Drug licencing and further therapeutic benefit

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Introduction

The process of discovering new uses for old pharmaceuticals is known as drug rediscovery, drug repurposing, or drug repositioning, and while it is a novel topic, it is not a new idea. Several successfully rediscovered medications are now commonly utilised in clinical practise. Sildenafil, for example, was originally meant to treat angina pectoris but was repurposed as an erectile dysfunction medicine due to prolonged erections as an unforeseen side occurrence. Similarly, minoxidil was created to treat ulcers, but early studies revealed that it was a vasodilator, and it was subsequently repurposed for severe hypertension. Then, minoxidil's effectiveness studies as an antihypertensive medication revealed unexpected hair growth as a side effect, and the medicine was repositioned for the treatment of alopecia. Many successful drug rediscoveries were fortuitous, and hence lucky, events that occurred during or before the medicine's commercial exclusivity. Drugs that are already authorised, on the other hand, can be repositioned for new indications. As an example, thalidomide was licenced for morning sickness in pregnant women in the 1950s and repositioned for the treatment of multiple myeloma in 2006. Traditional drug development, which is expensive and time-consuming, has (financial) benefits over drug rediscovery. Because the medicine has already been studied and used, there is a wealth of information accessible concerning the safety and quality of the repurposed drug. There is also a lower likelihood of unanticipated adverse effects as a result. The rediscovery of generic medications is a difficult task in the Netherlands and other European nations since there is no consistent regulatory framework or marketing legislation in place. This absence of a legal framework was highlighted in 2001, when thioguanine, which was initially designed for leukaemia, was repurposed as a rescue immunosuppressive medication for the treatment of patients with Inflammatory Bowel Disease (IBD). The European Thioguanine Working Party advocated re-registration of thioguanine to widen the spectrum of treatment choices and raise awareness about alternative medicines for IBD. Pharmaceutical and health insurance firms initially expressed little interest for a variety of reasons, including but not limited to pharmaceutical (an expired patent), medical (controversial outcomes of this medicine in early clinical studies), and financial (reimbursement) concerns.

The issue over timely access to novel therapies, product withdrawals, and post approval label changes regularly undermines public and political faith in the present medication development and approved process. The quantity of upfront data necessary to promote a new medicine has increased, partly in reaction to consumer advocates and the medical community as well as developments in regulatory, bench, and clinical sciences. Current scientific and regulatory methods to marketing authorisation rely on Randomised Controlled Trials (RCTs) to offer evidence on safety and efficacy, but data on real-life comparative effectiveness are needed to support clinician and payer choices. The issue over timely access to novel therapies, product withdrawals, and postapproval label changes regularly undermines public and political faith in the present medication development and approved process.

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The Licensing Industry- Until around 35 years ago, big pharmaceutical businesses vertically integrated drug discovery, development, and marketing operations. This structure shifted as a result of a succession of scientific advancements beginning in the mid-1970s that significantly abolished entry barriers to medication research. In the decades that followed, a sliver of biotechnology businesses concentrating on early-stage innovative activities emerged. These firms, which are often backed by venture capital, are typically led by academic scientists with the purpose of "translating" their research discoveries into medicinal technology. Their innovations are commercialised in three ways: I by licencing, through trade sales and through self-commercialization. Biotechnology businesses that choose the first option dominate the supply side of the licencing market. Licensing occurs when the "inventing" business sells the commercialization rights to another firm for a group of developing cures. Those who sell are referred to as "out-licensors," while those who buy are referred to as "in-licensors." Because we are focusing on huge pharmaceutical "buyers," we will use "licencing" instead than "in-licensing" (unless difference is essential). These deals are based on negotiated contracts that generally provide the majority of the possible remuneration on a contingent basis (milestone payments and market income royalties). This contingent component's goals are to disperse risk, reduce informational issues, and secure the biotechnology firm's continuous participation in development efforts. Incentives for Licensing- From the perspective of in-licensing pharmaceutical companies, licencing is the most efficient and fastest way to incorporate cutting-edge innovations into their pipelines.

The ability to profit from the "complementary assets" of the (in-licensing) partner is a significant reason for biotechnology enterprises to choose licencing over self-commercialization. Aside from money, these competencies may include "know-how" (e.g., regulatory affairs and clinical trial execution) as well as assets critical for mass commercialization (e.g., branded reputation and existing sales teams). As a result, licencing, as opposed to self-commercialization, is better suited for the development of medicines aimed at big markets or requiring sophisticated or costly clinical studies. The present medication licencing system is based on the idea that regulators should force drug firms to complete the whole scope of work to completely prove safety and effectiveness before licencing. To a large portion of the general population, this means that any patient receiving the medicine receives 100 percent benefit and bears zero danger. In truth, no medicine is 100% safe and effective, thus this is unattainable under any licencing scheme. The concept of AL may give rise to the assumption that authorities are decreasing initial entry barriers and letting untested medications on the market. This is not supported by current findings. One of the primary goals of the AL scheme is to collect more robust and useful data sooner and throughout the product development process. Any shift toward a more adaptive approach would have to be accompanied by appropriate disclosures to key stakeholders and assurance that the necessary post–

initial authorization capabilities exist for continuing monitoring of medical items for which AL has been applied.

Suggestions for Improving the Rediscovery of Ancient Medications

Needless to mention, proper usage of outdated medications helps public health. There is presently no clear structured drug regulation mechanism in the EU that assures the development and registration of new generic pharmaceuticals. To prevent pharmaceutical corporations from charging exorbitant prices for pharmaceuticals, drug regulatory reform and marketing authorisation for new drugs, as well as government control, are required. Previously, comparable issues in the administration of orphan and paediatric pharmaceuticals were resolved by implementing regulations in the EU and FDA, indicating that assisting patients with rare diseases was more important than profit. In the instance of generic drug rediscovery, such as in the case of thioguanine, an analogous treatment strategy may be required to help patients through rescue medicines. Another proposal would be to follow the FDA's strategy for rediscovered generic medications. A longer duration of market exclusivity regulation should be more than three years to make this proposition of financial interest to pharmaceutical corporations. and EMA is critical for encouraging an open discussion between regulatory bodies and pharmaceutical applicants. A procedure of this type should ensure patient safety by avoiding ineffective and harmful medications from re-entering the market and by providing clear directions for the successful development and clinical usage of a rediscovered medicine. The benefit risk profile (i.e., the effectiveness and safety of the medicine in the population) should be favourable, and the clinical equivalence of the repurposed drug should be thoroughly explored and demonstrated. Furthermore, clinical trial data should show that the rediscovered medicine meets the medical demands of patients. Drug rediscovery is significant because it can expand treatment alternatives while lowering drug-development costs. However, a planned methodology for continued research of existing medications is required to maximise licencing and minimise lengthy procedures, as was the case with the repositioning of thioguanine for IBD in the Netherlands. In Europe, regulatory reform and market control are required to guarantee that every generic medication is used to its maximum potential and to prevent pharmaceutical corporations from charging exorbitant prices. Thiosix, the current conditionally approved thioguanine molecule, has been accessible since 2015 and is progressively being prescribed in the Netherlands for the treatment of IBD.

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