TheSocialMedwork: providing access to overseas medicines

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TheSocialMedwork is an online service that helps patients across the world to access new medicines that are not approved in their own country. Joy Ogden talks to its founder and CEO Sjaak Vink about the service’s achievements, obstacles and long-term goals.

When you have a diagnosis of breast cancer, as I know from personal experience, you are scared. You want expert medical help and you want it right away. You want the best medication there is, and you want it right away.

Sometimes you are lucky – as I was – in getting the expert medical help quickly and you don’t need extensive surgery, chemotherapy or new, possibly life-saving drugs that you hear about but then discover are approved for use overseas but are not yet available for patients in the UK.

Not everyone is as fortunate as I was, and many people who have life-threatening or seriously debilitating conditions, or whose relatives do, feel desperate about their own or their loved one’s situation, and angry at the inequity when they hear about the cutting-edge drugs available to, for instance, American and Japanese people but not to UK citizens.

Sjaak Vink found himself in this situation when his friend was diagnosed with amyotrophic lateral sclerosis (ALS; more commonly known in the UK as motor neurone disease) and his doctor had heard of a medicine that was approved in the USA but was not yet available in his home country. Mr Vink says it became available there three months after his friend died, adding: “So we will never know whether he might have benefitted from it.”

Spurred by his friend’s death, in 2012 he co-founded myTomorrows, a social enterprise based in Amsterdam, with former Crucell CEO Dr Ronald Brus, to help patients gain early access to drugs undergoing clinical trials, via compassionate use laws.

Addressing delayed access to approved drugs

Mr Vink then began to investigate the pharma industry’s regulatory processes and discovered that there are differently named regulations in place in every country throughout the world to enable access to treatments that have already been approved somewhere else in the world but are not yet available in the patient’s own home country. In 2013, using the new-found information, he began to advocate for medicines access for a group of cancer patients, in a bid to combat the
blatant unfairness of differing access to medicines approved in one country but not yet available across the world.

He says: “It was really out of personal motivation that I got onto this topic.”

These early experiences then inspired Mr Vink to found TheSocialMedwork as a social enterprise in 2014, together with James Heywood (scientist, big-data expert and co-founder and Chairman of Patients Like Me), Bernard Muller (founder of Project MinE and Treeway) and Katrin Schepp, Attorney-at-Law, all with personal experiences of the distressing effects of delayed access to new, potentially life-changing drugs.

TheSocialMedwork became the first ever holder of the medicine intermediary licence, created by law from an EU directive in the Netherlands, which allows them to source medicines within the EU for personal use, unlike wholesalers and pharmaceutical companies, who are not allowed to sell medicines to individuals.

**Providing faster access to medicines**

TheSocialMedwork is registered with the Dutch Ministry of Health in The Hague and works in accordance with the UK government’s Medicines and Healthcare products Regulatory Agency (MHRA). Mr Vink is CEO and its mission is to give all patients throughout the world the same opportunity to buy newly developed medicines for serious and life-debilitating conditions safely, securely and legally as soon as they are approved by the first authority. This could give patients access months or even years faster and mean the difference between life and death for some.

TheSocialMedwork has a comprehensive website, listing a wide range of new medicines under the categories of oncology, dermatology, hepatology, infectiology, neurology, pulmonology and rheumatology (see Figure 1). To date, TheSocialMedwork says it has supplied over 2500 medicines in over 70 countries, each of which must have a prescription signed by a local specialist and a doctor’s letter to say it is for personal use only. It notes that “at a conservative estimate over 1000 doctors worldwide have agreed to prescribe medicines to patients in this way”.

The three drugs most often delivered by TheSocialMedwork to patients in the UK are: erenumab (Aimovig, for the prevention of migraine, granted an EU marketing authorisation in July 2018 but awaiting a final decision from NICE); ibudilast (Ketas, used for the treatment of bronchial asthma and cerebrovascular disorders); and edaravone (Radicava, used to treat ALS, approved by the US Food and Drug Administration [FDA] in May 2017 and awaiting EU approval).

TheSocialMedwork says its records show that only 12 to 14 doctors in the UK have so far written prescriptions to get medicines from the organisation, adding that: “One of the big reasons we don’t have as many prescriptions from the UK is that you have a lot of medicines available to you already, which is a good thing!”

Mr Vink says: “There is only one solution to making newly approved medicines available as quickly as possible, and that is a globally harmonised approval system, at least among those countries that have trustworthy regulators in place. That would be really helpful, but you can see that the EMA has been struggling for over 10 years to get a harmonised system in Europe and to date has only partially succeeded in that. Once a medicine is approved within Europe then every home country still has to approve as well – you guys in the UK with the NHS don’t do a bad job on that because, most of the time, you take it up rapidly, and Germany is similar, but in many countries, after EMA approval, it still takes 12, 18, sometimes 24 months before the medicine is available. Up to me, it would happen tomorrow!”

**Brexit’s possible impact**

However, with Brexit looming, doctors and patients in the UK have new anxieties about possible disruptions in accessing medicines, with concerns about the potentially profound consequences for the NHS and the health of the UK population.

If the Brexit concerns become realities, might TheSocialMedwork find a new role there? Mr Vink says: “If there’s a need to co-operate to help bridge a gap that occurs all of a sudden because of Brexit, then for sure we will do that. As a patient, you are so vulnerable and also as a doctor you are trying, with your toolkit, to do the best thing possible for your patient, so if part of your toolkit is suddenly taken from you it’s really horrible. So, yes, for sure we welcome every co-operation needed to guarantee that patients will be able to access the medicines they need.”

The MHRA held an online consultation from 4 October to 1 November 2018 on how its legislation and regulatory processes would have to be modified in the event of a ‘no-deal’ UK exit from the EU, with no implementation period, and has now published updated guidance on this.¹ MHRA Chief Executive Officer Dr Ian Hudson said: “The MHRA’s vision for the future of medicines and medical devices regulations is underpinned by three clear principles: that patients should not be disadvantaged; that innovators should be able to get products to the UK market as quickly and simply as possible; and that the UK continues to play a leading role promoting public health. In the unlikely event of a no-deal [Brexit] scenario, the UK will strive to be at the forefront of regulatory innovation and processes. For example, looking at ways to reduce the length of time required to approve new medicines.”

Responding to the consultation, the Association of British Pharmaceutical Industries (ABPI) Deputy Chief Scientific Officer Dr Sheuli Porkess said: “It is important that the UK puts plans in place for a ‘no-deal’ Brexit. Pharmaceutical
companies continue to plan for all possible outcomes from the negotiations and we will continue to work closely with the government on their plans.

“But we have been very clear that the best way to protect patients and public health in the UK and in the EU is to agree future co-operation between the MHRA and the EMA on the regulation of medicines. We continue to urge both the UK and EU negotiators to rapidly agree the terms of the UK’s withdrawal and a future relationship based on co-operation to protect public health, control infectious diseases and manage medicine safety.”

Negotiating drug prices
Some of the drugs not yet available are phenomenally expensive, so what can be done about this? Mr Vink says: “Almost every week we succeed in getting price reductions on certain products. One person in our team is constantly negotiating prices. We are working extremely hard to try to lower these prices and very often we see that a product just recently introduced to the market has a high price, then gradually, where it becomes available in more countries and for more markets, prices drop. Just one example – we had to sell a specific type of breast cancer drug for about €16,000 because at the time that was the industry price, and now, about 18 months later, it is only €4000. But that’s not unusual – it often happens.

“Next to that, we are working with a couple of professors from Erasmus University Rotterdam on an algorithm they have developed on fair pricing of medicines, which they published in Nature recently. If you know the market prices at any one moment, you use the algorithm to calculate the price it should actually be. We look forward to using these algorithms as much as possible, then having very open-ended discussions with the industry because there is no use in blaming or shaming, we want to try to find new ways and have more dialogue with each other.”

The cost of individual medicines and for individual patients varies, depending on the type of medicine and the country it is being delivered to. For instance, a biological medicine such as the antimigraine drug erenumab needs to be refrigerated during transport, therefore it costs more to ship, and the price will be determined by how long it needs to be kept cold, how urgent delivery is, etc. In some countries with national health systems, the costs are reimbursed but in the UK, the patient is required to pay all the costs, plus a named-patient support fee, which is 10% of the cost of the medicine, but capped at €295.

What are TheSocialMedwork’s long-term goals?
Mr Vink has plans for the data that TheSocialMedwork collects and says: “Sometimes there are rare diseases with only small numbers of patients in each country, but because we have patients in over 70 countries, we sometimes have really insightful data on these patients. We are starting to grab these data and improve their quality. Gradually we’ll reach a situation in which the data will give really good insights into the efficacy of medicines and we intend to share that very transparently with the world, because that’s what we’re also about – improving health and creating transparency.”

Mr Vink says that accessibility was the thing that worried him most when he started, because of his friend’s situation, but now affordability is high on his list of priorities. He explains that he and his colleagues are working on creating better pricing mechanisms, while still maintaining a very innovative culture. Ultimately, he would like to help to create a universal basic healthcare system, where industry, doctors, patient organisations and politicians work together.

He adds: “Will it happen tomorrow? No, it will not. But can we dream about it, please? Can we talk about it? Can we work on it and make a change by taking a step every single day? Yes, of course we can.”

Meanwhile, if in the short term TheSocialMedwork could extend access to effective drugs for personal use – and offer help in the event of disruptions in the wake of Brexit negotiations – it could provide a welcome ray of hope to doctors and patients.

Reference

Declaration of interests
None to declare.

Joy Ogden is a freelance journalist