

DIRECT COMMUNICATION WITH HEALTHCARE PROFESSIONALS (DCHP) (DEAR HEALTHCARE PROFESSIONAL LETTER)

This is the letter forwarded by the registration holder or the Ministry directly to healthcare professionals, and that includes information concerning safe and effective use of drugs.

Basic Principles on Public Communication Concerning Drugs

Basic principles to be considered in communicating with the public through healthcare professionals are as follows:

- Sharing information on safe and effective use of drugs should be considered as a public health responsibility and should support appropriate use of the product.
- It should be considered that transferring such information is a significant part of the risk management process.
- The right message should be given to the right people at the right time.
- In principle, it should be preferred to offer significant or new information to the attention of healthcare professionals first, before communicating to the public.
- It is fundamental for such information to be communicated to healthcare professionals and their organizations, relevant associations and other parties by the registration holder.

Cases When Establishing Direct Communication with Healthcare Professionals May be Necessary

Withdrawal of a drug due to safety reasons related with the active substance, the suspension or annulment of its registration and major amendments in Summary of Product Characteristics; for instance, an amendment because of an urgent restriction for safety reasons (emergence of new contraindications or warnings about the drug, modification of recommended dosage, restriction of indications, restriction of drug use), it may be necessary to establish direct communication with healthcare professionals.

Other Cases When Establishing Direct Communication With Healthcare Professionals is Recommended

- In cases when the result of the evaluation of the risk-benefit ratio concerning the drug changes according to the reasons below, direct communication with healthcare professionals may be necessary.
 - Cases when it is established that data coming from a research or spontaneous reports are different from the frequency or severity of a previously unknown or known risk,
 - When there are new data concerning risk factors and/or how to prevent adverse effects,

- When confirmed information is found indicating that the drug is not as effective as it was previously thought,
- In case of evidence that a specific drug has more risks compared to its alternatives with similar efficacy.
 - When there are new recommendations for the treatment of adverse effects.
 - While a significant potential risk is in the process of being evaluated, when data is insufficient within a certain time period in order to take any regulatory measures (in that case DCHP should encourage closer monitoring and notification on the safety subject concerned, or should inform about methods to minimize potential risk),
 - Particularly in situations when the media shows considerable interest in the subject, in case it is necessary to convey other important information as well,
 - In any country around the world, in case of a DCHP distribution by the country's competent authority (considering the differences between medical applications among countries, the drug's registration holder in Turkey is obliged to inform the Ministry immediately. In case the DCHP to be submitted to the Ministry is a DCHP published worldwide, the said DCHP shall be submitted together with its translation approved by a notary).

Exceptions

“Dear Healthcare Professional Letter” should not include any material or statement that can be accepted as promotional; or should not create the impression that it is for promotional or commercial purposes. Direct communication with healthcare professionals concerning quality defects of drugs is outside the scope of pharmacovigilance studies.

DCHP should not be used for safety information that does not require urgent communication and for disseminating information that should not necessarily be communicated to healthcare professionals individually, such as changes in SPC that have no effect on the drug's conditions of use.

Basic Principles Concerning Preparation of Texts To Be Used in Direct Communication with Healthcare Professionals

While preparing a DCHP text, in addition to the principles defined below, the enclosed template and instructions should also be complied with:

- DCHP message concerning the safety issue should be clear and concise. The length of the text should not exceed two pages.
 - The reason for distributing a DCHP particularly on that date should be explained.
 - If known, recommendations should be included towards healthcare professionals concerning how to minimize risk.
 - Information concerning safety issues should not be presented by itself; the problem should be presented within the context of the treatment's benefits in general.

- Registration holder should guarantee the pharmacovigilance information presented to the public (also includes healthcare professionals) is objective and not misleading. (Registration holder may not communicate information to the public on matters of pharmacovigilance concerning his registered drugs without prior notification to the Ministry. In any case, registration holder shall ensure this information to be presented in an objective way and is not misleading. The Ministry shall take all measures to impose effective, proportional and deterrent penalties in case a registration holder does not undertake these obligations.)

- In order for members of the Ministry of Health to prepare answers to potential questions from patients, all information that is directly communicated to the public should be included in the DCHP. In case of the registration being suspended or cancelled, the DCHP should include details on the procedure to recall the drug from the market and the type of recall (such as pharmacy or patient level, date of recall).

- Safety information communicated to any target group by competent authorities or public institutions worldwide should be considered.

- DCHP should include a reminder that, in accordance with national spontaneous reporting system, suspected adverse effects of drugs should be notified.

- If necessary, an estimated time frame should be given concerning the follow-up procedures foreseen by the Ministry or the registration holder.

- A list of contacts to apply for receiving more detailed information, their web sites, phone numbers and correspondence addresses should be enclosed to the DCHP.

- In order for literature on the subject to be accessed when necessary, a relevant bibliography should be enclosed to the communication document.

- Within the DCHP text, a statement may be included declaring that the said correspondence has been prepared in mutual agreement with the Ministry.

Execution of Direct Communication with Healthcare Professionals

Role and Responsibilities of the Registration Holder and the Ministry

When the registration holder recommends doing a DCHP distribution or when the Ministry requests the registration holder to do a DCHP distribution, the following documents should be submitted to the Ministry:

- Proposed communication plan
- Recommended text to be used for the DCHP
- Other relevant communication documents or text recommendations (ref: Phases of processing)

The date by which to send the documents to the Ministry should be established in a way so as to enable the Ministry to declare opinions concerning the communication plan and recommended communication texts to be submitted.

When necessary, the Ministry shall inform the Public Relations Coordination Office concerning the DCHP.

Phases of the Process

The DCHP process is realized in four phases:

1. Analysis phase : Initiating the process

The process may be initiated by the registration holder or the Ministry.

- **When the registration holder thinks that a DCHP may be required**, he applies to the Ministry and after his request for DCHP distribution is accepted, the registration holder should submit a communication plan including the following:

The purpose of the DCHP, draft DCHP and other communication texts [in a way as to include changes in product information (SPC package leaflet/patient information leaflet and labelling information)]. Changes might be referred to in the DCHP text; or if final product information is available, they may be added to the draft DCHP as a supplement. Furthermore, basic messages to be conveyed to the public should be sent simultaneously.

- **When the Ministry thinks that an DCHP may be necessary**, the decision taken after the subject has been discussed in the relevant commission, and a letter of request with reason requesting preparation of a draft DCHP as well as a communication plan are sent to the registration holder (If it is an urgent case, registration holder is further contacted by phone or through e-mail). If the registration holder is of the same opinion with the Ministry, he has to submit the decision concerning his opinion and the Dear Doctor Letter that he has prepared urgently (latest within 15 days) to the Ministry. The Dear Doctor Letter approved by the Ministry is sent to the registration holder to be forwarded to authorities determined by the Ministry in the shortest possible time. The registration holder has to make the necessary changes in the package leaflet/SPC/patient information leaflet and apply to the Ministry within 15 days in order to get approval.

In case of an objection to the decision concerning safety, the objection should be presented to the government together with its reasons latest within 15 days. The objection is then re-evaluated by the relevant commission. The decision taken is final, and there is no right for a second objection. If the Ministry approves of writing a "Dear Doctor Letter", the registration holder has to submit the Dear Doctor Letter prepared in accordance with this final decision to the Ministry. The Dear Doctor Letter approved by the Ministry is then sent to the registration holder in order to be forwarded to relevant authorities determined by the Ministry. The registration holder has to make the relevant amendments in the package leaflet /SPC/patient information leaflet, and apply to the Ministry within 15 days in order to get approval.

If the registration holder believes that preparing a DCHP is not appropriate and if additional relevant explanations are needed, he might send a written request to the Ministry. In cases when an agreement is not reached with the registration holder concerning the distribution of the DCHP; the Ministry may publish a DCHP and/or a formal statement to the public.

The registration holder has to comply with the criteria established by the Ministry concerning the content of the information to be conveyed, recipients, and the time schedule.

In cases concerning more than one drug (drug interaction, class effect of a drug, or drugs with generics), there might be situations where more than one registration holder is concerned for the distribution of the DCHP. In such cases the aim is to supply consistent information to healthcare professionals and to avoid confusion to be created by many DCHPs on safety coming from different registration holders. In cases when the number of relevant registration holders does not exceed three, they have to cooperate in order to publish a single DCHP. If the number of registration holders is more and if an agreement cannot be reached on a single common DCHP, the Ministry may exercise its right to publish a DCHP.

2- Pre-communication phase: Preparation of the DCHP

In the pre-communication phase:

- A list of proposed recipients (target groups; e.g. GPs, specialists, pharmacists including hospital pharmacists, nurses; hospitals/medical centers/other institutions).
- Description of the mechanism through which the DCHP will be distributed (e.g. by mail).
- If appropriate, a list of the relevant communication texts (e.g. press release, questions and answers document, patient information document)
- Description of the strategy to be valid in the post-communication phase; as mentioned in heading No. 4 of this section, this strategy should include the evaluation of the effectiveness of the DCHP.
- Summary of proposed follow-up activities, and if suitable, draft of the written engagement to be given by the registration holder concerning further studies.
- A list concerning contact information of relevant parties should be prepared.
- If a similar DCHP is decided to be prepared for more than one drug, their list is given in the DCHP.

Date and hour proposed for distribution should be calculated carefully; ideally, a DCHP should be distributed at the beginning of a week; however, distribution of urgent information should not be delayed only for this reason.

While target groups to be informed are defined, the importance of establishing communication not only with those healthcare professionals that may prescribe or administer, or potentially prescribe or administer the drug; but also with people who may diagnose adverse effects; e.g. emergency services, employees of national toxicity center, or with relevant specialists such as cardiologists should be considered. Also considering that pharmacists, who operate as information resources in healthcare, help the public by supplying information to patients and healthcare professionals particularly in cases of increased media interest, the importance of distributing the DCHP to relevant pharmacists should be also noted. In addition to being target groups, national associations of doctors, nurses, and pharmacists should receive all DCHPs systematically in order to convey information to their members later.

In order to enable the DCHP to immediately attract attention, a striking red warning box may be used. The Ministry encourages use of such signs in order for healthcare professionals to easily recognize and focus on the text.

3- Communication Phase: Distribution of the DCHP

The communication phase should be executed in accordance with the communication plan agreed between the registration holder and the Ministry and should be closely monitored by all parties. All relevant parties should be immediately notified of a significant event or problem during the communication phase. If this situation shows that there is reason for an amendment in the communication plan or the need for further communication with health professionals, the registration holder and the Ministry should come upon an agreement on this.

4- Post-communication phase: Follow-up of DCHP

After the DCHP is distributed, a closing investigation should be carried out by the registration holder. During this investigation, it should be established whether there is any event or problem that arose during the communication phase and that necessitated any change in the communication plan; whether the communication plan has been implemented to the letter; and furthermore, whether there were any difficulties experienced during any of the phases above. These difficulties may concern the recipients' list, or the date or mechanism of distribution. The Ministry should be informed of the results of this investigation.

If the Ministry is not satisfied with the investigation, it may send a written request to the registration holder to correct the situation. Based on this information received, measures should be taken to prevent similar problems arising in the future. As part of integrated quality management, all parties should undertake an internal investigation concerning their own performances, and take appropriate measures in areas that need to be improved. In general, the DCHP's effect and reflections on public health should be evaluated with basic questions such as; "Has the DCHP been received on time? (This can be checked on a small sample group representing the target population)"; "Have recommendations and basic messages been understood and complied with? (This can be studied through surveys concerning healthcare professionals or other study designs)". This evaluation should be carried out by the registration holder, and in times when the DCHP is in particular a part of risk minimization activities compatible with a risk management plan, such an evaluation is very appropriate.

Template for Direct Communication with Healthcare Professionals

<Date>

<Document reference no.>

Direct Communication with Healthcare Professionals concerning <INN and Commercial Name(s)> with a <safety problem>

Summary

<Brief definition of a safety problem, recommendations to minimize risk (e.g. Contraindications, warnings/precautions) and if applicable, switching to alternative treatment under preferably subject headings >

< If applicable, recall information (e.g. Pharmacy or patient level, date of recall)>

<If applicable, declaration that the information has been approved by the Ministry/Registration Holder>

Style guide: Fonts used in the summary section should be larger than fonts used on other sections of the DCHP.

Detailed information on the safety issue

<At this point, important details on the safety issue together with the reason for the publication of the DCHP, (adverse drug effect, seriousness, declaration on suspected causality relationship, e.g. Pharmacodynamic mechanism, time relation, positive re-challenge or removal of the challenge, risk factors)>

<Risk/benefit evaluation of the drug>

<Amended Product Information text or preferably reference to an enclosed Product Information>

<An estimate concerning the frequency of the adverse effect, or estimate on reporting rates together with the estimated number of patients using drug>

<If applicable, declaration stating any relationship between the adverse drug effect and non-indicated usage>

<If applicable, a program for the follow-up activity(ies) to be conducted by the Registration Holder/Ministry>

Detailed information concerning activities for healthcare professionals

<If necessary, details of recommendations to minimize risk>

<If necessary, detailed additional instructions on how to use the new safety or therapeutic efficacy information>

Call for notification

<Reminder concerning the necessity of notification of adverse effects in accordance with the national spontaneous reporting system>

<Details of ways to make entries in the national reporting system (name, postal address, fax no., web site address)/ details on how to notify the Registration Holder>

Communication information

<Date of public communication and key points>

<If applicable, scope and distribution mechanism of the information to be given to the public or patients>

<Details on contact points to be applied for receiving more detailed information, relevant web site address(es), phone numbers and postal addresses>

Appendices:

<If applicable, amended Product Information text (with the amendments shown in a visible manner)>

<If necessary, detailed scientific information>

<If applicable, list of literature references>