AESGP comments

Proposal for a Directive of the European Parliament and of the Council amending:

- **Directive 2000/60/EC establishing a framework for Community action in the field of water policy,**
- **Directive 2006/118/EC on the protection of groundwater against pollution and deterioration and**
- **Directive 2008/105/EC on environmental quality standards in the field of water policy**

To ensure that the proposed "amendment directive" will deliver on its objective to protect environment and society, it is critical that the system and decision making is underpinned by a thorough and transparent process and a robust risk approach rooted in high quality scientific data.

The power to change the lists of surface and ground water pollutants will be transferred to the Commission who will be empowered to adopt delegated acts. This changes the legislative process drastically from a co-decision procedure with involvement of EP and Council to delegated act which gives additional power to the EC and only a veto power to the EP and Council. This is likely to lead to less transparency and democratic decision procedures, which we do not endorse.

Scientific assessments and reports are to be prepared by ECHA. Pharmaceuticals are not 'any' chemical, and it will be key that ECHA collaborates with EMA and the national competent authorities very closely to be familiar with the relevant information on medicinal products for human use and the respective environmental data which are already available in the European medicines network (EMA and NCAs). Currently stakeholders are involved within the WG chemicals and EQS dossier subgroups and it is critical that stakeholders continue to be closely involved in the process.

In addition, a few changes proposed are either vague or may lead to unclarities compared to the current versions of the three impacted directives as detailed below:

Water Framework Directive (2000/60/EC):

Art. 2, b Point 30:

"Priority substances' … via the aquatic environment in a high proportion of Member States." It should be specified what a "high proportion" is meant by to ensure a consistent application of that requirement. It is important to prioritise use of scientific resources and laboratory capacity, when identifying priority substances and establish EQ standards.

Art. 2, c Point 30b: 'River basin specific pollutants' (RBSP):

The new proposal may have serious effects on emission permits for manufacturing and even may prohibit new manufacturing processes in the EU, if the chemical quality of a specific river basin system is related to RBSPs, because these specified compounds are not allowed to be increased by any new manufacturing activity (prohibition of deterioration.). We ask to remain with the current legislation on RBSPs.

Art 2, d Point 35:

> "Environmental quality standard' means… or a trigger value for the adverse effect on human health or the environment … measured using an appropriate effect-based method [EBM]." We support in general EBM to identify potential concerns for water bodies. Consequently, substance specific EQSs need to be established, based on high-quality science. More science outcomes, standard & validated methods and a reference guidance document are needed for EBM and EBT (Effect Based Trigger) applications.

Annex II (amending Annex VIII of Dir 2000/60/EC), Point 10:

> This paragraph lists the groups of compounds which are indicative of 'main pollutants'. Amongst those "Materials in suspension, including micro/nanoplastics" is not sufficiently specific and does not ensure that this requirement can and will be applied in a meaningful way as it could include many unproblematic materials. We therefore ask that this is deleted.

Groundwater Directive (2006/118/EC):

Annex III to the "Amendment Directive" (will become Annex I of 2006/118/EC):

> A groundwater EQS of 0.25 ug/L for active pharmaceutical substances (total) is proposed. The proposal defines this group of substances to include "the sum of all individual pharmaceuticals detected and quantified in the monitoring procedure, including relevant metabolites and degradation products".

The Commission has not transparently presented any relevant scientific data as the background of this proposed EQS. Based on this, we would request that this proposed EQS be removed from the final directive. If regulation is warranted for individual active pharmaceutical substances in groundwater the Commission should propose EQS for each individual substance following scientifically justified and transparent processes.

Environmental Quality Standards (EQS) (2008/105/EC)

(7) - Article 8b, Point 1e – watchlist:

> Multiple sources for candidate compound selection for the watch list are listed. The use of modern technologies and validated modelling programmes are certainly useful for identifying compounds of potential concern, but only based on scientific knowledge, while unvalidated, anecdotical or spontaneous (e.g. citizen science data, leveraging the opportunities offered by artificial intelligence) proposals for candidate compounds should not find their way into the official selection process.

Annex V, amended Annex I of Directive 2008/105/EC, (2) Part A:

> The proposed new table lists EQSs for a number of active pharmaceutical substances (EE2, E2, E1, Azithromycin, Carbamazepine, Clarithromycin, Diclofenac, Erythromycin, Ibuprofen). We have serious concerns, which have been raised multiple times before, about the established EQSs for the estrogenic hormones, diclofenac, and ibuprofen. The EQSs derived do partly either not consider most recently published high quality data or use studies of questionable quality, which, however, were influencing or deciding the EQSs.

Annex V, amended Annex I of Directive 2008/105/EC (2) Part A: No.70 in the proposed new table:

> The Commission has not transparently presented any relevant scientific data as the background of the proposed EQS for “Total of active substances in pesticides, including their relevant metabolites, degradation and reaction products”. Therefore, we would request that this proposed EQS is removed from the final proposal for this updated Annex.

Annex VI, new Annex II of Directive 2008/105/EC, Part A:

> The term under 4. "… which may affect steroidogenic … functions via the environment" appears not to be sufficiently precise and does not consider common ED criteria as, e.g., defined under REACH.