

FACTSHEET

Direct-to-consumer genetic tests

What are direct-to-consumer genetic tests?

The idea of direct-to-consumer (DTC) genetic tests is to provide consumers with information that is hidden in their genomes. These tests can be health-related (i.e. diagnostics, probability of getting a disease) and non-health-related (such as ancestry, matchmaking or even to detect ear wax type).¹ Such tests are becoming increasingly popular, because they are very easy to obtain and use, and genetic revelations seem to be just a click away. In 2019, more than 26 million people worldwide took an ancestry test at home.²

How does it work?

Consumers can easily order genetic tests online from commercial companies. After an order is placed, a testing kit is shipped directly to the consumer. They just need to send back to the company a sample of saliva or hair. After the genetic material has been analysed, the consumer is provided with the tests results via email or a dedicated website.



The catch

DTC genetic tests are relatively affordable (prices range from €79 to €200) and easily accessible. This accessibility strongly encourages consumers to choose this option over conventional genetic tests performed by qualified professionals in specialised centres.

However, the 'you get what you pay for' saying applies here. The lower cost, compared to genetic tests done in clinics, can be explained by the fact that during the DNA analysis, the lab will only look at specific gene variants, instead of the complete set of a person's genes (genome). This often gives inaccurate results.

Why such tests cannot substitute a visit to the doctor

Genetics are complex, and even when tests results are accurate, they have little utility if they are not complemented by the advice of a geneticist. Such counselling is crucial, as DTC tests overlook factors such as lifestyle and environment, which might reduce or increase the chances of getting sick. Serious results – such as the probability of getting cancer – can have a dramatic psychological impact. For-profit companies, often from overseas, are hardly the right interlocutor for consumers on such important matters.

¹ L. Kalokairinou et al, [Legislation of direct-to-consumer genetic testing in Europe: a fragmented regulatory landscape](#), Journal of Community Genetics, 2017.

² A. Regalado, [More than 26 million people have taken an at-home ancestry test](#), MIT Technology review, February 2019.



Why you should care about your genetic data

Our DNA stores massive amounts of personal information which can be extremely sensitive. It is also very valuable data for all kinds of research, e.g. drug development. Therefore, DTC genetic testing companies often tremendously benefit from the sale of genetic data to third parties such as pharma companies.³

Companies operating in Europe must comply with the General Data Protection Regulation (GDPR) to ensure consumers' personal data is respected. However, most of the DTC companies are based outside of the European Union and operate online, which makes them difficult to prosecute⁴ and puts an extra burden on consumers.

A regulatory wild west

Regulations have not kept up with the fast pace of this new technology. As a result, European countries have different regulatory approaches: for instance, in France, such tests are banned, whereas in Poland, there is no specific regulation for DTC genetic tests.

At the EU level, diagnostic DTC genetic tests will be covered by the In-Vitro Diagnostics Medical Devices Regulation as of May 2022. However, the Regulation lays down requirements only limited to the clinical validity of those tests, i.e. whether they are reliable. Otherwise, the law allows Member States to adopt or maintain their national legislation on medical supervision, genetic counselling, and informed consent of DTC genetic tests.

WHAT BEUC RECOMMENDS:

- **SAME RULES FOR EVERYONE.** The EU should establish a harmonised approach to DTC genetic tests to ensure that all EU consumers are equally protected. Such tests should not be sold, unless they are tied to a mandatory consultation with a qualified professional, especially when it comes to health tests.
- **REGARDLESS, TESTS MUST BE RELIABLE.** Clinical validity of both health and non-health DTC genetic tests must be thoroughly checked by competent authorities. When it cannot be proven that a testing kit is reliable, it should not be sold to consumers.
- **ENFORCE WHAT WE HAVE IN PLACE.** National and European authorities must make sure that companies abide by existing legislations in relation to DTC genetic tests (e.g. the GDPR) and national laws on genetic testing.
- **AWARENESS-RAISING IS NEEDED.** The tests' terms of reference must be communicated in lay language, so users are well informed before they give their consent. Awareness about the implications of DTC tests must be raised both among consumers and policy makers.

³ R. M. Hendricks-Sturupp & C. Y. Lu, Direct-to-Consumer Genetic Testing Data Privacy: Key Concerns and Recommendations Based on Consumer Perspectives, *Journal of personalized medicine*, 9(2), 25, 2019.

⁴ Consumer groups Consumentenbond (Netherlands), Forbrukerrådet (Norway), Sveriges Konsumenter (Sweden), EKPIZO (Greece), OCU (Spain) have filed complaints to their respective national Data Protection Authorities against some companies (May 2020).