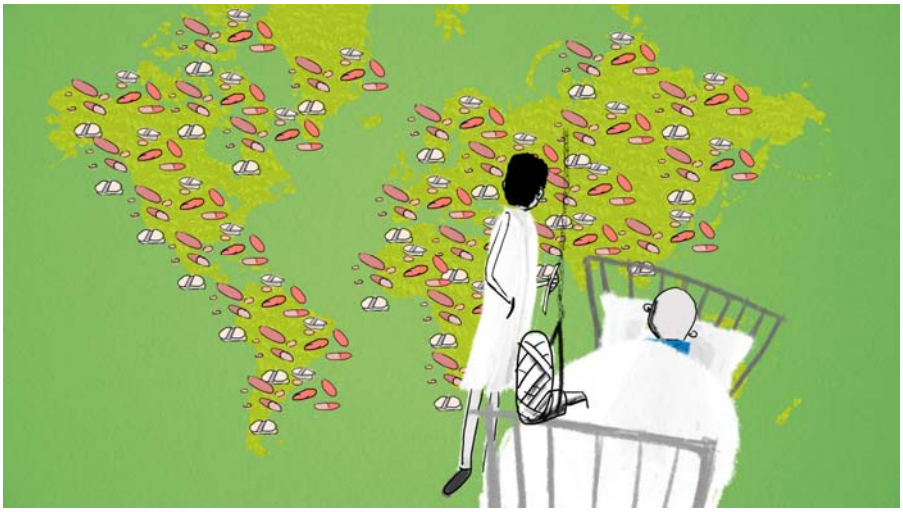
Added Therapeutic Value: European citizens should get their money's worth

Purpose

This paper highlights an alarming trend in the European pharmaceutical market, in that the majority of medicines authorised for use have little to no added therapeutic value (ATV) in comparison to existing medicines. It demonstrates how policy makers can take steps both to reduce the number of these so-called 'me too' drugs and to stimulate true innovation meeting public health needs.

Problem description

Since the 1990s, independent reviews have found that 85 to 90 per cent of all new drugs provide few or no clinical advantage to patients. In a study that was published in the British Medical Journal[1], scientists stated that there has been a decline in the production of medicines which offer clinical advances on medicines already on the market. This is cause for concern as this means that public money is spent on new costly medicines which have limited added therapeutic value while urgently needed medicines such as antibiotics are not being developed. It is especially alarming in the context of the current economic crisis. Often only large injections of public funds or the promise of patent extensions persuade the pharmaceutical industry to develop drugs with a less interesting commercial profile. Thus European citizens are paying twice; they pay a high price (through insurance premiums) for unnecessary, low ATV drugs whilst paying (through taxes) for the development of the drugs they really need. It is time that EU citizens get their money's worth.



1. Lexchin and Light, 2012.

Evidence

These figures are substantiated by recent data from three EU member states, collected with assistance from three independent bulletin members of the International Society of Drug Bulletins (ISDB). Their findings are consistent.

Germany:

As of 1 January 2011 the Act on the Reform of the Market for Medicinal products (AMNOG) came into force, requiring firstly that drugs be evaluated to see if they are better than existing treatment or not and, secondly, that a price be assigned in light of this assessment. Of the 78 judgments made by September 2013,[2] 1% of the drugs evaluated had less benefit than existing treatments (- -), 55 % had no additional benefit (-), 24 % had minor additional benefit (+/-), 12 % had considerable additional benefit (+), and 0 % had major additional benefit (++).

France:

Over the last 10 years, an exhaustive analysis by La Revue Prescrire of all new drugs marketed in France finds that less than 25% of drugs represented a therapeutic advance, including very minor advances. Over 50% represented no advance at all, and on average 15 to 20 % were judged to be even of more harm than benefit.[3] Different studies showed that, over the years, Prescrire's ratings of ATV are consistent with the results of the ratings by the French "transparency committee" (Haute autorité de santé), the Swedish drug regulatory agency and the Canadian Human Drug Advisory Panel.

The Netherlands:

From September 2000 to February 2014 the Geneesmiddelenbulletin (Dutch Drug Bulletin) reviewed 112 new drugs that were mainly relevant for primary care. It appeared that 1 % of the drugs had less benefit than existing treatments (- -), about 50 % had no additional benefit (-), about 45 % had a doubtful additional benefit (+/-), 4 % were judged a useful medicine(+), and 0 % had major additional benefit over the current existing arsenal (++).[4]

EU Policy framework

The pillars of EU medicinal products legislation are Directive 2001/83/EC and Regulation 726/2004 which describe the requirements and procedures for pharmaceutical companies to be granted a marketing authorisation for their new drugs.

Currently the European Medicines Agency and national Drug Regulatory Agencies use three criteria for marketing authorisation: Pharmaceutical quality, safety and efficacy. A new medicine can be granted access merely by showing some efficacy when compared to a placebo (sometimes on outcomes which are not clinically relevant), while not being too toxic. However, new drugs are not required to be compared to the prevailing alternative and there is no requirement for added therapeutic value in EU legislation. That leads to innovation failure and even to therapeutic regression when new drugs are more dangerous than well-established alternatives.

2. Pharma-Brief 8-9/2013
3. Drug developments in 2013: little progress but the authorities take a few positive steps to protect patients." Prescrire Int 2014; 23 (148) 107-110
4. In 2010 the 5 categories were changed into 3 categories because of the fact that the two categories on the outskirts (++ and - -) were hardly used.

5. The so-called 'adaptive-licensing' approach is presented as a "prospectively planned process starting with the early authorisation of a medicine in a restricted patient population, followed by iterative phases of evidence-gathering and the adaptation of the marketing authorisation to allow broader patient populations to access the medicine". Contrary to conditional marketing authorisations (MA) or compassionate uses., it will not be restricted to situations where there is an unmet medical need, but rather used to speed up the marketing authorisation procedure for all new medicines even if they do not meet a public health need.

It is in the interest of the European citizen that added therapeutic value is assessed before granting a marketing authorisation. This issue should be prioritised at EU level and added therapeutic value should be mainstreamed in policies of the EMA. It would benefit the European citizen more than recent approaches such as "adaptive licensing"[5], which will weaken evaluation requirements. Moreover, evidence on added therapeutic value would help national reimbursement agencies in their decision-making. Linking the reimbursement of a drug to its added therapeutic value makes it less profitable to develop "me-toos", and the pharmaceutical industry will thereby be stimulated to invest more in medicines that address public health needs.

We ask the European Parliament, the European Commission and the Council of Ministers to acknowledge the importance of added therapeutic value in new medicines both for the benefit of public health and to stimulate the development of truly innovative medicines and a competitive European pharmaceutical market.

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