ARAŞTIRMA RESEARCH

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Analysis of the Lack of Providing the Patient with Satisfactory and Reliable Information About Imported Medicines in Terms of Safety and Ethical Problems: Qualitative Research

Yurt Dışı İlaçlar Hakkında Hastaya Yeterli ve Güvenilir Bilgi Sağlanmamasının İlaç Güvenliği ve Etik Sorunlar Açısından Analizi: Nitel Araştırma

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ABSTRACT Objective: The Imported Medicine List was published for the first time on October 11, 2013 by the Ministry of Health of the Republic of Türkiye. The purpose of importing drugs from abroad is to supply the human medicinal products that are not licensed in our country and/or that are not available in the market for various reasons despite being licensed, on prescription for use in the diagnosis and treatment of diseases in emergencies. The aim of this qualitative research is to examine the information presented about these medicines on the imported medicine list and to evaluate the possible ethical problems that may be caused by insufficient information presentation. **Material and Methods:** The medicines on the 25/02/2022 Turkish Medicines and Medical Devices Agency imported medicine list were included in the analysis. First, between the dates 07-27 February 2022, it was determined whether these medicines had short product information and instructions for use on the Turkish Medicines and Medical Devices Agency website by searching for active substances. Then, all medicines were searched in the RxMediaPharma database by the active substance name, and those not found by this method were searched by the ATC code. Finally, the ethical implications of the issue were discussed and suggestions were presented. **Results:** The change in the number of active substances in the imported medicine list by years and the presence of generic and medicine-specific information in different Informed Consent Forms have been determined. The ambiguity of the criteria for keeping the unlicensed essential drugs used to meet the priority health needs of the population in the foreign-dependent list has been determined. **Conclusion:** The risks to patients' right to autonomy have been determined as the result of the lack of sufficient, adequate, and accurate information in the Informed Consent Forms carries risks for patients' rights to autonomy.

Keywords: Imported medicine; informed consent; ethical problem; right to health; autonomy

ÖZET Amaç: Yurt Dışı İlaç Listesi, Türkiye Cumhuriyeti Sağlık Bakanlığı tarafından ilk kez 11 Ekim 2013 tarihinde yayımlanmıştır. Yurt dışından ilaç ithalinde amaç, ülkemizde ruhsatı olmayan ve/veya ruhsatlı olmasına rağmen çeşitli nedenlerle piyasada bulunmayan beşerî tıbbi ürünlerin acil durumlarda, hastalıkların tanı ve tedavisinde kullanılmak üzere reçeteli olarak yurt dışından teminini sağlamaktır. Bu nitel araştırmanın amacı, yurt dışı ilaç listesindeki ilaçlarla ilgili sunulan bilgileri incelemek ve yetersiz bilgi sunumundan kaynaklanabilecek olası etik sorunları değerlendirmek ve öneriler sunulmaktır. **Gereç ve Yöntemler:** Bu araştırmaya, 25.02.2022 tarihinde yayımlanan Türkiye İlaç ve Tıbbi Cihaz Kurumu yurt dışı ilaç listesindeki ilaçlar dâhil edilmiştir. İlk olarak, 07-27 Şubat tarihleri arasında bu ilaçların Türkiye İlaç ve Tıbbi Cihaz Kurumu internet sitesinde etken madde taraması yapılarak kısa ürün bilgisi ve kullanım talimatı olup olmadığı belirlenmiştir. Daha sonra RxMediaPharma veri tabanında tüm ilaçlar etken madde adına göre aranmış ve bu yöntemle bulunamayanlar ATC kodu ile taranmıştır. Son olarak, konunun etik sonuçlarıyla ilgili tartışma yürütülüp, öneriler sunulmuştur. **Bulgular:** Yurt dışı ilaç listesindeki etken madde sayısının yıllara göre değişimi ve Aydınlatılmış Onam Formları'nın bazılarında jenerik bazılarında da ilaca özgü bilgilerin bulunduğu belirlenmiştir. Nüfusun öncelikli sağlık ihtiyaçlarını karşılamak için kullanılan ruhsatsız esansiyel ilaçların yurt dışı bağımlı yaratan listede tutulmasına ilişkin kriterlerin belirsizliği tespit edilmiştir. **Sonuç:** Aydınlatılmış Onam Formları'nda yeterli ve doğru bilgilerin bulunmaması sonucunda hastaların özerklik haklarına yönelik riskler belirlenmiştir.

Anahtar Kelimeler: İthal ilaç; aydınlatılmış onam; etik sorun; sağlık hakkı; özerklik

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In Türkiye the main purchaser of licenced drugs on the market is the Social Security Institution, as the general health insurance provider. This institution determines the pricing of licenced drugs with the "Decision on Pricing of Medicinal Products for Human Use".[1] According to this decision, the main buyer state reserves the right to determine the exchange rate value.

Another method for drugs that are not on sale in Türkiye but are prescribed by the physician considering that they must be used for the treatment of a patient is to import the drug by following the necessary procedures for that patient. This process is regulated by the "Guideline for Supply and Use of Medicines from Abroad" published by the Turkish Ministry of Health. In addition, the Ministry of Health has been making the process easier by regularly publishing a list of Overseas Medicines since October 11, 2013. The Imported Medicine List (IML) was published for the first time on October 11, 2013 by the Turkish Medicine and Medical Device Agency.[2] The purpose of importing medicines from abroad is to ensure the supply of medical products for human use, which are not licensed in our country and/or are not available in the market despite being licensed.[3]

When the sources related to importing drugs from abroad were examined, it was determined that the main documents were the guide, the drug list, and various informed consent forms, one general and a few drug specific. In our preliminary examination, we thought that there may be deficiencies in the information to be presented to the patient in order to inform a patient about drugs and to make an autonomous decision about her health. In addition, the number of drugs on the foreign drug list and the duration of being on the list were also remarkable. Another important issue was that some of the drugs on the list were also included in the World Health Organization (WHO) Essential Medicines list.[4] Essential drugs are defined by WHO as drugs used to meet the priority health needs of the population. The list was created for the first time in 1977 and it is updated every 2 years. This list, one of the main goals of which is the promotion of rational drug use, is based on first-line treatments. Countries and institutions create their own drug lists based on this list.

In this context, we thought that there could be three main ethical problems based on our preliminary investigations on drugs imported from abroad with the permission of the Ministry of Health:

1. Right to access adequate information: Insufficient information about the drug to be presented to the physician and the patient, whether the physician and the patient can access Turkish information about the active substance.

2. Respect for autonomy: Whether the informed consent forms (ICF) presented to the patient adequately support the patient's autonomous decision-making process in terms of the information they contain.

3. Right to access essential healthcare: Patients can only access some of the drugs in the WHO Essential Medicines List with this method.

Based on these 3 main ethical problems, we conducted various analyzes to examine the possible sub-ethical problems that this situation may cause, especially on a patient basis. We looked at situations that could have negative effects on a patient basis, so we focused on informed consent in particular. In addition, we also touched on the negative aspects of the misuse of limited resources for public health. Should the imported drug supply system be reconsidered in terms of aspects that have the risk of adversely affecting both the individual patient and the public health? What are the shortcomings in this regard? We carried out this study in order to determine such questions.

Accordingly, this study aims to examine the content and sufficiency of the information presented in the summary of product characteristics (SmPC) and user manuals about the ingredients of the medicines that are on the IML and to discuss 3 main ethical problems given above that may be caused by insufficient information presentation.

MATERIAL AND METHODS

The study was carried out between February 07-27, 2022. As the first IML was published on October 11, 2013, we selected one IML from the TMMDA website for a similar date (11^{th}±4 days of the October of

each year) and compared the number of active ingredients listed.[5] Then we evaluated the active ingredients in the most current list (February 25, 2022) at the time of the analysis for the presence of a SmPC and instructions for use (IU) on the TMMDA website.[6] Then, all active ingredient names were searched in the interactive drug information resource RxMediaPharma (İzmir, Turkey) database by the active substance name, and those not found by this method were searched by the ATC code. We also checked the WHO's Essential Medicines List if any of the active ingredients in the IML are also listed there. Comprehensive monographs of active substances without approved SmPC and/or IU were also examined in terms of the adequacy of information to be presented to the patient.

First, IML contents published by the Ministry of Health every year were compared according to years. Then we evaluated the general and 5 medication-specific ICF available at the TMMDA website for the presence of information that will fulfill the aim of the procedure, which is to able the patient to make an independent decision after receiving all the necessary information needed. It is important that the patient not only gets the information they need from the physician but also keeps them with ICF, which is a written document. In this regard, we have compiled the basic elements that should be in ICF by scanning both national and international sources as follows:[7,8]

- The patient's current state of health and the diagnosis made by the physician.
- The type, chance of success, and duration of the treatment are recommended by the physician.
- Who will perform the treatment, when, where, and how?
- Possible risks, and complications that may occur.
- Advantages and disadvantages of alternative treatment options.
- The possible outcomes in case of delay or rejection of treatment.
- Possible side effects of the drugs to be used.
- The living standards that the patient should follow after treatment.

Based on these key elements, we included the following criteria given in results in our generic and drug-specific ICF content comparison.

RESULTS

First, IML on the TMMDA website was dated October 11, 2013 and included 292 active ingredients and increased to around 400 in less than 1 year and stayed at this number since then. About half of the total of 419 (n=208; 52.2%) medicines have been on the list since 2014. The change in the number of active substances in the imported medicine list by years is shown in Figure 1. Among the active substances that were on the list since the first time IML published, there are products such as multivitamin-mineral complexes, vitamins, or medicines such as dapsone, and benztropine, which have been used since the 1950s and for centuries such as colchicine. There are also some products, for example, acebutolol, that were licensed and produced domestically but are not currently produced.[9]

There are some discrepancies in the list; amiloride+hydrochlorothiazide a licensed but not on the Turkish market or phenobarbital, again a licensed product in Türkiye, are on the list. The number of new active substances entered into the IML according to the years and their ratio to the total number is given in Table 1 as follows.

There was accessibly written information for patients and physicians regarding the active ingredients for 372 (88.78%) of the medicines. The number of active substances with SmPC and IU was 138 (32.94%) on the TMMDA website.[10] In TMMDA, the number of active substances that do not have

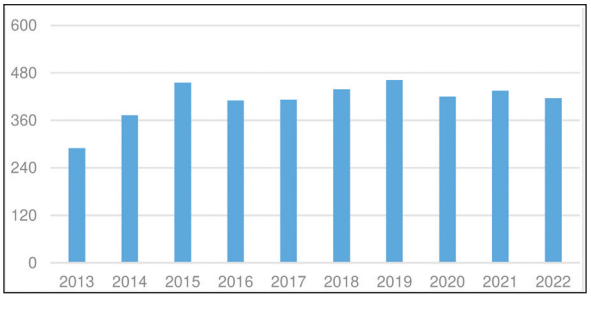

FIGURE 1: Change in the number of active substances in the imported medicine list by years.

TABLE 1: The number of new active substances entered into the Imported Medicines List according to the years and their ratio to the total number.

2014	2015	2016	2017	2018	2019	2020	2021
208 (49.64)	20 (4.77)	33 (7.88)	26 (6.21)	33 (7.88)	30 (7.16)	35 (8.35)	25 (5.97)

SmPC and IU, and that have information accessible as a monograph in the RxMediaPharma database, was found to be 29 (6.92%), while the number of SmPC and IU was 37 (8.83%). The information accessible via RxMedia is available for 66 (15.75%) active substances, not in TMMDA.

On the TMMDA IML page, there were one general, 5 (albumin-bound paclitaxel, anakinra, asparaginase erwinia chrysanthemi, idelalisib, risdiplam 1.19%) medicine-specific ICFs.[11] The medicine-specific ICFs contain approximately 2 pages of information about possible serious side effects. These forms were prepared in such a way that patients signed the statement about accepting all predicted or unpredicted side effects of the treatment. Table 2 comparatively shows how much of the information that should be provided by the generic and medicine-specific ICFs is presented in the current ICFs for medicines on the IML.[7,12]

Generic ICFs can be specified by filling the blanks let for the name of the treating physician, the diagnosis, and the name of the medicine. One of the generic ICFs contained a declaration that this medicine is the only treatment option, it is not subject to the Ministry of Health and TMMDA Good Manufacturing Practices guidelines, the indication for the

TABLE 2: Presence of generic and medicine-specific information in Informed Consent Forms.

	Generic ICF	ICF for paclitaxel bound to albumin	ICF for anakinra	ICF for asparaginase erwinia chrysanthemi	ICF for idelalisib	ICF for risdiplam
The patient's health status and diagnosis	Yes	No (There is only information that it is used in the treatment of adult breast cancer patients)	Yes	No	Yes	Yes
Type of treatment proposed	Yes	Yes	Yes	No	Yes	Yes
Chance of success and duration	No	No	No	No	No	No
Expected benefits from treatment	No	No	No	No	No	No
Risks of the treatment method for the patient's health	No	No	No	No	No	No
Use of prescribed medicines and possible side effects	No	Yes	Yes (no usage information)	Yes (no side effect information)	Yes (no usage information)	Yes
The consequences of the disease if the patient does not accept the recommended treatment	No	No	Yes	No	No	Yes
Possible treatment options and risks	Yes (information that it is the only option for treatment)	No	No	Yes (indirectly)	No	Yes
Special arrangements for different age groups and patients with reading difficulties/inability	No	No	No	No	No	No
Patient's voluntariness/willingness	Yes	Yes	Yes	Yes (The relative of the patient)	Yes	Yes
The information that the doctor can be reached when a problem is encountered during treatment	No	No	Yes	No	No	Yes
Signatures (physician, patient and at least 1 witness)	Only patient	Patient+physician	Patient+physician+ witness	Patient+physician+ witness	Patient+physician+ the relative of the patient+witness	Patient/the relative of the patient

ICF: Informed consent form.

use of the medicine is determined by the physician, and the patient is taking all responsibility for side effects.[11]

The SmPC for albumin-bound paclitaxel is only available in the English language.[10] Other formulations of paclitaxel active ingredients are licensed and the SmPC IU is available in Turkish. These SmPCs are more detailed than ICFs. In the form, *"I was informed by the physician about the side effects that may occur with the treatment to be given, taking into account the importance of my disease that requires the use of the medicine. I accept the administration of this medicine to me for the treatment of my current disease."* statement is included.

RxMediaPharma contains more comprehensive adverse effect information for anakinra than.[11] In the ICF prepared for asparaginase erwinia chrysanthemi, very superficial information was given.[11] The monograph is available on RxMedia and is more comprehensive.[9] The most comprehensive ICFs are for idelalisib. In addition, the patient signature is not *"I accept all possible risks of side effects",* it is *"I have been informed, my questions have been answered"*.[11]

The ICF prepared for risdiplam contains information that the patient can call the physician if a problem is encountered during the treatment.[11]

The efficacy and Side Effects Feedback Form (Annex-4) is designed as a general form. It was stated that a follow-up form should be filled out as soon as possible in case of serious side/adverse effects, progression of the disease, or death during the use of the imported medicine.[11] However, although there is a space to write the name of the medicine used in its content, the active substance, and the duration of the dose, the changes that occur with the use of the medicine in ophthalmology patients were questioned. The Turkish Pharmacovigilance Center (TPC) form, which is universally accepted and more comprehensive and more suitable for reporting adverse effects. Moreover, according to the current legislations and regulations, adverse drug reactions are reported using the form accepted and published by TPC and then forwarded to WHO Uppsala Monitoring Center.[5] In this state, the form seems to have been designed specifically for medicine.

Sixty-one of the active substances on the IML are also on WHO' essential medicine list (EML). Several of these medicines have been in use in the world since the 1950s and 1960s, such as procarbazine, diazoxide, and praziquantel were in the list since the first published one, or rifapentine which entered the list in 08 June, 2018. The SmPCs of 40 of these medicines is accessible via TMMDA. These are active ingredients that are either licensed in different formulations in Türkiye or have been licensed before and are no longer produced and/or imported or have not yet been put on the market despite being licensed. Only one of the products, meglumine antimoniate, used in the treatment of Leishmania, does not have a monograph in RxMedia. There is detailed monograph information about the other 60 active ingredients.

Four of the active substances on the WHO-EML is used in Public Health General Directorate, Zoonotic and Vectorial Diseases Department. Medicines specific to the treatment of this disease are also available and distributed by this department.[12]

Although 13 of the active substances on the WHO-EML are licensed, one of them is no longer produced in Türkiye, and another one is licensed and yet has not been put on the market.[9] These include well-known important medicines such as nitroprusside, naloxone, erythromycin, and amiloride.

DISCUSSION

According to Article 11 of the Law on Pharmaceutical Trades, No. 984, dated 2/3/1927, "*... It is obligatory to obtain a license within 2 years from the application date at the latest. The President is authorized to decide on the continuation of the supply of medicines for which a license application has not been made or for which a license has not been obtained.*"[13] The 6th paragraph of Article 5 of the Guidelines for the Supply and Use of Medicines from Abroad also refers to this law and states that "*... among the products that have completed 3 years, those that are deemed suitable to be included in the list after being evaluated by the Overseas Medicines Evaluation Commission, will be submitted to the approval of the Presidency*."[11]

These legislations allow some medicines to remain on the IML for long periods without applying to obtain a license. The criteria to keep unlicensed medicines on the list are not clear. Depending on this ambiguity, some essential medicines have been kept on the list for a long time. For example, human coagulation factors XI and XIII, which are vital in hereditary bleeding disorders, are on the WHO-EML, but since they are not licensed or produced in the country they have to be brought in with an import permit. Likewise, other medicines on the WHO-EML, such as rifapentine, procarbazine, diazoxide, and praziquantel have been in use in the world since the 1950s and 1960s are still on the IML in Türkiye.[2,14] Access to essential medicines is a fundamental element of the right to health; therefore, the fact that these drugs are in the IML does not correspond to the purpose of creating the IML in question.

As long as the medicines on the IML are not licensed they pose risk for the patients in 3 ways.

First, the reluctance to apply for a license puts the fulfillment of the right to health, indirectly, if not firsthand, at risk. The Alma Ata Declaration states that health is a fundamental human right and the attainment of the highest possible level of health is the most important worldwide social goal.[15] The concept of essential medicines was launched by WHO in 1977. Since then, sustainable and timely access to essential medicines has been one of the key elements of exercising the right to health and fairness in the health system.[16] The difficulties experienced in accessing essential medicines such as slowness or ignorance of licensing processes or the information about these in the native language limit the right to health. Therefore, prioritizing incentives for the in-country production and licensing of these medicines is recommended.

Second, there is no legislative obligation regarding the provision of written information for unlicensed medicines. This avoids both patients' and physicians' access to adequate information about the medicine in their language. In the boxes of imported medicines, there is information only in the language of the country from which it was imported. This may turn into a vital safety risk when an emergency and/or life-threatening adverse reaction develops.

Third, the legal responsibility that is put on companies for licensed medicines is vague in terms of unlicensed medicines on the IML. According to Turkish legislation, the license holders of the products bear the legal responsibility for adverse reactions to licensed medicines on the market. However, it is not clear who bears the legal responsibility for imported medicines that are not licensed in Türkiye. Current ICFs suggest that this responsibility is entirely encumbered on the patients by stripping health authorities or medicine companies from their responsibility of accountability to the patients. This situation puts patients in a vulnerable position both legally and ethically. Placing all responsibility for the consequences of the decision taken at the end of the informed consent process on the patient damages the element of accountability for the other actors and deepens the vulnerability of the patients.

Moreover, the lack of sufficient, adequate, and accurate information in the ICFs carries risks for patients' right to autonomy.[17] The ICF is a written document to provide adequate information to the patients to exercise their autonomy in decision-making regarding their health care.[18] There are 3 main criteria for an ethically appropriate informed consent; first, the patient must be competent, second adequately informed, and third not coerced.[19] The lack of information about the suggested treatment protocol limits the autonomy of the patients and breaches the element of trust in physicians doing their best to provide benefits to their patients.

Finally, the economic feasibility of keeping the medicines on the IML has ethical implications in terms of the allocation of scarce resources. In the United States, certain types of medicines are excluded from the definition of a prescription medicine eligible for importation including controlled substances, biological products (including insulin), infused medicines, intravenously injected medicines, and inhaled anesthetics.[20-22] Before the last update in February 2022, import drug pricing was based on 1 Euro=4.58 TL, and after the update, the Euro rate was calculated to be 6.30 TL, resulting in an increase of

30% in prices. When this decision is taken, if it is taken into account that the Euro exchange rate of the Central Bank of the Republic of Türkiye is 15.35 TL, there is a difference of approximately 2.5 times.[23,24] This difference makes Türkiye an attractive market for imported drugs and creates the risk that some drugs will not be put on the market. Medicines that are not put on the market due to pricing can only be accessed by importing from abroad, and this may put more burden on the health budget. Although we haven't evaluated the economic burden of accessing medicines via this system, it is not unreasonable to assume it is costly based on the more than 2.5-3 times difference between the exchange rates set by Ministry of Health and current real rates.

CONCLUSION

Our main aim was not to denigrate the current imported drug system from abroad but to illuminate some improvement points. We have shown that there are points of improvement that we predict with the results we obtained such as the presence of active substances that were on the list since the first time IML published, some discrepancies in the list, the inadequate information in the generic and drug-specific ICF and the presence of the active substances on the IML are also on the WHO-EML. As a result of our analysis the following revisions regarding the IML process are recommended:

- Under the responsibility of TMMDA, Turkish Pharmacists' Association, which is the responsible agency for importing the medicines, and a few private companies, should translate the SmPC of the medicine approved by an institution such as FDA/Europe, the Middle East and Africa and present it to both the prescribing physician and the patient.
- Encouraging domestic production of medical products for human use with expired patents and relaunching products previously licensed in Türkiye. Institutional factories can be encouraged to produce essential medicines to reduce foreign dependency. Medicines such as diuretics or anti-epileptics, which are very easy to manufacture, can be produced in Türkiye.
- Taking steps for these medicines to enter the Turkish market instead of using foreign medicine procurement procedures for chronic and emerging diseases; eg. taking measures to make the Turkish market more attractive for pharmaceutical companies.
- Considering the risks of a high number (approximately 400) of medicine dependency in the event of a disaster (natural or man-made) in terms of public health safety.

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Conflict of Interest

No conflicts of interest between the authors and / or family members of the scientific and medical committee members or members of the potential conflicts of interest, counseling, expertise, working conditions, share holding and similar situations in any firm.

Authorship Contributions

Idea/Concept: *Müberra Devrim Güner;* ***Design:*** *Müberra Devrim Güner, Perihan Elif Ekekçi, Banu Buruk;* ***Data Collection and/or Processing:*** *Müberra Devrim Güner;* ***Analysis and/or Interpretation:*** *Perihan Elif Ekekçi, Banu Buruk;* ***Literature Review:*** *Müberra Devrim Güner, Perihan Elif Ekekçi, Banu Buruk;* ***Writing the Article:*** *Müberra Devrim Güner, Perihan Elif Ekekçi, Banu Buruk;* ***Critical Review:*** *Müberra Devrim Güner, Perihan Elif Ekekçi, Banu Buruk.*

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