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DTC-GT : between a regulation by the market, and a medical regulation ?

Abstract : Many works on DTC-GT focus on the consumer side, from an ethical point of view, wondering if lay people should be authorized to access it. Here, our article focuses on the other side of the market, the production one, and goes beyond the question of the regulation *of* the direct access market, to ask the question of the regulation *by* the market. For a long time, direct-to-consumer genetic testing (DTC-GT) legal status was not clear on a European level, and tools for devices regulation were missing (or in construction). A new text (a Regulation, not a Directive) is changing this situation, but some points related to medical regulation remain national choices (such as the mandatory medical prescription, the status of medical doctors accredited to sell genetic testing, and the kind of interaction with the buyer). « Whatever » these choices will be (reduce, or wide), one can expect professional regulation will have an impact (directly or indirectly) on DTC-GT market.

Keywords : direct-to-consumer, genetic testing, predictive testing, diagnostic-in-vitro, professional regulation, market regulation

JEL :

I11, K23, L11, L51, O30

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1 The new European IVD (*in vitro* diagnostic) Regulation (EU/2017/746)¹ legislates the direct-
2 to-consumer genetic testing (DTC-GT) market, whose emergence in the late 90s came to
3 question the genetic testing legal status (at least on a European level). For companies selling
4 DTC-GTs (notoriously the e-based one), the consumer should not need to hire a health
5 professional to buy the test (to obtain medical prescription), neither should medical
6 practitioners be involved when accessing the results. Furthermore, DTC-GTs subvert more
7 widely the professional regulation. Indeed, they may be defined from a variable geometry
8 perspective (Borry and al., 2011), which may include tests sold outside the traditional health
9 care system (such a definition doesn't exclude *a priori* cases where health professionals are
10 involved to provide the service).

11 In addition to this, the innovative character of these devices take root at many levels. For
12 example, what has been termed the 'genomic revolution' resulted in not only an important
13 development of predictive tests for multifactorial diseases (cancers, parkinson, *etc.*), but also
14 in tests targeting physiological and/or behavioral traits. Tests are subject to change and
15 evolution dependant on potential breakthroughs in the scientific litterature) and, the most
16 elaborated products offer a risk calculation analysing a wide range of genetic markers² (Ng
17 and al., 2009). Some companies believe these devices should not to be classified as medical
18 device, and should be given a specific status reflecting their low to trivial '*clinical utility*', and
19 a '*personal utility*' that would be usefull (in regards to « life styles » : eating behaviours, *etc.*).
20 The later concept was formulated by the companies (and not by the clinical world) and its
21 validity remains to be demonstrated, this partly explains why these kind of device have not (at
22 this present date) been integrated into the healthcare system.

23 European legal texts have not tackle the emergence of these innovative devices, in a timely
24 manner, and therefore there remains ambiguities and loopholes, particularly concerning direct
25 selling (Borry, 2008 ; Grimaldi, 2011). In fact there are « as many » DTC-GT regulations as
26 there are states (Borry, 2012), and it also applies for Unite-States of America (Markets
27 Research, 2009 ; Genetics and Public Policy Center, 2007). As the Regulation project said,
28 long time ago (European Commission, 2012), the « *tremendous technological and scientific*
29 *progress* » in biotechnology joins the fact that « *European countries interpret and apply*
30 *differently the actual rules* ».

31 Proposed by the European Commission, this project was under a co-decision procedure
32 between the Parliament and the Council. Two options appeared on the matter of DTC-GT
33 (Kalokairinou and al., 2015). Whereas the European Parliament focused on tests professional
34 guidance tests, which translate into a traditional medical model (prescription, and sometimes
35 prohibition of advertisement for medical products ; the health professionnals controls the risk
36 inherent to a test), the European Union Council has trended toward a regulation organised
37 around the actual tests themselves (scientific and clinical quality, accuracy of claims made in
38 advertising, *etc.*), for pre-market evaluation or post-market control.

39 Finally, on the whole, the concil's approach was adopted. Devices for human genetic testing
40 are classified as class C (on a scale of risk from A to D), thus enforcing quality assesment
41 (security, performances, *etc.*) and a post-market surveillance plan. Tests obtaining a
42 certification will be identified by unique single identification and listed in a database
43 (Eudamed). The objectives of the data base is, among others, to enhance overall transparency,
44 notably through better public and healthcare professionals access to information, including the
45 details of « notification bodies » (that deliver conformity assessments and certifications). All
46 this will be in a language easily understandable for the intended user (and provided in the
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48 ¹ Translated the 5th of may 2017 in each european language, it shall apply from 26 May 2022.

49 ² Most of results are reported in absolute risk (it is derived from two parameters: 'relative risk' and 'average
50 population disease risk').
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1 official Union language-s determined by the Member State in which the device is made
2 available to the user). Furthermore, the Regulation gives clear requirements for distribution
3 (legal status of manufacturer, importer and distributor shall be declared, *etc.*). The Regulation
4 will (for the given reasons given above) reduce information gap about genetic testing quality,
5 or traceability. Indeed, serious defects have been flaged by the higher Europeans institutions
6 (Hennen, 2008), as by the Americans ones (GAO, 2006; FTC-FDA-CDC, 2006; GAO, 2010).
7 In addition, our own research into DTC-GT e-market development (for the 2000-2012 period)
8 suggests they face many challenges related to company traceability for example registration
9 based in tax havens, and/or distributors rarely disclose. Also some companies fail to provide a
10 national commercial register identifier (stating where the company is declared, *etc.*), and/or
11 are declared as a 'laboratory' on their web sites but without any evidence of their credentials
12 on display, or companies declared as a laboratory status on their web sites but without
13 administrative evidence, absence of indications about national commercial register where the
14 companie is declared, *etc.* (Jautrou, 2016). In a nutshell, the internet promotes this lack of
15 reliable data and the breaching of national regulations (for example, quality standards for
16 laboratory or tests, prohibition of sales which occured without a medical prescription, *etc.*).
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21 Nevertheless, from a medical professional regulation point of view, the option adopted by the
22 Parliament has not been totaly evaded. The requirement for a medical prescription remains a
23 national choice. Distance sales orchestrated on phone by a medical doctor (some companies
24 offer this option) are not considered (whereas distance sales and information society services
25 are considered in Article 6). So, the new Regulation is less restrictive than the additional
26 protocol (2008) to the Convention on Human Rights and Biomedicine. If the protocol
27 concerns only genetic testing for health purposes, it implied a direct individualised medical
28 supervision (a mere telephone contact was not allowed). But it was not mandatory, as it only
29 involves European member states who signed up (Borry, 2008). However, under the new
30 Regulation, when a genetic test (even a predictive one) is used on individuals, in the « context
31 of healthcare » (services provided to patients by health professionals), Member States are free
32 to adopt or maintain others measures which are more protective of patients, more specific or
33 which deal with informed consent. Besides, for tests that provide to patient information on the
34 genetic predisposition for medical conditions and/or diseases which are generally considered
35 to be untreatable according to the state of science and technology, Member States shall ensure
36 that there is appropriate access to counselling.
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40 In any case, « *in vitro* medical diagnostic » legal status is designed for all genetic testing
41 (diseases and traits, predictive or not, in the context of healthcare or not). This status also
42 covers softwares (whereas those intended for well-being purposes are not qualified as IVD
43 medical devices). Somes autors, which prefered the Council's option, underlined the
44 Parliament's one was, among others points, problematic in regard to the lack of expertise for
45 some medical doctors, and that an opportunity to establish robust criteria of clinical validity
46 was missed (Kalokairinou and al., 2015). Aside from the former fact this analysis has limited
47 viability in strong professional regulation system, such as the French one (where medical
48 doctors, laboratory and tests are specifically accredited and certified, and prescription occured
49 in a face-to-face consultation), it is also limited, now, as the new Regulation mixes the two
50 options, and as it mentions that advertising of devices (as well as label and instructions for
51 use) shall not mislead the user or the patient with regard to the device's intended purpose,
52 safety and performance.
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56 Moreover, one have to keep in mind that, in the long run, the genetic testing market is very
57 competitive (Jautrou, 2018), which reflects significant innovations at scientific or
58 organizational level on young markets (Klepper, 1997), and structuration process (Powell and
59 al., 2005). Firstly, products evolution was important. Number of genetic markers (even genes)
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1 considered, and therefore number of diseases and traits, was very limited for first DTC-GTs,
2 but was expanded drastically with the chips invention for GWAS. In the wake, whole genome
3 sequencing appeared (however, the development of this niche product will probably stay
4 moderate). An intensive « price war » started, and is till ongoing (as it is shown by a recent
5 one day commercial offer at 20\$³, whereas initial price was 999\$ for a simplest product), with
6 an introductory offer for bottom range product (at least for the number of diseases detected)
7 starting just under 1000\$. Secondly, the market is particularly dynamic⁴. If the market is
8 extremely volatile, as one can judge with the increasing number of annual apparition of
9 companies selling tests free of prescription (for the 2000-2009 period), the companies failure
10 rate has increased since 2007⁵. Companies massively stop their offers and most of them have
11 had a short life expectancy (less than 5 years). This high turn over is typical of young and
12 very concurrential markets. Thirdly, the market is in a structuring process, which was
13 foreseeable as the scientific industry grow from large inter-organizational networks. This
14 structuration involves many dimensions : sectorial or disciplinary ones with scientific or
15 technical partnerships (information technology, pharmacology, optic, *etc.*), geographical (with
16 clusters, such as Silicon Valley and San Diego biotechnology area), professional ones with
17 medicine (distribution, or medical research), marketing ones with distributors (from medical
18 distribution to mass distribution), commercial ones with economic partnerships or research
19 results transfer (co-development of different products, from medical to well-being), financial
20 ones with investors, *etc.* The « chain-linked model » developed by economists encapsulates
21 well the continuous loops between research and market (Kline, 1986), and is suitable to
22 describe the economic model of some companies.
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28 In other words, companies which will dominate both medical markets and the DTC-GT one
29 will partly be selectionned by the markets logic (concurrence, concentration, *etc.*). Therefore,
30 missing medical prescription for sales doesn't mean medical regulations (and notably
31 regulation by experts) won't influence the DTC-GT market in the long term.
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57 ³ 23andMe's offer for USA mother's day (2017).

58 ⁴ Our study focused on tests for health, physiology, performance and behavior. Tests for filiation and
59 « ancestry » were not considered.

60 ⁵ Disappearances have been signaled by others autors since 2010 (Borry and al.).
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