# Freedom of Information Act code list

1 May 2022

**Introduction**

The point of departure of the Dutch Freedom of Information Act [*Wet open overheid*] (Woo) is that all documents which the MEB has in its possession and are of a kind that relates to the public duties of the MEB are public. Information can only be kept confidential insofar as it is covered by one of the grounds for exceptions referred to in Chapter 5 of the Woo.

Anyone who submits information to the MEB can rest assured that said information will be handled with care. After all, the main thrust of Article 2:5 of the General Administrative Law Act [*Algemene wet bestuursrecht*] (Awb) is the duty of confidentiality with regard to data which people who are involved in the execution of a task of an administrative body know, or reasonably should suspect, is confidential. This Act does not go so far as to stipulate that all data and documents submitted by companies to the MEB remain, by definition, confidential. At the moment that the MEB receives a request on the grounds of Article 4.1 of the Woo, the MEB must assess whether the data and documents are actually confidential.

The MEB has developed the grounds for exceptions listed in Chapter 5 of the Woo for the processing of freedom of information requests [*Woo-verzoeken*]. In doing so the MEB has used, among other things, a European guideline which states which information in any medicinal product dossier is or is not confidential.[1] This led to the following list of codes which shows the information which the MEB considers to be confidential, divided into different categories and codes. An indication is given for each code as to why the MEB considers the information in question to be confidential. This code list forms the guideline which the MEB uses as a basis to assess the requested information against the grounds for exceptions.

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**A = Company and manufacturing data**

Information will not be provided pursuant to the Woo if it concerns company and manufacturing data which natural persons or legal entities have communicated to the government confidentially (Article 5.1, paragraph 1, introduction and under c of the Woo). According to established case law company and manufacturing data is taken to mean all data from which facts can be derived regarding technical or financial operations, the production process, the sale of products, or the circle of customers or suppliers[2]. The data must have been communicated to the government confidentially. An explicit notification that certain information has been communicated to the government confidentially is not required for this. It is sufficient for the data to have been issued via contact which a company could reasonably regard as confidential.[3]

The MEB is of the opinion that the following data concerns company and manufacturing data which has been communicated to the government confidentially and which should not be made public:

**A1 = Contracting parties**

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[1] https://www.ema.europa.eu/documents/other/heads-medicines-agencies/european-medicines-agencyguidance-documentidentification-commercially-confidential-information_en.pdf

[2] See, for example, Administrative Jurisdiction Division of the Council of State (ABRvS) 17 July 2002, ECLI:NL:RVS:2002:AE5445.

[3] Parliamentary Papers II 1986/87, 19 859, no. 3, p. 33

Information about/names of parties involved/contracted manufacturers, laboratories and other companies (with the exception of the Contract Research Organisation (CRO), batch release manufacturer, pharmacovigilance company, marketing authorisation holder) and all data which can be traced back to these manufacturers/companies.

*This information is confidential because it provides an insight into mutual cont(r)acts, partnerships between companies, the circle of suppliers and customers and operations. Knowledge of this information gives competitors an insight, without having to do any research (time/costs), into who to contact if they, for example, wish to purchase the same substances, as well as an insight into how they can frustrate processes, for example by bringing pressure to bear on a certain supplier only to supply to them, or even by buying up this supplier and thereby cutting off the supply of raw materials to the other party.*

**A2 = Pharmaceutical development and manufacturing process**
Information regarding the formulation and manufacture, including control processes, CEP numbers, batch information (number/size/type/manufacturing/expiry date), specific calculation formulas.

*This information is confidential because facts can be derived from it about the production process. The pharmaceutical development takes time and costs money, and publication would result in a competitor no longer having to do any research.*

**A3 = Testing methods, characterisation methods and validation of these methods and the manufacturing process**
Information about testing methods and characterisation methods of the active substance, excipient, finished product, by-product, degradation product and impurity, as well as the validation of these methods and validation of the manufacturing process. This includes batch information (number/size/type/manufacturing/expiry date), devices used, units (e.g. mg/ml if there are several possibilities) and specific calculation formulas.

*Insofar as no generally known standards are followed, this information is confidential because facts can be derived from it about the production process. The development of a testing/characterisation methods takes time and costs money, and publication would result in a competitor no longer having to do any research.*

**A4 = Specifications, acceptance criteria and test results**
Information about specifications, acceptance criteria and test results of the active substance, excipient, finished product, administration device. This includes batch information (number/size/type/manufacturing/expiry date), stability data, CEP numbers, polymorphism and particle size.

*This information is confidential because facts can be derived from it about the production process. Setting the correct specifications and acceptance criteria takes time and costs money, and publication would result in a competitor no longer having to do any research. It would also be possible to find out which route of synthesis is used for the active substance. A cost price applies to a particular route of synthesis. It would save a competitor costs and therefore give the competitor an advantage in terms of finding out about the cheapest properly functioning and validated synthesis route. Standard testing methods in accordance with the pharmacopoeia are an exception. These methods are public knowledge and generally applicable, and they do not, in*

*advance, reveal everything about the chosen synthesis route. Polymorphism can affect the success of a medicinal product (positive benefit/risk balance, granting of a marketing authorisation). Acquiring this information without having to make an effort saves costs and is therefore beneficial to competitors. Particle size can affect the success of a medicinal product (positive benefit/risk balance, granting of a marketing authorisation). Acquiring this information without having to make an effort saves costs and is therefore beneficial to competitors.*

**A5 = Impurities, by-products and degradation products**
Qualitative and quantitative information (nature and quantity) relating to impurities, byproducts and degradation products.

*This information is confidential because the synthesis route can be derived from data on impurities and by-products and decomposition products. The development of a synthesis route takes time and costs money, and it would save a competitor costs and give the competitor an advantage if they find out about the cheapest synthesis route.*

**A6 = Solvents**
Information and data about solvents incorporated into the medicinal product.

*This information is confidential because facts can be derived from it about the production process. The development of solvents takes time and costs money, and publication would result in a competitor no longer having to do any research.*

**A7 = Packaging**
Information and data about the packaging of the medicinal product or the active substance.

*Detailed information about packaging is confidential because facts can be derived from it about the production process. The development of packaging takes time and costs money, and publication would result in a competitor no longer having to do any research.*

**A8 = Active Substance Master File – Restricted Part**
An 'Active Substance Master File' is a separate dossier about the active substance of the medicinal product. This dossier is drawn up by the manufacturer of the active substance. The marketing authorisation applicant has no knowledge of the (entire) contents of this dossier. At the request of a marketing authorisation applicant, an Active Substance Master File (ASMF) holder supplies one or more substances required for the production process.

*This ASMF is confidential because facts can be derived from it about the production process. The development of the Active Substance Master File takes time and costs money, and publication would result in a competitor no longer having to do any research. The name of the ASMF holder must also be kept confidential. Although the name is known to the marketing authorisation applicant, it is not known to anyone else. The identity of the ASMF holder provides an insight into mutual contacts and partnerships between companies. Knowledge of this would give competitors insight into who they should contact if they want to purchase the same substances without having to do any research. The restricted part of the ASMF is confidential in its entirety and even the marketing authorisation applicant does not have access to it. Competitors could use the information to frustrate application processes, for example by bringing pressure to bear on a certain supplier only to supply to them, or even by buying up this supplier and thereby cutting off the supply of raw materials to the other party.*

**A9 = List of materials of animal and/or human origin**
A description of the materials of animal and/or human origin used to make the medicinal product.

*This information is confidential because facts about the production process can be derived from the description.*

**A10 = Production and sales figures**
Production and sales figures relating to the medicinal product.

*This information is confidential because this data provides an insight into product operations and sales. This data provides an insight into the 'value' of the company. This data is not published in order to prevent competitors acquiring this data and thereby gaining an unfair advantage.*

**A11 = New/temporary product names**
Proposal for new product names ('invented names'), including temporary product designation, unless it becomes the eventual product name.

*This information is confidential because facts can be derived from it about the product process. The development of a new name for a medicinal product takes time and costs money, and publication would result in a competitor no longer having to do any research.*

**A12 = Table of changes**
A table showing changes to a company's operating and manufacturing processes.

*This information is confidential because changes to a company's operating and manufacturing processes provides an insight into the internal operations. These changes require an exceptional effort (time/money) and the data provides an insight into the company's strategy. Publication of the changes would be detrimental for the company because competitors would not have to do any research and could simply copy the eventual processes.*

**Other company and manufacturing data**

Information other than the competitively sensitive company and manufacturing data listed in paragraph 1, under c, will not be provided either insofar as its importance does not weigh up against the importance of protecting such company and manufacturing data (Article 5.1, second paragraph, introduction and under f of the Woo). This refers to data that were not communicated confidentially to the government as such but which, if made public, would result in disproportionate detriment to the company concerned. Examples include:

**A13 = Innovative study design or analytical method in non-clinical and clinical data, including specific calculation formulas**
Descriptions of and information and data about non-clinical and clinical studies and their results. The information is necessary in order to demonstrate the efficacy and safety of medicinal products. Studies are designed in accordance with a standard method or in accordance with an innovative method.

*The description of the innovative study design and the results from which that innovative study design can be derived are confidential because creating an innovative study design or an innovative analysis method with regard to the clinical and non-clinical data requires exceptional effort (time/money). Their publication, with the risk of being simply copied by another party, is so detrimental for the party that developed the study design or method that confidentiality is required, even if the data is not strictly company and manufacturing data.*

**A14 = Draft product information**
Proposals by companies with regard to product information (SmPC/package leaflet/label), as well as RMP and educational material.

*Draft versions of documents drawn up by the company are confidential because draft versions provide an insight into the company's strategy during its application. This relates, for example, to drafts of the SmPC, package leaflet and RMP. Drafts provide an insight into which elements were successful during an application procedure (approved by the MEB) and which were not. Publication would save effort on the part of competitors. The MEB considers that the importance of publication does not weigh up against the importance of preventing disproportionate detriment for the company that submitted the document.*

**A15 = Company's conclusion in a bibliographical application**
Public (scientific) literature can be used during an application. The applicant describes this literature and draws the conclusion that the medicinal product has already been used frequently in medicine and is effective and safe. Simply submitting literature does not, therefore, complete a company's application. A follow-up process is required during which the applicant draws conclusions from this literature. Drawing conclusions from the literature requires substantial power of thought and creativity on the part of the applicant.

*The conclusions are confidential because if third parties find out about them they may have a disproportionate advantage, particularly when submitting their own application. Publication of the conclusion is disproportionately detrimental for the company in question because the competitor would not have to make an effort and could simply copy the outcomes.*

**B = Disproportionate benefit or detriment**
In exceptional cases, no information will be issued pursuant to the Woo insofar as disclosure would cause disproportionate detriment to any interest other than those listed in Article 5.1, paragraph 1 and 2, and the general interest of transparency does not weigh up against this disproportionate detriment (Article 5.1, paragraph 5 of the Woo).

**C = Personal data**
No information will be provided pursuant to the Woo insofar as its importance does not weigh up against the importance of respecting the privacy (Article 5.1, paragraph 2, introduction and under e of the Woo).

*The importance of respecting privacy is incompatible with publication of the names of employees who do not act publicly due to their position (at both government bodies and companies), unless the parties submitting the freedom of information request in question has made a plausible case that the importance of publication weighs heavier in a specific case.*

*Data which can be traced back to individual patients and participants in clinical studies is confidential. This concerns data about health and, with that, special personal data as referred to in Article 9 of the General Data Protection Regulation [Algemene Verordening Gegevensbescherming]. Publication should not take place on the grounds of Article 5.1, paragraph 1, under d of the Woo.*

*The MEB considers the following information in a registration dossier confidential:*

- Pseudonymized personal data and identification numbers concerning participants/ subjects and investigators

  This includes: case IDs, manufacturing numbers, subject IDs/ subject numbers, investigator numbers and other (identification) codes for participant, investigator or trial site.
- Race
- Ethnicity
- Gender and related pronoun
- Age
- Weight
- Height
- Site identifier, name and address
- Country
- Organisational name and address (e.g. investigator site information)
- Lab values
- Event date (e.g. date of birth, death, visit, adverse event, and procedure)
- Medical history
- Adverse event preferred terms and verbatim terms
- Concomitant medications
- Lot/ Batch numbers
- Drug brand name
- Sensitive diagnoses and behaviors
- Verbatim text

In addition, the MEB assesses on a case-by-case basis whether there are other data that can be trace back to a person.

**D = Personal opinions on policy on behalf of internal (MEB) deliberation**
In the event that a request concerns public information from documents drawn up for the purpose of internal deliberation, no information will be issued about personal opinions on policy included therein (Article 5.2, paragraph 1 of the Woo).

*This means documents drawn up by MEB employees in preparation of adopting policy, or the taking of decisions by the MEB. Employees must be free to make a contribution without hindrance to policy preparations and decision-making and to write about this. In the interest of public health, it is also important to be able to exchange ideas freely in order to make the best judgement. The documents are internal recommendations. They are the vision and interpretation of employees and do not, by definition, reflect the position of the MEB. These documents are intended for internal deliberation and contain personal views and are therefore confidential.*

**E = Inspection, check and supervision by administrative bodies**
No information will be issued pursuant to the Woo insofar as its importance does not weigh up against the importance of inspections, checks and supervision by administrative bodies (Article 5.1, paragraph 2, introduction and under d of the Woo).

*Information relating to cases being investigated by, for example, the Health and Youth Care Inspectorate [Inspectie Gezondheidszorg en Jeugd] (IGJ) is confidential. Publication prevents adequate exercising of the IGJ's authorities.*

**F = The relationships between the Netherlands and other states and international organisations**
No information will be issued pursuant to the Woo insofar as its importance does not weigh up against the importance of the relationships between the Netherlands and other states and international organisations (Article 5.1, paragraph 2, introduction and under a of the Woo).

*It has to be possible for medicines authorities to exchange information freely in order to come to the best judgement. It is detrimental to public health if this exchange of information is hindered, for example because the information on which country made a particular comment during a procedure becomes public. Publication of the information may result in other member states being reticent when it comes to making comments and this could damage the proper working of the European medicines system and the relationships between the Netherlands and other member states. It is important that member states can exchange ideas freely when preparing decision-making in a similar way as civil servants can freely exchange ideas within government in connection with decision-making and policy preparation.*

**G = Text in a foreign language other than Dutch and English**
The MEB will not publish information in a language other than Dutch or English because it will then be impossible to assess properly whether a ground for an exception is applicable. The knowledge for the assessment is missing and a Dutch administrative body cannot reasonably be expected to provide it.

**H = Proper functioning of the State, other public-law bodies or administrative bodies**
No information will be provided pursuant to the Woo insofar as its importance does not weigh up against the proper functioning of the State, other public-law bodies or administrative bodies (Article 5.1, second paragraph, introduction and under i of the Woo).

**Z = Information which falls outside the freedom of information request**
*Documents which are covered by the freedom of information request because they contain information asked for in the freedom of information request may also contain information which falls outside the freedom of information request. The information which falls outside the freedom of information request will not be issued. A single document may, for example, contain information about various medicinal products. If the freedom of information request only relates to one of those medicinal products, information about the other products will not be made public.*