Trends in Animal Use and Replacement in the ‘Three Is’ of Industry

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Trends in animal use and replacement vary between the pharmaceutical, cosmetics and chemical industries. This article will briefly examine some of the drivers responsible for those trends. Overall, the pharmaceutical and cosmetics industries appear to have the edge over the chemical industry in terms of innovation and the replacement of animal tests.

The Cosmetics Industry

The main driver here has been public opinion, fuelled by organisations campaigning for the replacement of animals in cosmetics testing. Historically, the campaign began in 1980 with a full page advertisement in The New York Times, entitled “How many rabbits does Revlon blind for beauty’s sake?” Although progress has been slow, validated replacement tests and testing strategies are becoming available, largely funded by the cosmetics industry itself. Examples include the use of in vitro human skin and human cornea models for the evaluation of phototoxicity, skin corrosivity, and skin and eye irritation.

In June 2011, the US-based company, Allergan, announced that the Food and Drug Administration (FDA) had approved its in vitro cell-based assay for use in the stability and potency testing of the company’s proprietary botulinum toxin A product, Botox. Allergan estimates that the new assay will replace the company’s use of animal-based tests for cosmetic botulinum toxin products by 95% or more over the next three years, as other regulatory agencies around the world approve the new assay. Interestingly, the 10-year time-frame required by Allergan to develop the in vitro assay coincides with the 10-year botulinum toxin testing campaign waged by The Humane Society of the United States and FRAME.

Based on examples such as this, it seems likely that consumer pressure, coupled with innovative technologies, will continue to drive the development, validation and implementation of non-animal replacements in relation to cosmetic ingredients and products.

The Pharmaceutical Industry

The sequencing of a reference human genome should be seen as a significant step forward in the replacement of the animal models used in human drug discovery and development. Although animal data are still required by the regulatory agencies, the submission by drug companies of human genomic data is actively encouraged by bodies such as the FDA and the European Medicines Agency (EMA). This trend appears to reflect the initiative launched by the US National Research Council in 2007, entitled Toxicity Testing in the 21st Century: A Vision and a Strategy, in which human-sourced data increasingly occupy centre stage. The evolving field of personalised medicine is an illustration of a potentially win-win situation, in which pharmaceutical drugs are tailor-made to suit an individual’s DNA, and where potentially fewer adverse drug reactions mean increased consumer confidence. According to the Personalized Medicine Coalition, there were 72 prominent personalised medicines in 2011, compared with just 13 in 2006. However, many challenges still remain. Some of the complexities inherent in personalised medicine were voiced in a recent opinion piece in The Scientist, entitled What is the Human Genome? This article is a reminder of the fact that the human genome is not a static entity, but rather one with components which are constantly being moulded by the forces of epigenetics and other drivers of gene mutation, all of which point to the emerging concept of ‘real-time’ personalised medicine as a standard of care. In the field of oncology, that future is already here, since chemotherapy can be tailored to an individual, based on genomic data obtained from a tumour biopsy and the study of immune system biomarkers of the individual. These developments point to a shift away from reliance on animal models in favour of real-time, human-sourced data.

The Chemical Industry

While there are fairly clear indicators of what is happening in the pharmaceutical and cosmetics industries, there is less developed research on the replacement of animal tests in the chemical industry. There are several reasons for this, including the complexity of chemical testing and the lack of public pressure for change. However, some progress has been made in the development of alternative models and testing strategies. For example, in vitro skin models have been used to evaluate skin irritation and phototoxicity, and in vitro eye models have been developed to assess ocular irritation.

In conclusion, while there is much to learn from the cosmetics and pharmaceutical industries about the replacement of animal tests, the chemical industry still has much room for improvement. It is hoped that continued innovation and consumer pressure will drive the development of non-animal replacements in this industry as well.
industries, the chemical industry appears to be something of an ‘outlier’. There are several possible explanations for this. For instance, consumers have been made largely aware of the link between cosmetic products and animal testing, but much less so with respect to other chemicals of social interest and concern. Although the public have recently become more aware of animal testing for household products, the number of animals required for such tests pales to insignificance in comparison to those required by the EU chemicals testing programme, REACH. However, consumer pressure is beginning to build from another source — namely, consumer health protection groups — who are concerned about chemicals that possess endocrine disrupting properties, in particular, phthalates and bisphenol A. But, even assuming that industry removes or replaces these compounds wherever possible, the impact on the sheer number of chemicals to be tested under the REACH programme will be minimal when one considers that the number of pre-registered substances was in the region of 143,000 (although it is thought that the eventual number of substances registered will be lower than this figure).5,6

Clearly, other options must be sought, if society wishes to see animal tests replaced in the chemical industry, whilst the impact of those chemicals on human health and the environment is also reliably assessed. There are at least two options that appear within our grasp.

The first relates to the wider use of non-animal methods in the cosmetics industry, by virtue of the fact that around 90% of the substances contained in cosmetic products are industrial chemicals with other uses. Hence, replacement methods that are validated for chemicals used in cosmetics could conceivably be adapted and applied to their wider uses. The forces driving replacement methods for cosmetics would, indirectly, also be driving replacement in the chemical industry.

The second option relates to the provision in Annex XI of the REACH regulation for applying a ‘weight-of-evidence’ approach to obviate further animal testing. When applied in the broadest sense of the term, in conjunction with a tiered testing strategy, this concept could be used to provide a useful screening tool for single chemicals, as well as common mixtures of chemicals. The task of evaluating thousands of individual chemicals, and some of their more common combinations, is daunting, but not impossible, in an age of platform-based high-throughput robotised analytical systems, such as those employing ‘-omics’ technologies.

It will be interesting to watch the race to the finish by all three industries.

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References


