The physician’s guide to importing a medicine approved abroad

A step by step guide on how to import a medicine that is not yet approved in your country
How do Patients import their own medicines?

Patients with life-threatening or debilitating disease have the right to access, purchase, and import medicines that are potentially life-saving or able to improve quality of life.

Patients and/or their doctors can do this on the so-called named patient import basis, a legal exception (implemented in the national regulations of >80 countries) of the general rule that a medicine can only be marketed with market approval.

The general requirements for the exception to import a non-approved medicine are:

- Not available in the patient’s country but approved elsewhere,
- Life-threatening or debilitating disease,
- No alternative available,
- Personal Use for an individual patient,
- Prescription from the patient’s treating doctor.

You can contact TheSocialMedwork at support@thesocialmedwork.com and we’ll provide you with the relevant legislation for your country.

What does this mean for healthcare providers?

Everyday, our knowledgeable and compassionate support team is in contact with treating doctors, medical specialists and institutions, as well as pharmacists. As a healthcare provider you can expand your treatment portfolio and enable your patient to access the best possible not (yet) approved medicine in your country.

When we work with healthcare professionals we get asked some common questions and this guide tries to answer some of these questions.
Is this legal?

TheSocialMedwork is a legally recognised company registered with and audited by the Dutch Ministry of Health in The Hague, as a pharmaceutical wholesale distributor and medicines intermediary under TheSocialMedwork B.V., registration numbers 6730 BEM and 6258 G. We operate in over 85 different countries and have serviced thousands of patients to date with a 100% safe and successful delivery rate.

We are required to follow a strict set of rules laid out by the Ministries of Health, the Named Patient regulation and customs agencies in those areas of the world.

We carefully choose and audit our suppliers based on the origin and quality of the products they offer as well as their company’s qualifications and ability to maintain a reliable stock. We negotiate to get the lowest price so we can pass along these savings to the patients we support.

What are the risks to me?

Prescribing medicines not yet approved in your country to your patient is done completely at your best judgement and discretion. Our support, legal and sourcing teams are here to answer any questions to mitigate any questions or risk you might have.

It is completely safe and legal for physicians to prescribe unlicensed or not yet approved medicines to their patients as long as you are prescribing what you believe is according to medical and ethical standards in the best interests of your patient in terms of their ongoing treatment.

When prescribing an unlicensed medicine you must:

- be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy;

- take responsibility for prescribing the medicine and for overseeing the patient’s care, monitoring, and any follow up treatment, or ensure that arrangements are made for another suitable doctor to do so;

- make a clear, accurate and legible record of all medicines prescribed and, where you are not following common practice, your reasons for prescribing an unlicensed medicine.
Is the medicine you supply authentic?

We only supply the original manufactured medicines which are sourced through our GDP-compliant Full-line Wholesaler (FLW) network and a partner network of manufacturers.

We know that treating doctors have so much to do in very little time and that a Named Patient often does not have the time or energy to explore every possible avenue, even though both doctor and patient may wish otherwise.

We happily share whatever information we have on the medicines that we can provide and their sources with you so that you can make the most informed, efficient and effective decision possible for your patient's best treatment results.

Who is TheSocialMedwork and what is your role?

Somewhere in the world, someone needs special medication to improve or save their life. Somewhere else in the world, this medication has been approved. Unfortunately, this is not an unusual scenario. TheSocialMedwork aims to bridge that gap.

We at TheSocialMedwork have all been impacted by this disconnect on a personal level. So we feel very strongly that our loved ones, your loved ones, your patients and everyone deserves a fair chance at a better life. Early access-type programmes are a means to achieve this and we want to connect you and your patients to those opportunities.

As one of the first companies to provide the Named Patient Service, we are aware that we are entering a new frontier. By providing more information on this subject, we aim to educate patients, healthcare professionals and policymakers all over the world so they understand that they have the power to effect positive change.

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When can you support patients?

At TheSocialMedwork our mission is to be a portal so that everyone, no matter who they are or where they live, has equal, fast and fair access to the latest and best medicines. As an intermediary registered with the Dutch Ministry of Health, we work on behalf of the individual patient, on a Named Patient import basis, in accord with their treating doctor. We support them in accessing medicines when certain requirements are fulfilled:

- There is no alternative on the market.
- The medicine is for personal use.
- The patient has a prescription-letter from their doctor in their home country.
- The medicine has market approval in another country and is not yet approved or available in their own country.
- The medicine must be dispensed from a pharmacy.

In the Named Patient Service that we provide, we encourage the patient to consult their doctor to establish their best course of treatment. Once we get a prescription from the treating physician for that treatment, we confirm the validity of the information given, then manage all the next steps - from sourcing to shipping, to customs and delivery, as well as following up to make sure that everything was received safely and in good order.

We can only help your patient access new and elsewhere approved medicines safely and legally with your support. We will happily also keep you updated of the process from the moment we support your patient and until the medicine is safely delivered to them.
Help with accessing and importing a medicine into your country.

Our Patient Support Team can also assist you and your patient when the medicine they are trying to access is approved somewhere else and not yet available in your country.

Email: support@thesocialmedwork.com
Call: +31 20 808 4414
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