Guidance on Blood Glucose and HbA1c Collected During Patient Support Programs (PSP) and Market Research Programs (MRP) Conducted in Patients with Diabetes

Version 2.0 April 2018 (update from v1.0 Nov 28, 2016)

Effective Date 23-Apr-2018

Rationale for Change

The guidance issued in December 2016, had been created at CSLs' request with the intent to standardize the approach for the collection of blood glucose, and HBA1c abnormal values as AEs in PSP and MR projects (MRP) conducted in patients with diabetes. At that time it had been decided that the guidance would be tested on new PSP and MRP during a pilot phase, and that it could be revisited contingent on the result of an impact assessment.

The assessment made in January/February 2018 has revealed that;

- Although the guidance was useful in terms of harmonization and standardization across countries, the thresholds defined, in the guidance could induce massive reporting of AEs in some PSP or MRP designs, with in general, no additional information allowing any interpretation of the clinical relevance of the abnormal value, and very often no possibility to perform any follow up to the initial information
- Furthermore, data collected in the context of a PSP or MRP should not be used to characterize the safety profile of a therapy
- Benchmarking shows that there is no consensus among pharma companies on whether laboratory data in PSP/MR programs should be collected as AEs.
- In Clinical trials, abnormal laboratory values are considered AEs only if assessed as such by investigators. The previously proposed guidance imposed more stringent collection of BG and HBA1c abnormal values as AEs compared to the other source of solicited reports which are considered the gold standard of safety data (i.e. clinical trials), which is disproportionate compared to the value of the collected data.

Thus, after 1 year implementation of the Pilot phase and considering the points above, a decision to revise the guidance was made.

Implementation Strategy for PSPs/MRPs

a. All New Programs

b. Ongoing Programs with/without the previous blood glucose guidance in place

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The following reported information should NOT be considered as safety data and should NOT be transmitted to the Sanofi pharmacovigilance department:

- **Blood glucose or HbA1c abnormal lab values if reported in isolation**

Conversely, if there is a report of worsening of glycemic control, lack of effect, or other AE, abnormal lab values supporting the AE can be reported with the AE.

In line with previous guidance, and in addition to the above, the following reported information should also be considered as safety data, to be transmitted to the Sanofi pharmacovigilance department:

- Symptomatic hypoglycemia or symptomatic hyperglycemia (whatever the reported BG level and the nature of the reported signs and symptoms)
- Hypoglycemia NOS* or hyperglycemia NOS (i.e. without reported info. on BG or symptoms)
- Asymptomatic hypoglycemia or asymptomatic hyperglycemia (whatever the reported BG level)
- Any blood glucose and/or HbA1c level(s) (whatever the level) if associated with at least one seriousness criterion (e.g., led to hospitalization)
- Worsening of Diabetes control, inadequate diabetes control, etc., even when no abnormal lab values have been reported

*: NOS means not otherwise specified