'The industry is committing itself to making information available on all clinical trials…'

editorial

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Transparency is the key to clinical trial agreement

Transparency and public trust are extremely important in the development of new medicines. If the pharmaceutical industry is to continue to provide innovative new medicines, there needs to be greater public understanding of how these developments come about. In an industry where the cost of developing new medicines is so high that breaking even, let alone making a profit, takes years, getting this right is crucial. The cost of developing a new medicine is approximately UK£550 million – 60% of which is spent in clinical trials. It is for this reason that the Association of the British Pharmaceutical Industry (ABPI) is delighted to play a key role in framing proposals to establish a worldwide register of clinical trials on new prescription-only medicines.

Suspicion

The difficulty of gaining coverage for all trial results in peer-reviewed journals, particularly trials that produce 'negative' results, and the increasing public interest in how their medicines are produced have left the industry open to accusations that it has 'something to hide'. It is important that pharmaceutical companies demystify the clinical trial procedure by making the process more accessible – thus, information that was not published for a variety of reasons will now be placed in the public domain.

This agreement is particularly important for the UK, which is second only to the USA in the R&D of new medicines. Nearly UK£9 million is invested each day in pharmaceutical research in the UK, which accounts for almost a quarter of all UK industrial R&D expenditure. This level of investment, combined with the high standards of UK science, has led to the pharmaceutical sector of the UK being responsible for the development of 24 of the top 100 medicines used worldwide.

Widespread use of the Internet has not only fuelled the demand for more information on medicines but has also made it possible for companies to examine alternative means of putting information in the public domain. The UK-based industry took a world lead in providing the public with information about clinical trials work more than 18 months ago with the establishment of the ABPI website for companies to register information about trials (https://www.cmrinteract.com/clintrial). Therefore, the ABPI is pleased that the pharmaceutical industry worldwide is moving to build on this by providing information about trials wherever they might have been conducted, and the initiative has the full endorsement of the industry in the UK.

Consensus

The worldwide clinical trials register initiative has been drawn up following discussions between the

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European Federation of Pharmaceutical Industries and Associations, the International Federation of Pharmaceutical Manufacturers' Associations, the Japanese Pharmaceutical Manufacturers' Association and the Pharmaceutical Research and Manufacturers of America. The agreement also has the specific backing of the largest companies in the pharmaceutical sector, many of which have been working on their own methods of disclosing trial information.

This is a voluntary agreement – a decision to take part will be made by each individual company. However, this is an international agreement supported by four main trade associations and several large pharmaceutical companies, which will ensure that the proposals are widely followed. Any company not complying is likely to be highlighted by researchers – or the media – early on in the process, and pressure duly applied. With the backing of all the major industry bodies, every major pharmaceutical company will be covered by the agreement and expected to produce an annual statement outlining how they are complying with its terms.

Under the proposals, a summary of results of all industry-sponsored clinical trials on a medicine that has been approved for marketing, and which evaluate its safety and benefit, will be disclosed via free, publicly accessible databases, regardless of outcome.

Also, details of all clinical trials being performed to determine the therapeutic benefit of a medicine will be publicly registered at initiation to ensure that patients and clinicians will have information on how to enrol. Both requirements will be adopted by the pharmaceutical industry worldwide during 2005, and it is hoped that trials sponsored by others, including academia, the National Health Service (NHS) and charities, will follow our lead.

Agreement

The industry is committing itself to making information available on all clinical trials, with the exception of exploratory trials: however, even those results will be published if they are of significant medical importance. The results should normally be published either within one year after the medicine is approved or, for post-approval trials, within one year of completion.

The agreement also defines detailed standards for what data should be made available and the fields in which they are presented. The aim is for consistency in information, no matter which country initiated the clinical trials. The results will be published in a standard, non-promotional summary that will include a description of trial design and methodology, findings of primary and secondary outcome measures (reported in the protocol) and safety results. Alternatively, if results are also published in a peer-reviewed medical journal, the database will include a link to the relevant article and, in some cases, the summary. Contact details to the trial investigators will also be provided to ensure that those in need of detailed information and data on any given trial can find out more.

A unique identification code for each trial is also part of the agreement: this will be particularly important because, in the future, researchers who find a listing in the proposed trial database will then be able to locate quickly that specific trial in the results database. Because several companies and countries have already set up their own arrangements for publishing trial activity, the information will not, at this stage, exist on a single website. Furthermore, although a single and unified world database of clinical trials is not part of this agreement, the building blocks are in place and can be worked towards in the years ahead. The industry will ensure that all current clinical trial sites are linked and the World Health Organization is making plans to produce an authoritative portal to cover this network.

Future

It is hoped that these new measures will go a long way to allay public fears about the clinical trials process and to highlight the rigorous assessment of quality, safety and efficacy that goes into the development of each new medicine. The use of independent ethics committees within hospitals, the stable healthcare system of the NHS and the extensive regulation of the pharmaceutical industry are factors that already ensure that UK clinical trials are performed for the benefit of patients and provide scientifically reliable results. The full publication of these trials will not only make the process more accessible to the public but will also show the depth and range of the fascinating research carried out by pharmaceutical companies to produce the lifesaving medicines of tomorrow.

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