting it. Since far more information is now both stored and shared over the internet, this has created some slightly grey areas. For example, it remains unclear whether e-mails, SMS messages or unsolicited mailing lists fall under the jurisdiction of the Act. Again, more guidance would be welcome, though any proposed refinements of the current law should focus on these newer forms of communication to ensure that every person has same level of protection regardless of medium.

Question 21.

Comments: Novartis would be happy to consider this in detail if specific proposals were made

Question 22.

Comments: Novartis uses privacy enhancing techniques such as anonymisation or pseudonymisation and considers that subject to appropriate minimum security and associated standards, this achieves a balance between the need to conduct research whilst protecting individual privacy rights.

### **Section 6: International comparisons**

Question 23.

Comments: Novartis believes that the DPA and associated Codes of Practice should be routinely reviewed in the light of developments in other jurisdictions but has no specific examples to note.

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Question 25.

Comments: The US has a permissive approach to sharing of personal information which has provided significant flexibility for business and has encouraged the conduct of research and development, which would benefit the UK and EU if such flexibility were made available. However, US patent law also authorises patenting of databases which leads to significant business costs.

Question 26. Are you aware of significant differences in public attitudes to the sharing of personal information in other countries? Please provide examples and an explanation for why you believe this to be the case.

Comments:

Since companies such as Novartis are global – and becoming more so – more resources are increasingly being used which originate from outside of the EU. This can cause difficulties when sharing information alongside another country which applies a different standard of data protection. In some countries, organisations are virtually mandated to share information, whereas in other countries the exact opposite is true. In such cases, Novartis will always err on the side of caution by adopting the strictest rules between either country. In the case of Novartis' own global database for example, the risk of compromising patient data will be mitigated through a feature of the database which disables printing of personally identifiable information.

In overcoming such potential problems, further guidance would be welcome setting out the international responsibilities of data-collecting organisations such as Novartis. Additionally, we are sure that the pharmaceutical sector as a whole would welcome the UK's contribution or even leading on securing an international agreement on the sharing of information for research purposes.

## **Section 7: Additional questions**

Question 27.

Comments:

Question 28.

Comments: