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European Federation of Pharmaceutical Industries and Associations

EFPIA Response to the EDPB Consultation on the Guidelines on the processing of personal data based on legitimate interest.

EFPIA welcomes the opportunity to comment on the draft Guidelines released by the European Data Protection Board ("EDPB") on the GDPR's "legitimate interest" legal basis (Art. (6)(1)(f) GDPR). Like any other industry sector, companies in the pharmaceutical sector rely extensively on this legal basis in many aspects of their operations, from human resources, to research, to medical information activities and commercial practices. In this contribution, EFPIA wishes to highlight some matters in which an overly restrictive application of the legitimate interest legal basis, possibly informed by regulators' experiences with other sectors, could have a disproportionate impact on the pharmaceutical sector to the point of jeopardizing public health.

1. Hierarchy in legal bases

The draft Guidelines appear to support a hierarchy in the available GDPR legal bases, with consent as the preferred legal basis, at the expense of the legitimate interest legal basis. EFPIA does not support this and wonders if this interpretation may be influenced by certain sector particularities, especially in the behavioural advertising space. If so, EFPIA calls on the EDPB to not present this as the standard interpretation and adopt a more nuanced approach. In fact, EFPIA's experience with how regulators approach consent, for example, in scientific research, is precisely the reverse, with a clearly expressed apprehension about reliance on consent in favour of other legal bases, such as legitimate interest.

In the same vein, EFPIA calls on the Board to clarify that the second step of the legitimate interest test (necessity of the processing) should not be conflated with the choice of legal basis. In other words, this step assesses whether a *processing operation* is necessary and whether less intrusive *means of processing* are available, not whether consent as a legal basis is such a less intrusive means of processing (*contra* C-621/22, KNLT v. Autoriteit Persoonsgegevens, §51).

2. Reasonable expectations

EFPIA noticed the increased focus in the draft Guidelines on the reasonable expectations of data subjects. Among other things, the Guidelines highlight that meeting the GDPR's transparency requirements does not equal meeting reasonable expectations. EFPIA is concerned that this position is once again heavily influenced by regulators' experiences with particular sectors. It would like to point out that in many cases, notably in research, providing information to data subjects, sometimes through a third party, is the only way in which the reasonable expectations of data subjects can be addressed. The contextual elements referred to by the Board can have an impact on *how* controllers meet their *transparency obligations* (*e.g.*, more detailed information for laymen than professionals, simpler information for minors than for adults, *etc*.). However, the reasonable expectations of data subjects will inevitably primarily be set by the information that the controller provides them to satisfy transparency obligations. There may simply be no other means than GDPR transparency to raise reasonable expectation. Excluding or underestimating that would make the legitimate interest basis very difficult to rely upon – in circumstances where it is often the only one that is realistically available to a controller.

Finally, the concept of reasonable expectation is not new in EU and Member State law. It is not clear to EFPIA why the Board does not draw on decades of experience with the concept in those other legal regimes and why the standard would be different (and significantly lower) for data subjects under the GDPR.

3. The balancing test

The third step in the legitimate interest test consists of balancing the interests of the controller against the interests and rights of the individuals concerned. The draft Guidelines point out that if such a balance cannot be achieved, additional measures must be taken to protect individuals. Those measures must come on top of the protections afforded by the GDPR which controllers are required to put in place anyway.

To EFPIA, this approach makes sense *provided* the protections afforded by the GDPR are taken into account when assessing the impact of the processing on individuals. At some point in the legitimate interest assessment, the existing GDPR protections, such as transparency and data subject rights, must be taken into account. If not, the balancing test becomes overly complicated and burdensome to meet. Indeed, the impact of a processing operation on individuals could be evaluated without any restraint, whereas the measures in place to mitigate this impact could not take into account the law adopted to reduce this impact in the first place. EFPIA calls on the Board to clarify this point in the Guidelines.

4. Importance of context

While the draft Guidelines indicate that context is important in the assessment of the legitimate interest legal basis, for example, in the area of reasonable expectations of individuals, EFPIA would call on the Board to make that even clearer.

In the pharmaceutical field, for example, controllers generally interact with highly educated and often specialized health care professionals ("HCP"). These professionals understand how the pharmaceutical sector operates, what their rights are and how to exercise them. In a context like this, reliance on the legitimate interest legal basis should be easier to justify. This is also true for processing operations that sit on the fence between scientific information and advertising. Medical information is an example on point. Whether specifically requested by the HCP or pro-actively provided by the pharmaceutical company concerned, the objectives of medical information include informing prescribers about the characteristics, availability and correct usage of pharmaceutical products, with important benefits not just for the companies concerned, but also for the HCP concerned, patients and the medical community at large. This should also apply to "tailored" advertising (including profiling), at least when this happens in ways that are not overly intrusive for HCPs.